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Federal Trade Commission
Office of the Secretary
Room H-135 (Annex F)
600 Pennsylvania Ave, NW
Washington, DC 20580

Re: Emerging Health Care and Competition and Consumer Issues – Comment, Project No. P083901

Momenta Pharmaceuticals, Inc. (“Momenta”) is pleased that the Federal Trade Commission (the “FTC”) is inviting comments on the competitive advantages offered by the creation of an abbreviated regulatory approval pathway for follow-on biologics as it prepares for its announced workshop in November. Momenta is an innovative biotechnology company that was founded to develop technology to enable the characterization and understanding of complex mixtures and proteins. We believe our experience as an innovator that develops both complex generic and follow-on biologic drugs, as well as novel drugs, affords us a unique opportunity to provide the FTC with a balanced and moderate perspective on how the establishment of the follow-on biologics pathway will promote investment, spur research and development, and lead to the creation of a new category of companies that will inject novel and creative competition into the marketplace. We would be pleased to participate in the panel discussions, and hope that our comments will assist the FTC as it develops a pro-competitive policy in support of legislative change guiding follow-on biologics.

Before addressing the questions in the federal register notice, we believe it would be helpful to provide background information about Momenta to help put our comments in context. Momenta was formed in 2001 to overcome the conventional thinking and address the technical barriers that impeded the scientific understanding of complex molecules. The initial goal was to unravel and thoroughly characterize the chemical structures of these important complex molecules to gain insights into their biological activity and the process for manufacturing them. Over the past 6 years, Momenta has continued to pursue these goals, and has further expanded its capabilities to the understanding of complex polysaccharide, polypeptide and protein drugs.

Our focus has been in three areas of product development. The first area is to develop technology and analytic tools to develop generic versions of complex products that can be filed as traditional abbreviated new drug applications or ANDAs. The second focus is novel drug development, where we use our understanding of chemical structures to unlock the biology of complex sugars and engineer novel new drugs. The third focus, and the most relevant to these comments, is to apply our innovative analytical technology to the development of follow-on

biologic products. Our complex generics pipeline includes M-Enoxaparin and M356, which are partnered with Sandoz, a division of Novartis. M-Enoxaparin, our generic version of Lovenox® (ANDA filed in August, 2005), and M356, our generic version of Copaxone® (ANDA filed in December, 2007), are currently both under review at the FDA. These complex mixtures were once thought to be impossible to characterize thoroughly and manufacture reproducibly, but our investment in characterization and analytical tools applied to the manufacturing process, resulting in two ANDA filings to date, represents an example of the kind of innovative research and investment that could be further encouraged with the creation of an abbreviated regulatory pathway for follow-on biologics.

With this in mind, we have also invested heavily in adapting our technology and our tools to characterize proteins with the intent of creating follow-on biologic, or protein products. Our investment in this area enables the potential to thoroughly characterize protein products, which due to the lack of more advanced analytical tools have not been fully characterized and are defined in large part by their manufacturing process. These new tools can enable thorough characterization and offer the very real potential to develop equivalent versions of protein products. The resulting process and product characterization analytics also offers the opportunity to substantially improve the quality of all complex mixture and protein products, as we gain more knowledge and insights into these complex molecules. For example, we collaborated with FDA and other academic institutions this past spring in helping to resolve the heparin contamination crisis. Through the use of our innovative analytic approach, we aided the FDA in identifying the nature and the source of the contaminants in the heparin imports, and through our expertise in disease biology we helped to establish the biological plausibility linking the contaminant to the observed adverse event profile. See Gerrini et al., "Oversulfated chondroitin sulfate is a contaminant in heparin associated with adverse clinical events," *Nat Biotechnol.* 2008 Jun;26(6):669-75. Epub 2008 Apr 23 and Kishimoto et. al., "Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System," *N Engl J Med.* 2008 Jun 5;358(23):2457-67. Epub 2008 Apr 23.

Attached, as Exhibits A and B, are a Momenta Company Overview and a copy of our 2007 Annual Report that set forth in greater detail the activities in which we are engaged, the significant investment we are making in preparing for a follow-on biologics pathway, and a description of the significant technology breakthroughs we have achieved that should make it possible to demonstrate generic equivalence of complex mixture and protein products.

A key challenge facing us, and innovator companies like us, is raising investment capital to fund the development of these ground-breaking technologies. While we believe our work with M-Enoxaparin and M356 have demonstrated the power of our technology to make abbreviated pathways possible for complex mixtures, and that our on-going work on proteins indicates that the same will be possible with follow-on biologics, the absence of unambiguous legislation authorizing the FDA to implement an abbreviated pathway may be the rate limiting factor restricting availability of investment capital for us and companies like us.

We believe that the enactment of an abbreviated pathway will open the doors for competition and innovation by Momenta, and companies like Momenta, by facilitating investment in research and development. More importantly, we believe that enactment of the pathway will ultimately result in improved patient access to high quality, safe, effective, and potentially life-saving medications at a more affordable price. We also believe that the FDA is fully qualified to evaluate the efficacy of our technology and should have the discretion to review each follow-on biologic application based on the science presented, and facilitate the entry of generic biologic competition while assuring the highest standards of product quality to ensure patient safety. We consider ourselves to be an innovator company and are concerned that the more traditional innovator companies are seeking to erect legislative, regulatory, and market barriers to legitimate, technology based competition. Opening the door to such innovative analytical science will not only lead to increased competition and advances in patient care, but will also improve the quality of both innovative and generic drugs in the future.

We are very interested in participating in the proposed panel discussions and believe we are uniquely positioned to contribute to the discussion for the reasons articulated above, and will follow up with you to discuss the opportunity. The following are more specific comments on the questions posed in the Federal Register Notice. While we recognize that many product definitions are used when discussing follow-on biologic products, we will use two terms “Biogeneric” and “Biosimilar” in an effort to more accurately reflect our position through our answers -- Biogeneric products being those follow-on biologic products that are approved and designated interchangeable to the innovator product, with Biosimilar products being those follow-on biologic products approved but not designated by FDA as interchangeable to the innovator product (e.g., Omnitrope®).

Regulatory Exclusivities and Follow-On Biologic Drugs

1. What is the likely competitive effect of the market entry of a follow-on biologic competitor? Are there empirical models that predict the nature of this competition based on existing biologic drug product competition? How has competition developed between referenced and follow-on products in European markets? Would referenced product manufacturers lower their prices, offer discounts, and/or engage in enhanced marketing activities?

The likely competitive effect of a follow-on biologic entering the market is the gradual reduction in prices of the biologic. Hatch-Waxman has provided consumers with significant savings of up to 80 percent of the brand product for generic drugs. We believe that the introduction of follow-on biologics, while occurring incrementally at first due to the investment required to develop the analytical tools and characterization technology and the development effort that will be required to achieve FDA approval, will lead to significant savings within the first 5-10 years. However, even more significant savings, comparable to what we experience today for small molecule drugs, will become a reality in the future as scientific innovation continues to advance and unlock the complexities of these biologic drugs. While the introduction of Biosimilar products will offer alternatives to innovator drugs at

lower prices, the most significant competition will come from Biogeneric products where direct substitution for the innovator product can be driven more at the pharmacy and payor level.

The EU and U.S. drug approval systems are quite different. Price controls are a major component of the EU system and often limit the price of innovative brand products. Since the U.S. does not have price controls, innovator company profits are not capped as they are in the EU. This permits a higher rate of return in the United States for innovator products and makes the establishment of a follow-on biologic pathway even more important in the U.S. than in the EU. By allowing innovators to extend their lawful monopoly beyond their valid patent life, consumers and other purchasers of prescription biologic drugs in the U.S. are in many cases deprived of the benefits of competition.

2. What is the likely impact of a follow-on biologic product being designated “interchangeable” (i.e., receiving an approval that would permit pharmacists, without physician authorization, to fill a prescription for the referenced product with the follow-on product)? What are the prospects for the use of “authorized follow-on biologics” in these circumstances? Do the answers to these questions differ based on the type of biologic product involved?

A designation of “interchangeability” by FDA would significantly increase the competitive impact of a follow-on biologic product and consequently the potential for cost savings. We believe the legislation should empower the FDA to decide, based on the characterization technology and other supportive data presented by the follow-on applicant, whether to grant “interchangeability” status. We believe that the technology is emerging that will allow for demonstration of equivalence for follow-on biologics based both on our work with M-Enoxaparin and M356 as well as our initial work in characterizing proteins. This legislative authority would recognize the need for the FDA to establish a standard for demonstrating “interchangeability” but would allow for consumers and payors to benefit from innovation in manufacturing and product characterization technology. Having an appropriate high standard would ensure product quality and reward innovative follow-on manufacturers for their investment. On the other hand, if we merely adopt a Biosimilar pathway for biologics that does not allow for the possibility of Biogeneric approvals and interchangeability, we will remove the necessary incentive for the development of Biogeneric enabling technology. In the absence of such technology, consumers would not fully realize the potential benefits from the competition, price reductions and savings that Biogenics would offer.

At Momenta, we are developing the technology that we believe will make it possible to demonstrate equivalence of a Biogeneric to an innovator biologic. Unlike traditional generic manufacturers, we are engaged in substantial research and development efforts, and the innovations we are bringing to the field will not only make it possible to develop Biogeneric products, but will improve and enhance the characterization, release testing and quality of brand products and their raw materials. If we, and companies like us, do not have the opportunity (i.e., a new legislative pathway) to commercialize products based on this more advanced technology, we will not have the ability to raise investment capital to bring these important, price competitive products to market. If legislation prevents the FDA from making

interchangeability determinations, scientific innovation from technology companies will be held back because the incentive to invest in innovation will not be there. Given the need for high quality, affordable, safe and effective biopharmaceuticals in the marketplace, and the need to maintain state-of-the-art science and technology to determine their interchangeability, it is very important that the FDA be given authority to use its expertise to make critical judgments to determine that two products are interchangeable. The FDA's scientific team, which currently approves and regularly monitors the innovator biologic drugs, certainly has the experience and working knowledge of this class of therapeutics to set the appropriate quality standards for approval of follow-on biologics and ensure patient safety.

3. What competitive concerns are raised by joint research and development, supply, licensing, marketing, and distribution agreements between referenced biologic manufacturers and their follow-on biologic competitors? What would be the likely impact of a requirement that agreements between referenced drug product manufacturers and follow-on biologic applicants be filed with the FTC and the Department of Justice Antitrust Division?

We believe that the current rules and regulations under the Hart Scott Rodino Act already provide for the review of exclusive licensing and distribution arrangements and that these review mechanisms are serving their intended purpose. With the adoption of an abbreviated follow-on biologics pathway for both Biosimilar and Biogeneric products, there will be greater opportunity for companies to collaborate, to develop innovative characterization technology and to compete. We do not believe that further review mechanisms are needed because as competition increases, the collaborations will have less impact in the marketplace than they do today.

4. How would the prospect of competition from follow-on biologic drugs influence research and development for new biologic drugs, improvements to existing biologic drugs, and the timing and rollout of new and/or improved biologic drugs? Does the market experience with non-biologic generic pharmaceutical drug products provide insights into these issues?

We believe that the prospect of competition from follow-on biologics will have a significant pro-competitive impact on research and development for new biologic drugs. First, it will facilitate capital funding of emerging biotechnology companies like Momenta. At Momenta, we are developing the next generation protein characterization technologies that we believe will make it possible to demonstrate equivalence of a Biogeneric to the innovator biologic drug. The establishment of the pathway will enable us to continue our work and will make it possible for other companies to finance their entry into this field. It is also important to note that the investment in such analytical technologies has implications which go well beyond just the development of follow-on biologics. As more advanced analytical technologies are developed to understand these complex biologic products and their manufacturing processes, they can be applied to marketed biologics to ensure the highest quality control. Finally, as one links this increased process and product knowledge to gain broader insights into biology and disease mechanisms, it will support the development of other novel therapeutics to meet key unmet medical needs.

Our experience with our first two products, which are complex mixtures, is that we have substantially advanced the art of assuring product quality. Using our characterization technology, we have been able to submit ANDAs in collaboration with Sandoz.

Finally, by authorizing a path for both Biosimilar and Biogeneric products, brand companies will also have an incentive to re-direct their capital investment. Today, innovator brand companies often invest in “follow-on” brand products that do not lead to significant price competition due to the cost of development. If there was significant price competition from “interchangeable” Biogenerics, there would be a greater incentive for innovator brand companies to take greater risk and to focus their investment more on unmet medical needs where higher pricing could provide an appropriate return on investment while benefitting patients and consumers by meeting new unmet medical needs. Now, instead, this capital is often misdirected to a second or third drug in a class and priced to justify their investment in a full BLA development program.

5. How does the method used by Medicare for reimbursement of biologic drug products affect pricing and competition of referenced biologic products? What factors are important for this effect and why? How would the Medicare reimbursement system likely affect prices for both the referenced and follow-on biologic products? For example, does Medicare reimburse Part B drugs, including biological drugs, based on the Average Sales Price of all the biological drugs whose National Drug Codes (NDCs) reference the same Biologic License Application (BLA)? If so, how would a follow-on biologic drug that does not reference the BLA of the referenced drug affect the Medicare reimbursed price for referenced drug product? How will these and other Medicare reimbursement methodologies likely affect models of price competition after follow-on biologic drug entry?

As a new entrant to this field, without marketed products we do not have specific comments on the impact of the Medicare reimbursement system at this time. What we can say is that absent the legislative authorization of a pathway for follow-on biologics, the opportunity for cost reductions for the Medicare program associated with follow-on biologic products, and in particular with interchangeable Biogenerics will be very limited.

6. How are the patent portfolios claiming biologic drugs similar or dissimilar to the patent portfolios that claim small molecule (nonbiologic) drugs approved under the federal Food, Drug, and Cosmetic Act (FDCA)?

Patent portfolios for biologic drugs have many attributes in common with patent portfolios for small molecule products. The portfolios typically consist of (i) composition of matter patents of both broad and narrow scope, covering the active ingredient of a product (such as a protein or a small molecule), (ii) patents on methods or processes of manufacture of a product; (iii) patents on formulation and dosage forms, and (iv) patents on novel therapeutic uses or administration of a product, such as a small molecule or a protein. Some in the branded community have argued that patents on biologic products tend to be narrower than patents on

small molecules, leaving companies vulnerable to follow-on products that may not be covered by the patents on a branded product. We are not aware of any data that supports this contention. Indeed, a review of the extensive patent portfolios built by brand name companies around some of the most successful biologic therapeutics reveals patent claims that are quite broad on their face.

One difference is that patents on platform technologies may be more commonly relevant to biologic products than to small molecules. Such platform patents (for example, patents on certain host cell and vector components, and methods of making humanized antibodies or Fc fusion proteins generally) are widely known and broadly licensed in the biotechnology industry. Some in the branded community have argued that such platform patents may make patent portfolios more complex than small molecule patent portfolios. However, such complexity makes for very powerful patent portfolios, providing many more options for different types of claims that can be asserted against an accused infringer than would be provided by a simpler set of patents. Moreover, these patents provide for additional patent term extension opportunities for branded products.

Another important difference exists in the treatment of small molecule and biologic product patents with regard to patent term extension. Under the current Hatch-Waxman statute, both small molecules and biologic products are entitled to patent term extension based on the length of the regulatory review period. This is true for biologics despite the fact that there is no abbreviated regulatory mechanism for biogeneric approval and early patent challenge, as there is for small molecules approved under an NDA. As a result, innovator companies have the opportunity to extend their patent term on biologics by up to 5 years allowing for up to 14 or more years post regulatory approval patent life. The imbalance, if there is any, is the omission of the follow-on biologic pathway to balance the existing process for extending the patent monopoly available to biologic products.

7. Are the regulatory exclusivities currently provided to pharmaceutical drug products in the FDCA appropriate for new biologic drugs and/or significant improvements to existing biologic products? Are they appropriate for specific types of biologics? Why or why not?

As noted in question 6, biologics today benefit from the patent extension provisions even though there have been no provisions permitting an abbreviated approval pathway for biologics. Therefore, brand biologics are often able to obtain a longer market monopoly than their initial patent life would allow. In addition, in many high-priced orphan drug markets, the brand name company benefits from the opportunity to seek Orphan Drug Act exclusivity for seven years following approval.

For drugs, Hatch-Waxman strikes a reasonable balance between market incentives and competition to provide affordable access. Hatch-Waxman provides protection beyond that afforded to any other industry to achieve its goal of innovation and access. We believe that follow-on biologics legislation should leverage the success of Hatch-Waxman, five-year data

exclusivity along with intellectual property and the patent restoration provisions, which provides a reasonable balance between innovation and access.

We also believe that the history of Hatch-Waxman provides important lessons that should inform future legislation. The original law allowed for evergreening of patents and strategies to block generic competition through creative patent listings. The 2003 Food and Drug Administration Medicare Prescription Drug, Improvement, and Modernization Act addressed some of these concerns. As noted in Section B, below, careful consideration must be given to the patent component of any biogeneric legislation to assure timely resolution of patent challenges, such that invalid or non-infringed patents do not prohibit FDA approval. Patent considerations should be addressed in court following on or before the filing of an abbreviated follow-on biologics application with the FDA under legislation that provides the FDA with clear and unambiguous authority to act. The provisions that allow the FDA to proceed with approval of an abbreviated application following the filing of a certification that the patents listed by the innovator are invalid or do not cover the generic product are critical. Making it possible for the court system to resolve the matter without burdening the FDA with matters beyond its traditional substantive expertise is also very important. Experience with generic drugs suggests that it is now time to apply the same approach to biogenerics.

8. What are the appropriate factors to consider when determining the optimal length of regulatory exclusivity periods for biologic drug products? Do these factors change based on the type of referenced product involved, the extent of competition facing the referenced product, or patent portfolios claiming the referenced product, and if so, how?

We believe that there is no reason to apply different data exclusivity periods to follow-on biologics than to generic drugs. Five years for new biologics and three years for new indications appear to be appropriate. It is important to note that many biologics compete with small molecules. An inhibitor or agonist of a biologic pathway can be biologic protein, an antibody or a small molecule that regulates that mechanism. By treating these competitive molecules differently, we are reducing the incentive to invest in biologic innovation and development.

In addition, the patent term extension provision of Hatch Waxman already applies to both small molecule drugs and to biologics. Consequently, if the development and regulatory review of a biologic uses a significant portion of the patent life, there is a mechanism for restoring that exclusivity by up to 5 years for a post approval patent life of up to 14 years.

If data exclusivity is extended for biologics, it could also significantly extend patent life of biologics and reduce competition well beyond the current patent term extension periods enjoyed today by innovators. If an innovator has the opportunity to obtain more than 5 years data exclusivity (say for example 10 years data exclusivity), it would be able to rely on the data exclusivity period and could have greater freedom to rely on life cycle patents rather than the innovation related product patents when designating its patent for patent term extension. Remember that under the patent term extension provisions, an applicant has the right to pick

one patent for a product and one product for a patent. If afforded the benefit of an extended data exclusivity period, one could pick a narrower patent or a more recent patent for patent term extension than would be economically warranted in the absence of a longer data exclusivity period. In other words, it will afford innovators more opportunity to game the system and extend patent lives across multiple innovator products because platform or technology patents could be selected for maximum product portfolio patent life extension and formulation patents could be relied on more heavily to protect longer monopoly periods.

While it is generally recognized that the monopoly afforded innovators under patent law is pro-competitive, the ability to “evergreen” or extend monopolies beyond this period, or to game the system to create longer terms of exclusivity is generally recognized as harmful to innovation. See Kotlikoff, “Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity,” pages 4-5 (September 2008) (attached as Exhibit C; hereinafter “Kotlikoff”).

9. How does the European Medicines Agency’s approach to regulatory exclusivities in its abbreviated regulatory approval pathway for follow-on biologics inform the U.S. approach?

Because the EU has a reference pricing system, it is difficult to compare the differing impacts of generic competition in the EU and the US. It does appear though that the availability of an abbreviated pathway in the EU has increased the availability of follow-on biologic competition.

10. Is a marketing exclusivity period necessary to encourage companies to develop follow-on biologics and to seek their approval by the FDA? If so, why, and how should such an exclusivity period be structured?

A reasonable follow-on biologic marketing exclusivity period of 180 days for the first follow-on product to demonstrate equivalence is pro-competitive. The challenges of demonstrating equivalence for Biogenerics or similarity for Biosimilar products, and the financial expense of demonstrating that an innovator’s remaining patent estate does not cover the follow-on biologic or is invalid, requires a significant investment on the part of the follow-on biologics company. Just as is the case with new brand products, orphan drugs and pediatric approvals, the incentive offered by this market exclusivity will encourage development of competitive biogenerics and is probably necessary to attract the investment capital needed to encourage competition in this area.

B. Patent Dispute Resolution Issues

1. Would it be important to have the litigation of any patent disputes proceed concurrently with the abbreviated FDA approval process for follow-on biologics? Why or why not? What has been learned from the experience under Hatch-Waxman about the incentives necessary to encourage early resolution of patent issues?

An early and clear resolution of disputes is essential to encourage investment in follow-on biologics. The process established under the current Hatch-Waxman procedures balances the need for investment with the need to protect innovator patent rights. Under the current process, a generic ANDA filer must certify to the non-infringement or invalidity of publicly disclosed patent rights. The reference brand product owner must then either file suit in response to the filing or the FDA can proceed with the review of the application. This avoids putting the FDA in the position of determining patent rights – an expertise beyond its traditional area of experience. If suit is filed, a 30 month stay issues allowing for a reasonable time period for litigating the case, and is lifted if the suit is resolved and the FDA can proceed. If the suit continues after the stay is lifted and the ANDA is approved, then the generic applicant can decide to launch “at risk” or proceed with litigation before launching.

The current draft bills on follow-on biologics rely on private exchanges of information between branded and generic manufacturers to determine the relevant patents that cover a product. For transparency and efficiency, we recommend that any follow-on biologic legislation require branded manufacturers to list the relevant patents, in a mechanism synonymous to the Orange Book. If a process of private exchanges of information is considered, then we would recommend the following:

- *When the applicant notifies the referenced biologic drug manufacturer of the acceptance of its application, the referenced biologic drug manufacturer should be obligated to identify all of its patents that cover the referenced product (and any subsequently issued patents within a reasonable period of time)*
- *The applicant, upon an assessment of the identified patents, should make a certification to delay marketing of a Biogeneric or Biosimilar product until patent expiry, or if appropriate, a certification of non-infringement or invalidity*
- *The referenced biologic drug manufacturer must then be obligated to sue or should be estopped from bringing suit on the identified, challenged patents. Alternatively, the applicant should have an express right to declaratory judgment jurisdiction if the referenced biologic drug manufacturer does not sue.*
- *Third parties should not be permitted to take part in the patent challenge process as this would certainly make the process overly complex and burdensome. Surely the brand name manufacturer can be expected to have rights in any and all patents that are relevant or required for marketing the branded product.*

These changes would add certainty to the process and ensure the patent issues are resolved and not buried or delayed to a later date.

We believe this process allows for investors and follow-on biologic companies to evaluate the patent risk, and in cases where patent rights are weak, proceed with a well-defined process to obtain approval. If a different process were adopted for biogenerics, it would create further uncertainty and the opportunity for litigation that could delay new entry of competition and reduce the incentive for investment in biogenerics.

2. How long might the approval process for a follow-on biologic application take? What factors might influence this timing?

The Federal Food, Drug and Cosmetic Act requires that the FDA make a decision on ANDAs within 180 days although approval time has often ranged from 12-18 months. Filings of follow-on biologics will involve a careful review of the manufacturing process and analytical methods, as well as any additional supportive data required by FDA and, thus, the review period could in some cases take an additional period of time. Nevertheless, FDA currently makes decisions on break through therapeutics within 180 days. With adequate resources, the FDA should be able to make decisions on follow-on biologic applications within a 180 day timeframe, although it may have to be longer during the initial stages of the program as applicants and the FDA develop experience with new technology.

Because the approval of follow-on biologics applications likely involve the review of new technical approaches, the engagement of several FDA centers, and substantial filing of data, we would also support the adoption of user fees (with appropriate time limits for FDA review) to facilitate the appropriate staffing at the FDA. Without additional staffing, unnecessary delays in the review and approval of abbreviated applications could be expected and would delay the pro-competitive benefits of the legislation.

3. How might differences between patent portfolios for small molecule drugs and biologics affect patent litigation involving follow-on biologics? How long might patent litigation involving a follow-on biologic product take?

We do not believe that the differing subject matter of small molecules and biologics will impact patent litigation involving a follow-on biologic. Patent litigation has existed for many years on both types of products, and while individual cases may differ in complexity, we do not believe, and have seen no data, that there is a categorical difference that would warrant a different approach for follow-on biologics. The proposed legislation, H.R. 5629, which would authorize litigation on all patents regardless of whether they would delay a launch, could potentially overwhelm the follow-on biologic company and result in a loss of competition. A legislative regime like Hatch-Waxman that ties the initiation of litigation to the filing of the application by the applicant allows for an applicant to have certainty and provides the brand manufacturer with ample opportunity to seek relief during the 30 month stay period.

4. When is it in the interest of a referenced biologic drug manufacturer to resolve patent issues prior to marketing by a follow-on applicant? When is it in the interest of a follow-on biologic applicant to resolve patent issues prior to marketing its follow-on biologic? When is it in the interest of either party to resolve patent issues following commercial marketing of the follow-on product?

It should be in the interest of a referenced biologic drug manufacturer as well as a follow-on applicant to have an early resolution of any patent issues, although that has not proven to be the case for some referenced biologic manufacturers. Because of the size of the markets, there is an incentive for referenced biologic drug manufacturers to extend and defend questionable patent rights to preserve market share. As a result, in the absence of the Hatch Waxman or similar mechanism which forces litigation at the time an ANDA is filed, a referenced biologic drug manufacturer would not ordinarily bring suit until a follow-on applicant launches the product to maintain its patent position as long as is possible. Similarly, in the absence of a Hatch-Waxman or similar regime, a court may find that it does not have jurisdiction to resolve a patent dispute in advance of launch when the referenced biologic manufacturer does not threaten suit under the patent rights.

5. What are the legal impediments facing a follow-on biologic applicant that has not been sued for infringement to obtaining a declaratory judgment on patent infringement or invalidity issues prior to commercial marketing of its follow-on product?

As noted in response to question 4, absent a clear threat of litigation by the referenced biologic, there is questionable jurisdiction to bring a declaratory judgment action prior to commercial marketing of a product by a follow-on applicant. This creates significant uncertainty for the follow-on biologic manufacturer and disincentivizes investment in the development of follow-on biologics. Absent the opportunity to have early notice and an early opportunity to resolve patent conflicts, it is unlikely that innovator companies in the generic industry will be able to attract investment capital of sufficient size to undertake these activities and assume these risks. This is the reason for the adoption of the Hatch-Waxman certification and mandatory filing of suit mechanism for generic drugs.

6. Are regulatory exclusivities needed to encourage follow-on biologic applicants to challenge patents? Why or why not?

As noted in response to question A. 10, above, we believe that a reasonable regulatory exclusivity period for the first follow-on biologic approved that is consistent with that offered to generic drugs is necessary and appropriate to act as an incentive to follow-on applicants to invest in challenging invalid patent rights and in developing follow-on biologics on a timely basis.

7. What opportunities will biologic drug manufacturers and follow-on applicants have to manipulate proposed new regulatory obligations (e.g., application notification obligations, declarations of patents claiming biologic drugs, etc.) and exclusivity periods surrounding a concurrent patent resolution process? What are the prospects for the improper use of citizen petitions to delay approval of follow-on biologic applications?

We believe that the FDA has the necessary competence to determine whether applicants have met the necessary standards for follow-on biologic approvals, including the necessity for clinical trials. While appropriate in some cases, the Citizen Petition process has in our view been used to slow down approval of legitimate products because they threaten the competitive position of a brand product. We believe the appropriate course of action is to adopt legislation that makes it clear that FDA has the authority to review and approve follow-on biologics based on the science presented, without mandatory requirements for clinical trials or public guidance documents. FDA has the expertise and experience with these complex molecules to make science-based decisions on Biogeneric and Biosimilar product approvals. Innovator companies using the petition process to inhibit, and not support the pursuit of the best science-based decision would unnecessarily delay product approvals, competition, and access to quality, affordable medicines for patients in need.

The creation of an extended data exclusivity period or approval exclusivity period for branded products will serve to facilitate gaming by brand manufacturers. If the extension is longer than the current Hatch Waxman periods, it will facilitate strategic selection of patents for patent term extension. Patents with narrower coverage and patents covering formulation may be selected for patent term extension which, when coupled with the original patent life on the protein itself and the data exclusivity period, might extend the effective monopoly well beyond the 5 years under Hatch Waxman. Protein and antibody products, like small molecule products, frequently have multiple patent coverage involving their composition of matter, their underlying platform for production, their actual manufacturing process and their therapeutic use or dosing. Because these patents are often filed at different points in a product development cycle, a brand manufacturer acting rationally will wait until their marketing application is filed, and then select among many patent options for patent term extension. A longer data exclusivity period will allow for the selection of the patent with the longest life (even if narrower) because of the parallel data or approval exclusivity.

It is also worth noting that the legislative proposals that claim to ameliorate this problem by allowing a generic company to file for approval, but not obtain approval during this exclusivity period do not solve the underlying harm. As noted by Dr. Kotlikoff, the deferral of the opportunity to litigate and resolve patent challenges substantially increases the risk associated with generic development, and is clearly anticompetitive. Kotlikoff at 5-9. Kotlikoff estimates that several data exclusivity proposals would increase monopoly protection from the date of the patent application from 25 years under Hatch Waxman to 32 years under the Kennedy Bill and 37 years under the Eshoo-Barton Bill and the Inslee Bill. Kotlikoff at 7.

He also notes that a key benefit of the Hatch Waxman structure is the incentive Hatch Waxman creates for the rapid development of new therapies by brand name companies as a result of the clear limit on monopoly protection. If the effective monopoly period is extended, then the race to create new therapies would diminish.

8. How might referenced biologic product manufacturers and follow-on biologic applicants structure patent settlement agreements given the competitive dynamics arising from the marketing of follow-on biologic drugs? What incentives might exist for these companies to enter anticompetitive settlements? Should patent settlement agreements be filed with the antitrust agencies? What would be the likely effect of the filing requirement on settlements?

As a follow-on biologic innovator, we have not had direct experience with structuring a settlement of a patent case allowing for the marketing of a product. We believe the issues would be similar to those present in generic cases if the new legislation follows the Hatch-Waxman regime as we have proposed.

We appreciate the opportunity to submit these comments. We hope that our submission provides appropriate background on our company and our position on key elements of the emerging follow-on biologics legislation. We welcome further discussion, recognizing that there are multiple positions being offered on these complex issues. We remain committed, however, towards supporting final legislative language that will provide incentives for companies to compete and innovate, meet the appropriate high quality standards as set by FDA, and bring safe, affordable medicines to patients in need.

If you have any questions regarding our submission, please feel free to contact me at 617-395-5105. We would be very interested in participating in the November 21 panel discussions and believe that as a biotechnology based innovator company that is engaged in making it possible to develop follow-on biologics, we believe we can offer a unique view of the future opportunity as the policy alternatives are considered. We will contact your office to discuss our participation.

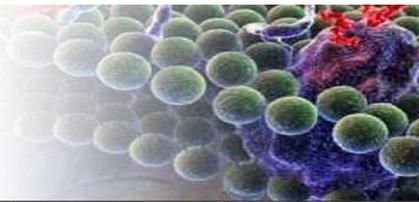
Sincerely,

Steven Bruggér
Chief Operating Officer



Exhibit A

Momenta Company Overview



Momenta Company Overview

Momenta is a biotechnology company, founded in 2001 based on a technology platform initially developed and licensed from Massachusetts Institute of Technology. We currently employ approximately 160 employees at our offices in Cambridge, Massachusetts. We are applying our innovative technology for the detailed structural analysis of complex mixture drugs to the discovery and development of both novel and complex generic biopharmaceuticals. We leverage this platform to study the *structure* (i.e., thorough characterization of chemical components), *structure-process* (i.e., design and control of manufacturing process), and *structure-activity* (i.e., relating structure to biological and clinical activity) of complex mixture drugs. The development product candidates and research programs from our generic and novel portfolios are outlined below.

Momenta Pharmaceuticals—Product and R&D Pipeline

	Complex Mixture Generic Drugs	Novel Drugs
Development Product Candidates	M-Enoxaparin [†] (Generic Lovenox®) M356 [†] (Generic Copaxone®) M178 [†] , M249 [†] (Follow-on Biologic Drugs)	M118 (Anticoagulant)
Research Programs	Follow-on Biologics (FOBs)	Oncology

[†] In collaboration with Sandoz/Novartis Pharmaceuticals

Complex Mixture Generics Portfolio

Our complex generics effort is focused on building a thorough understanding of the *structure* and *structure-process* of complex mixture drugs to develop generic versions of marketed products. We utilize a similar development approach across all of our product candidates. Our first objective is to apply our core analytical technology to thoroughly characterize the marketed product by defining its chemical composition. Using this information, we then build an extensive understanding of the structure-process relationship to design and control our manufacturing process to reproducibly manufacture the product. Our goal is to obtain FDA approval for and commercialize generic or follow-on versions of complex mixture products, thereby providing high quality, effective, safe, and affordable medicines to patients in need.

Our most advanced product candidate, **M-Enoxaparin**, is designed to be a technology-enabled generic version of Lovenox® (enoxaparin sodium injection), a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. This drug is a complex mixture of polysaccharide chains derived from naturally sourced heparin. An Abbreviated New Drug Application (ANDA) for M-Enoxaparin, submitted in August, 2005, is currently under FDA review. Our second major generic product candidate is **M356**, a technology-enabled generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis, or RRMS. Copaxone® consists of a complex mixture of polypeptide chains. With M356, we have extended our core characterization capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures. An ANDA for M356, submitted in December, 2007, is currently under FDA review.

Our next two product candidates, **M178** and **M249**, and our ongoing **FOBs Research Program** are focused on developing generic or follow-on versions of marketed therapeutic proteins. All therapeutic proteins are derived from natural or cell based manufacturing sources that create complex mixtures. With this effort, we are further extending our core characterization and manufacturing capabilities to additionally include the characterization of complex glycoprotein products.

Novel Drugs Portfolio

Our novel drug research and development efforts leverage our analytical technology platform and structure-process knowledge to study the *structure-activity* of complex mixtures and develop novel drugs. With our capabilities to thoroughly characterize complex mixtures, we are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex mixture drugs. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex mixtures to engineer novel drugs that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex mixture drugs can be applied across several product categories with significant therapeutic potential (i.e., polysaccharides, polypeptides and glycoproteins), our initial focus has been in the area of complex polysaccharide mixtures.

Our lead novel drug candidate, **M118**, is a LMWH that has been engineered to possess what we believe will be an improved therapeutic profile (compared with other currently marketed products) to support the treatment of ACS. We are currently conducting a Phase IIa study in patients undergoing percutaneous coronary intervention, or PCI. Within our research program, we are seeking to discover and develop novel therapeutics by applying our technology to better understand the function of these polysaccharide mixtures in biological processes, with an initial focus in **Oncology**.

Momenta Technology

Our integrated technology platform for the study of complex mixtures utilizes three different types of analytical tools. First, we have accumulated a comprehensive library of enzymes that we use to break down the components of a complex mixture into smaller, measurable units. Second, we apply proprietary improvements to established analytical techniques (such as Matrix Assisted Laser Desorption Ionization-Mass Spectrometry, or MALDI-MS, nuclear magnetic resonance, or NMR, and capillary electrophoresis, or CE, among others), to gather and analyze information regarding the components, structure and arrangement of the chemical building blocks of the complex mixture. Third, we apply proprietary mathematical methods that integrate the disparate information obtained from these analytical techniques to arrive at a specific, numerically-derived solution that describes the complete composition of a specific complex mixture. It is the combination of these tools that enables us to characterize complex polysaccharide, polypeptide and glycoprotein mixtures.

While a similar integrated analytical approach is applied across different product categories, we develop a unique characterization toolkit for each specific complex mixture. Once the chemical components of the complex mixture are known (*structure*), we (1) further employ these methods and data sets in the design and control of our manufacturing process (*structure-process*) to produce generic versions of marketed drugs, and (2) relate structure to biological and clinical activity (*structure-activity*) to engineer novel drugs which meet key unmet medical needs in various diseases.

Company Contact Information

Our principal executive offices are located at 675 West Kendall Street, Cambridge, Massachusetts 02142, and our telephone number is (617) 491-9700. Our Internet address is www.momentapharma.com.



Exhibit B

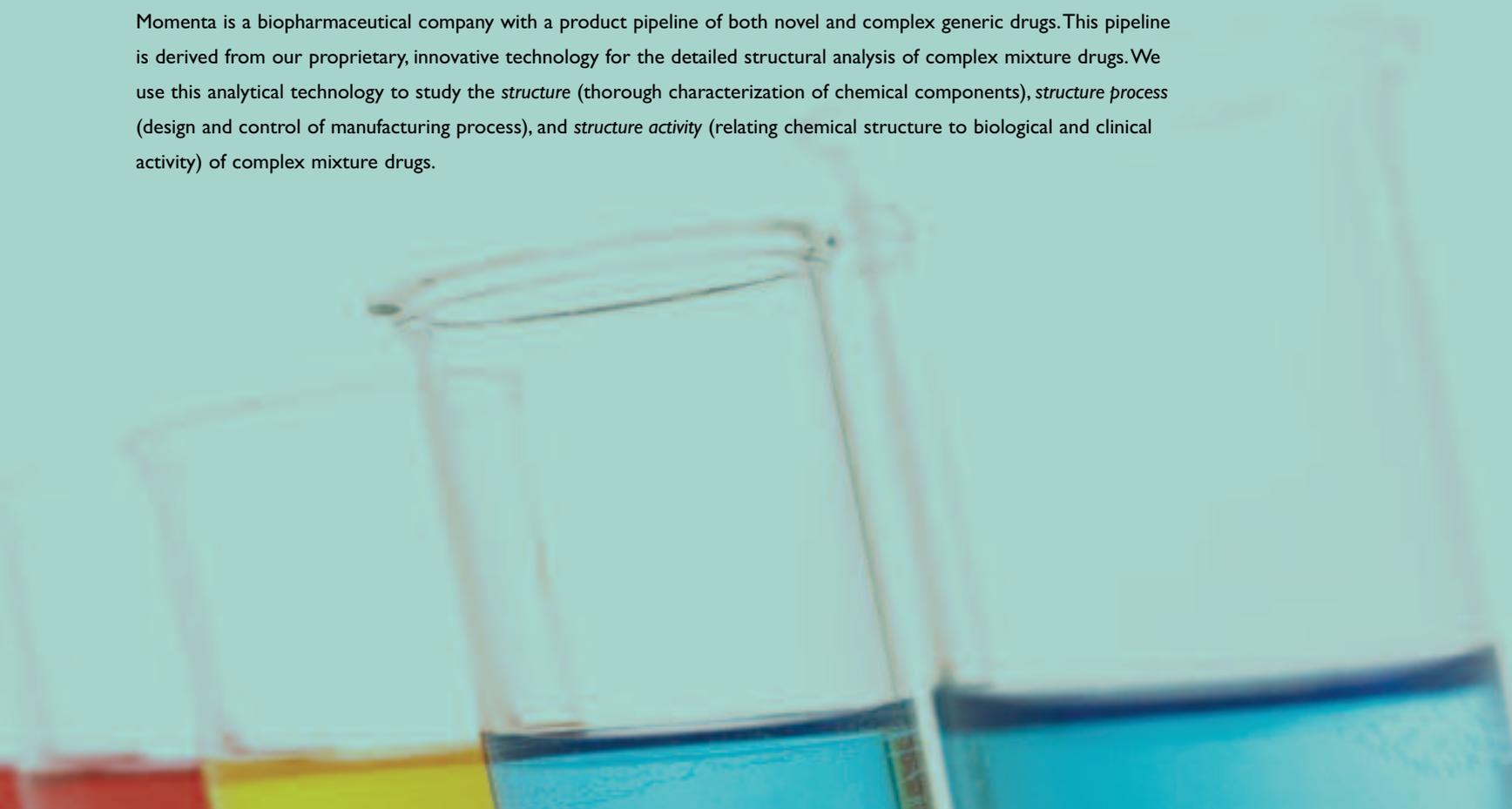
Annual Report 2007

PRODUCT PIPELINE

Drug Candidate	Program Objectives	Status
Complex Mixture Generics		
M Enoxaparin*	Generic version of Lovenox®	Under FDA review
M356*	Generic version of Copaxone®	In development
Glycoproteins*	Follow on versions of marketed protein drugs	In development
Novel Drugs		
MI18	Next generation anticoagulant engineered for Acute Coronary Syndromes	Phase 2a
Oncology	Novel sugar based anti cancer compound	In discovery

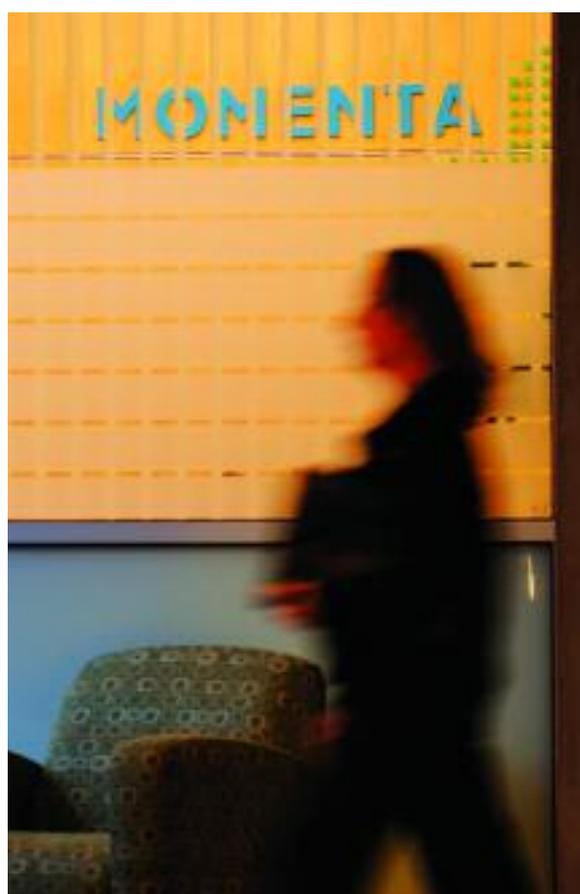
*In collaboration with Sandoz, the generic pharmaceuticals division of Novartis.

Momenta is a biopharmaceutical company with a product pipeline of both novel and complex generic drugs. This pipeline is derived from our proprietary, innovative technology for the detailed structural analysis of complex mixture drugs. We use this analytical technology to study the *structure* (thorough characterization of chemical components), *structure process* (design and control of manufacturing process), and *structure activity* (relating chemical structure to biological and clinical activity) of complex mixture drugs.



PROFILE ..>

We chose the theme “A Unique Perspective” for our 2007 Annual Report because it illustrates an essential truth about Momenta and the way we approach our business. Simply put, we look at things differently. Sugars play a fundamental role in cellular function and disease and, due to their complexity, have been poorly understood. Our founders took an unconventional approach to develop path-breaking analytics to crack the code of these complex molecules. Our business model is similarly unconventional, embracing the development of both high-value generics and novel therapeutics. The result of this unconventional approach to drug development is Momenta’s pipeline, comprised of complex generic products as well as emerging novel therapeutics. All this is made possible by a talented and dedicated team that continues to rise to the challenge of looking at things with a unique perspective.



Dear Shareholder:

Momenta's founders had a vision – to overcome the conventional thinking and technical barriers that blocked the scientific understanding of complex sugar mixtures. Their goal was to unravel the chemical structures of these important natural molecules to gain insights into their biological activity and processes for manufacturing them. Today, six years after commencing operations, Momenta continues to pursue that vision, advancing its capabilities to analyze complex polysaccharides, and extending the technology to analyze complex peptides and glycoproteins. At Momenta, we continue to strive for scientific excellence in everything we do while challenging the conventional. Our strength is our unique perspective.

focus, enabled by important technical advances in applying our analytics to glycoproteins, is development of differentiated follow-on biologics that have the potential to be not simply biosimilars, but true biogenerics.

Our traditional complex generics pipeline includes M-Enoxaparin and M356, both partnered with Sandoz, a division of Novartis. M-Enoxaparin, our generic version of Lovenox, is currently under FDA review. In November 2007 we received a request from the FDA to provide additional data to address the potential of the immunogenicity of the product. We are currently working with the agency to provide that data. Our M356 program continued to make exciting technical progress in 2007. This development product, a generic version of Copaxone, represents a challenging application

“At Momenta, we continue to strive for scientific excellence in everything we do while challenging the conventional. Our strength is our unique perspective. Our scientific advances have informed our strategic direction.”

Our scientific advances have informed our strategic direction. We have focused our efforts on three areas of product development. The first area of focus – which includes our most advanced product – is in using our technology to develop generic versions of complex products that can be filed as “traditional” abbreviated new drug applications, or ANDAs, and approved under existing FDA regulations. The second focus is novel drug development, where we use our understanding of chemical structures to unlock the biology of complex sugars and engineer novel drugs. The third

of our analytical technology to a highly complex polypeptide.

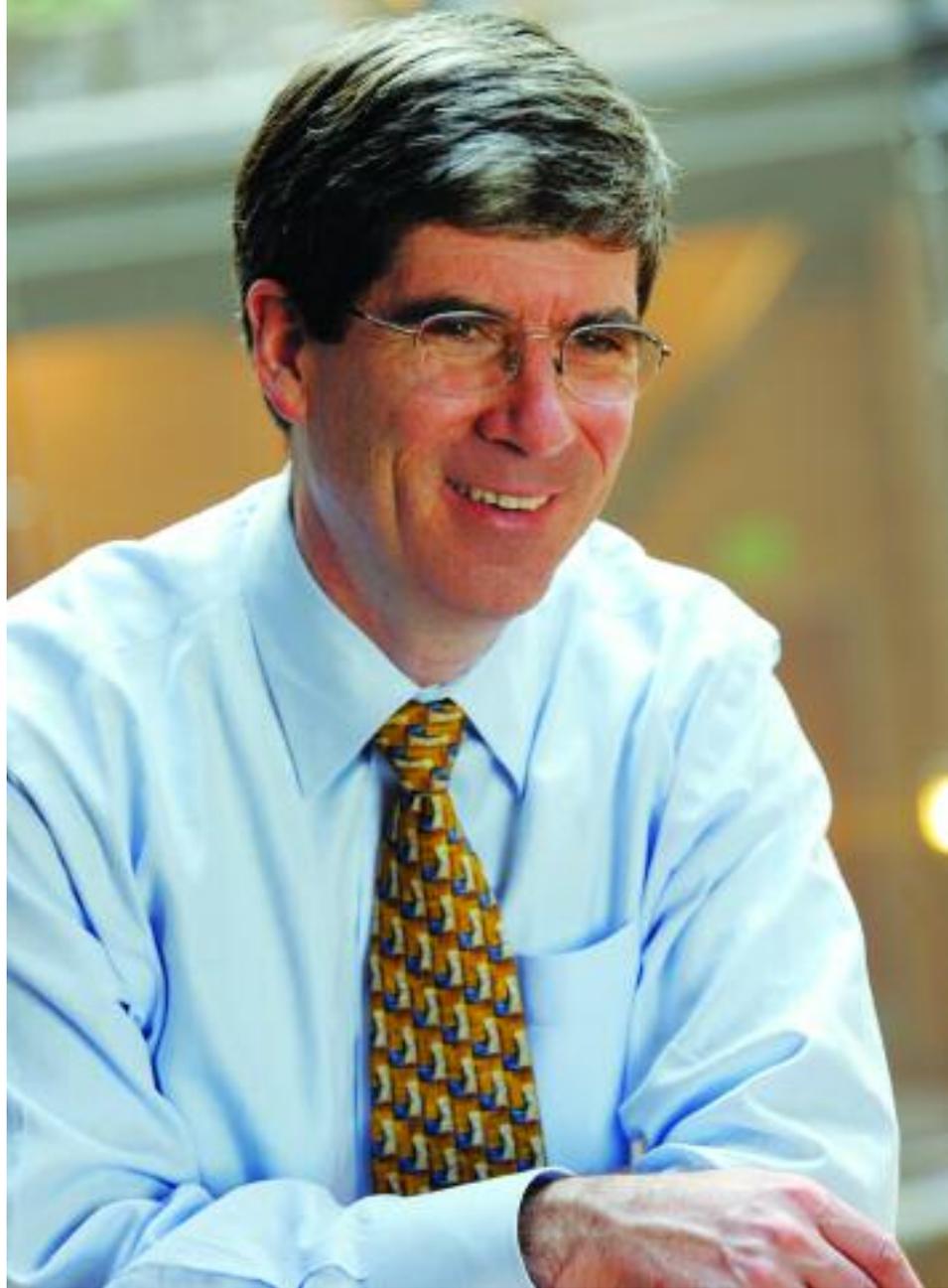
The first new drug to emerge from our analytic platform is M118, a novel anticoagulant with the potential to become the baseline anticoagulant in acute coronary syndromes (ACS). We are anticipating data from the M118 Phase 2a EMINENCE study by the end of 2008. In addition, we are developing a promising oncology candidate that we hope to advance into preclinical studies in 2008.

We also made outstanding progress in 2007 in adapting our tools to characterize complex glycoproteins with the intent of creating follow-on biologics. As part of our collaboration with Sandoz, we are applying our glycoprotein technology to two of their biosimilar products. Our analytical technology to characterize complex glycoproteins continues to advance, and we believe that Momenta can now develop differentiated follow-on biologic products to capture significant value in this global multi-billion dollar market. We are developing business strategies to capitalize on this potential.

In my second year as CEO of Momenta, I continue to be impressed by the accomplishments of the Momenta team and the quality of our science. The size of the commercial opportunities our products are addressing is tremendous. But the success of our strategy depends on more than our scientific achievements. It requires regulatory validation and legislative enablement. In 2008 we will be focusing our efforts on securing regulatory approval for M-Enoxaparin, while advancing our other development products and furthering the enabling science for follow-on biologics. In addition we will be working to ensure that the legislation to enable follow-on biologics allows for the potential of advances in analytical technologies like Momenta's to create equivalent biogeneric products. I am excited about what we can accomplish in 2008 and beyond.

Sincerely,

Craig A. Wheeler
President and Chief Executive Officer
March 31, 2008



Craig A. Wheeler
President and Chief Executive Officer



COMPLEX MIXTURE GENERICS ...>

Our complex generic product efforts are focused on building a thorough understanding of the structure and structure-process of complex mixture drugs to develop generic versions of marketed products. Our goal is to obtain FDA approval for and commercialize generic or follow-on versions of complex mixture products, thereby providing high quality, safe, and affordable medicines to patients in need. Our pipeline includes M-Enoxaparin, a generic version of Lovenox; M356, a generic version of Copaxone; and two glycoproteins being developed as follow-on biologics.

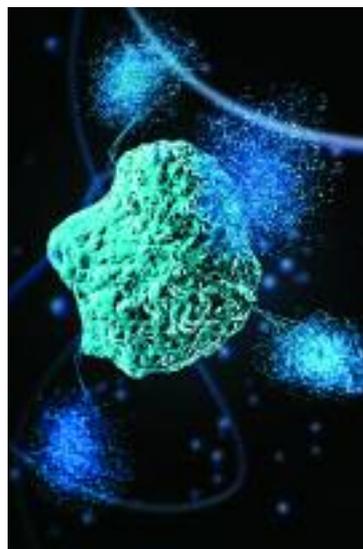
M-ENOXAPARIN . . . Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox (enoxaparin sodium), a low-molecular-weight heparin (LMWH) product marketed by Sanofi-Aventis. A complex mixture composed of thousands of distinct complex sugar chains, Lovenox is the most widely prescribed LMWH for the prevention and treatment of deep vein thrombosis and treatment of acute coronary syndromes. Our ability to apply our technology to sequence and analyze complex mixtures has allowed us to characterize Lovenox and develop a manufacturing process to make a generic version. We believe M-Enoxaparin contains the same active ingredients, dosage form, route of administration and strength as the innovator product, which are essential to satisfying the FDA's requirements for therapeutic equivalence. We have collaborated with Sandoz to jointly develop, manufacture and commercialize M-Enoxaparin in the U.S. and, more recently, the European Union. At this time, an Abbreviated New Drug Application (ANDA) for M-Enoxaparin has been submitted by Sandoz and is currently under review at the FDA.

M356 . . . M356 is a generic version of Copaxone (glatiramer acetate injection), a drug consisting of a complex mixture of polypeptide chains, marketed by Teva Neuroscience. Copaxone is prescribed for patients with relapsing-remitting multiple sclerosis, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. Copaxone is one of the leading products marketed for treating multiple sclerosis. Under our most recent collaboration with Sandoz, we and Sandoz have agreed to jointly develop, manufacture and commercialize M356 worldwide. Given its complex structure as a mixture of polypeptide chains of various lengths and sequences, there are significant technical challenges involved in

thoroughly characterizing Copaxone and in manufacturing an equivalent version. We believe our technology can be applied to characterize glatiramer acetate and to develop a generic product that has the same active ingredients as Copaxone. We made significant progress in this program in 2007 and look forward to substantial advancements in 2008.

FOLLOW-ON BIOLOGICS . . . Biologics represent a sizable segment of the U.S. drug industry, with sales expected to exceed \$60 billion by 2010. Most of these products are glycoprotein drugs, which contain branched sugars attached to a protein backbone that vary from molecule to molecule. These sugars can impart specific biological properties to the glycoprotein drug and often comprise a significant portion of the mass of the molecule. Given the inadequacies of standard technology, many of these glycoproteins have not been thoroughly characterized. Our follow-on biologics program is focused on extending our technology for the analysis of complex sugars and peptides to glycoproteins. The goal of the program is to facilitate the development of biosimilar, and potentially biogeneric, versions of major marketed glycoprotein biologics.

Momenta's technology enables thorough analysis of the molecular structure of complex drugs that cannot be characterized using traditional techniques.





NOVEL DRUGS ...

Momenta's novel drug research and development efforts leverage our analytical technology platform and structure-process knowledge to link the structure of complex mixtures to their biological activity. Our goal is to engineer novel drugs that meet key unmet medical needs. Our capabilities to engineer improved and novel complex mixture drugs can be applied across several therapeutic categories, with an initial focus on complex polysaccharide mixtures.

M118 ... Our most advanced novel product candidate is M118, a next generation anticoagulant. M118 was developed at Momenta to address what we believe to be a clear unmet need in the practice of cardiology – an improved anticoagulant used to support the treatment of patients diagnosed with acute coronary syndrome (ACS) and stable angina. We believe that M118 has the potential for use as a baseline anticoagulant therapy for patients with ACS and stable angina who require a coronary intervention or revascularization procedure, as well as those ACS patients who are medically managed and do not require intervention in order to treat their condition. M118 is designed to be a reversible and monitorable anticoagulant that can be administered intravenously or subcutaneously, and that has a pharmacokinetic profile similar to a LMWH. We believe that these properties have the potential to provide greater flexibility than other therapies presently used to treat patients diagnosed with ACS and stable angina.

M118 is currently being evaluated in a Phase 2 clinical trial known as EMINENCE. Based on analysis of Phase 1 data, M118 has demonstrated dose-dependent anticoagulant activity that is monitorable with a rapid point-of-care assay (Activated Clotting Time or ACT), is reversible with protamine sulfate and can be concomitantly administered with other agents typically utilized to treat ACS, including aspirin, thienopyridines, and glycoprotein IIb/IIIa inhibitors. We expect the Phase 2a study to provide important information about the safety of M118 as well as the ability to use M118 as a procedural anticoagulant. Subsequent

Phase 2b studies are designed to explore the use of M118 in patients diagnosed with ACS who are either managed medically or proceed to early intervention via percutaneous coronary intervention, or PCI.

ONCOLOGY ... Within our research program, we are seeking to discover and develop novel therapeutics by applying our technology to better understand the function of these polysaccharide mixtures in biological processes. Our novel pipeline includes a promising heparin-based oncology candidate, which takes advantage of heparin's natural antimetastatic and antiproliferative properties. We hope to move this drug candidate into preclinical development in 2008.

LOOKING AHEAD ... Looking to the future, we will continue to apply our technology to the development of both generic versions of complex drugs as well as to the discovery and development of novel drugs. We believe our proprietary technology, innovative business model and outstanding team provide us with the foundation to create a successful and sustainable business, and we look forward to delivering on that potential.

Sugars, together with DNA and proteins, play a critical role in regulating biological processes throughout the human body.





Momenta Executive Team

Front row, left to right:

Craig A. Wheeler
President and Chief Executive Officer

Jo-Ann Beltramello
Vice President, Human Resources

Middle row, left to right:

Catharine E. Johnson
Vice President, Corporate Development

Ganesh Venkataraman, Ph.D.
Senior Vice President, Research
and Chief Scientific Officer

Steven N. Avruch, Esq.
Deputy General Counsel

Back row, left to right:

Richard P. Shea
Senior Vice President and
Chief Financial Officer

Steven B. Brugger
Chief Operating Officer

James M. Roach, M.D.
Senior Vice President and
Chief Medical Officer

John E. Bishop, Ph.D.
Senior Vice President,
Pharmaceutical Sciences

Statements contained or incorporated by reference in this Annual Report that are not based on historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts and projections and the beliefs and assumptions of our management. Forward-looking statements may be identified by the use of forward-looking terminology such as “may,” “believe,” “could,” “will,” “expect,” “should,” “estimate,” “anticipate,” “would,” “continue” or similar terms, variations of such terms or the negative of those terms. We cannot assure investors that our expectations and assumptions will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2007 under the section “Risk Factors,” as well as other documents that may be filed by us from time to time with the Securities and Exchange Commission. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Our logo, trademarks and service marks are the property of Momenta. Other trademarks or service marks appearing in this Annual Report are the property of their respective holders.

INVESTOR INFORMATION

Corporate Information

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Tel: 617-491-9700
Fax: 617-621-0431
www.momentapharma.com

Investor Relations

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617-491-9700

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& Trust Company
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212-936-5100

Independent Auditors

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Boston, MA 02116
617-266-2000

Legal Counsel

Wilmer Cutler Pickering
Hale and Dorr LLP
60 State Street
Boston, MA 02109
617-526-6000

Executive Team

Craig A. Wheeler
President and
Chief Executive Officer

Steven N. Avruch, Esq.
Deputy General Counsel

Jo-Ann Beltramello
Vice President,
Human Resources

John E. Bishop, Ph.D.
Senior Vice President,
Pharmaceutical Sciences

Steven B. Brugger
Chief Operating Officer

Catharine E. Johnson
Vice President,
Corporate Development

James M. Roach, M.D.
Senior Vice President and
Chief Medical Officer

Richard P. Shea
Senior Vice President and
Chief Financial Officer

Ganesh Venkataraman, Ph.D.
Senior Vice President, Research
and Chief Scientific Officer

Board of Directors

Peter Barrett, Ph.D.
Chairman of the Board
Partner, Atlas Venture

John K. Clarke
Managing General Partner
Cardinal Partners LP

Alan L. Crane
President and
Chief Executive Officer
Tempo Pharmaceuticals, Inc.

Marsha H. Fanucci
Senior Vice President and
Chief Financial Officer
Millennium Pharmaceuticals, Inc.

Peter Barton Hutt, LL.B., LL.M.
Senior Counsel
Covington & Burling LLP

Robert S. Langer, Jr., Sc.D.
Institute Professor, MIT
Momenta Co-Founder

Stephen T. Reeders, D.M.
Managing Partner
MVM Life Science Partners LLP

Ram Sasisekharan, Ph.D.
Underwood-Prescott Professor
of Biological Engineering and
Health Sciences & Technology,
MIT
Momenta Co-Founder

Bennett M. Shapiro, M.D.
Former EVP/Head of Research
Merck & Co.

Elizabeth Stoner, M.D.
Executive Partner
MPM Capital

Craig A. Wheeler
President and
Chief Executive Officer
Momenta Pharmaceuticals, Inc.

Stock Listing

Momenta is traded on the
NASDAQ Global Market
under the symbol MNTA. As
of February 29, 2008 there
were approximately 63 holders
of record of our common
stock, which does not include
stockholders whose common
stock is held in street name.

Annual Meeting

The 2008 Annual Meeting of
Stockholders will be held on
Wednesday, June 4, 2008 at
10:00 a.m. at the offices of
Wilmer Cutler Pickering Hale
and Dorr LLP, 60 State Street,
Boston, MA 02109.

Stockholder Inquiries

Questions regarding stock
transfer requirements, lost
certificates and changes of
address should be directed to
the transfer agent as listed.
Other stockholder or investor
inquiries, including requests
for our filings with the
U.S. Securities and Exchange
Commission, should be
directed to Investor Relations
at our address or phone
number. SEC filings are avail-
able on our website at:
www.momentapharma.com

Photos

Cover: Zainab Mamuwala, Senior Research Associate, API Development;
Ian Fier, Vice President, Development Operations; Francis Awokang,
Chemistry/API Development; Kei Kishimoto, Vice President, Disease Biology;
Claire Coleman, Senior Scientist, API Development

Page one: Lynette Herscha, Assistant General Counsel

Page four: Jennifer Eppig, Sr. Associate, Market Research & Analysis; Maurice
Bedoni, Manager, Financial Planning & Analysis; Lorraine Shedoudi, Executive
Assistant, Strategic Business Operations

Page six: David Knisely, Senior Research Associate, API Development



Momenta Pharmaceuticals, Inc.

675 West Kendall Street

Cambridge, MA 02142

Tel: 617.491.9700

www.momentapharma.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission file number: 000-50797

MOMENTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware **04-3561634**
(State or other jurisdiction of incorporation or organization) (I.R.S. Employer Identification No.)

675 West Kendall Street, Cambridge, Massachusetts 02142
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: **(617) 491-9700**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.0001 par value (excluding Preferred Stock Purchase Rights, \$0.01 par value)	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of Class)

Preferred Stock Purchase Rights, \$0.01 par value

Indicate by check mark if registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 29, 2007, based on \$10.08 per share, the last reported sale price of the shares of Common Stock on the Nasdaq Global Market on that date, was \$216,699,235.

The number of shares outstanding of each of the registrant's classes of common stock, as of February 29, 2008:

Class	Number of Shares
Common Stock, \$0.0001 par value	36,759,169

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the information required by Part III of Form 10-K will appear in the registrant's definitive Proxy Statement on Schedule 14A for the 2008 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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PART I

Item 1. BUSINESS

The Company

Momenta is a biotechnology company with a product pipeline of both novel and complex generic drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixture drugs. 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. The development product candidates and research programs from our generic and novel portfolios are outlined below.

Momenta Pharmaceuticals—Product and R&D Pipeline

	Complex Mixture Generic Drugs	Novel Drugs
Development	M-Enoxaparin (Generic Lovenox [®])	
Product	M356 (Generic Copaxone [®])	M118 (Anitcoagulant)
Candidates	M178, M249 (Generic Protein Drugs)	
Research Programs	Follow-on Biologics (FOBs)	Oncology

Complex Mixture Generics Portfolio

Our complex generics effort is focused on building a thorough understanding of the *structure* and *structure-process* of complex mixture drugs to develop generic versions of marketed products. We utilize a similar development approach across all of our product candidates. Our first objective is to apply our core analytical technology to thoroughly characterize the marketed product by defining its chemical composition. Using this information, we then build an extensive understanding of the structure-process relationship to design and control our manufacturing process to reproducibly manufacture the product. Our goal is to obtain FDA approval for and commercialize generic or follow-on versions of complex mixture products, thereby providing high quality, safe, and affordable medicines to patients in need.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox (enoxaparin sodium injection), a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. This drug is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our second major generic product candidate is M356, a technology-enabled generic version of Copaxone (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis, or RRMS. Copaxone consists of a complex mixture of polypeptide chains. With M356, we have extended our core characterization capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures.

Our next two product candidates, M178 and M249, and our ongoing research program are focused on developing generic or follow-on versions of marketed therapeutic proteins. All therapeutic proteins are derived from natural or cell based manufacturing sources that create complex mixtures. With this effort, we are further extending our core characterization and manufacturing capabilities to additionally include the characterization of complex glycoprotein products.

Novel Drugs Portfolio

Our novel drug research and development efforts leverage our analytical technology platform and structure-process knowledge to study the *structure-activity* of complex mixtures and develop novel drugs. With our capabilities to thoroughly characterize complex mixtures, we are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex mixture drugs. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex mixtures to engineer novel drugs that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex mixture drugs can be applied across several product categories with significant therapeutic potential (i.e., polysaccharides, polypeptides and glycoproteins), our initial focus has been in the area of complex polysaccharide mixtures.

Our lead novel drug candidate, M118, is a LMWH that has been engineered to possess what we believe will be an improved therapeutic profile (compared with other currently marketed products) to support the treatment of ACS. Within our research program, we are seeking to discover and develop novel therapeutics by applying our technology to better understand the function of these polysaccharide mixtures in biological processes, with an initial focus in oncology.

Company Background

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, Massachusetts 02142, and our telephone number is (617) 491-9700.

In this Annual Report on Form 10-K, the terms “Momenta,” “we,” “us” and “our” refer to Momenta Pharmaceuticals, Inc. and its subsidiaries.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements and other information can be read and copied at the public reference facilities maintained by the Securities and Exchange Commission at the Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Information regarding the operation of the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site (<http://www.sec.gov>) that contains material regarding issuers that file electronically with the Securities and Exchange Commission.

Our Internet address is www.momentapharma.com. We are not including the information contained on our web site as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission.

Our logo, trademarks, and service marks are the property of Momenta. Other trademarks or service marks appearing in this Annual Report on Form 10-K are the property of their respective holders.

Our Technology

Our integrated technology platform for the study of complex mixtures utilizes three different types of analytical tools. First, we have accumulated a comprehensive library of enzymes that we use to break down the components of a complex mixture into smaller, measurable units. Second, we apply proprietary improvements to established analytical techniques (such as Matrix Assisted Laser

Desorption Ionization-Mass Spectrometry, or MALDI-MS, nuclear magnetic resonance, or NMR, and capillary electrophoresis, or CE, among others), to gather and analyze information regarding the components, structure and arrangement of the chemical building blocks of the complex mixture. Third, we apply proprietary mathematical methods that integrate the disparate information obtained from these analytical techniques to arrive at a specific, numerically-derived solution that describes the complete composition of a specific complex mixture. It is the combination of these tools that enables us to characterize complex polysaccharide, polypeptide and glycoprotein mixtures.

While a similar integrated analytical approach is applied across different product categories, we develop a unique characterization toolkit for each specific complex mixture. Once the chemical components of the complex mixture are known (*structure*), we (1) further employ these methods and data sets in the design and control of our manufacturing process (*structure-process*) to produce generic versions of marketed drugs, and (2) relate structure to biological and clinical activity (*structure-activity*) to engineer novel drugs which meet key unmet medical needs in various diseases.

Product Candidates

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of DVT and to support the treatment of ACS. Lovenox is distributed worldwide by Sanofi-Aventis and is also known outside the United States as Clexane® and Klexane®.

Description of Our Program

Lovenox is a heterogeneous mixture of complex sugar chains that, in our view, prior to the application of our technology, had not been adequately analyzed. The length and sequence of the sugar chains vary, resulting in a diversity of chemical structures in the mixture. The current description in the package insert of Lovenox includes molecular weight distribution and *in vitro* measurements of Lovenox's ability to inhibit blood clotting factors Xa and IIa, or its anti-Xa and anti-IIa activity. While molecular weight distribution provides a rough measure of the range of chain lengths, it provides no information about detailed sequences or chemical structures contained in Lovenox. Similarly, the *in vitro* measures of anti-Xa and anti-IIa activity describe certain aspects of anticoagulation but only partly define the biological and clinical activity of Lovenox. According to Sanofi-Aventis, only 15% to 25% of the chains in LMWHs contain sequences that bind to the factor that is responsible for anti-Xa and anti-IIa activity.

FDA regulations and guidelines require that a generic version of a product that was approved under a New Drug Application, or NDA, must be pharmaceutically equivalent to the branded drug product upon which the generic application is based. Generic drugs are considered pharmaceutically equivalent to their branded counterparts if, among other things, they have the same active ingredient(s), dosage form, route of administration and strength (or concentration). For a drug to be interchangeable with the branded product, it must be therapeutically equivalent, meaning that it is pharmaceutically equivalent and bioequivalent. Bioequivalent means that it has the same rate and extent of absorption as the innovator product. A therapeutically equivalent product is deemed to have the same clinical effect and safety profile as the innovator product. Our ability to apply our technology to sequence and analyze complex mixtures has allowed us to analyze Lovenox and develop a process to make M-Enoxaparin a generic version of Lovenox, which we believe will demonstrate the same active ingredients, dosage form, route of administration and strength, which are essential to satisfying the FDA's requirements for therapeutic equivalence.

In 2003, we formed a collaboration, the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc., together referred to as Sandoz, affiliates of Novartis AG, to exclusively develop,

manufacture and commercialize M-Enoxaparin in the U.S. In July 2006, we entered into a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG, and in June 2007, we and Sandoz AG executed a definitive collaboration and license agreement, or the Definitive Agreement, pursuant to which we expanded the geographic markets covered by the 2003 Sandoz Collaboration related to M-Enoxaparin to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world. We refer to this series of agreements collectively as the 2006 Sandoz Collaboration.

Potential Commercial Market

Sanofi-Aventis reported worldwide sales of Lovenox of approximately \$3.6 billion in 2007, with approximately \$2.2 billion coming from the United States market. Several analysts project that Lovenox will remain a leading LMWH product, with estimated annual sales nearing or exceeding \$4.0 billion in 2010.

Regulatory Matters

In accordance with our 2003 Sandoz Collaboration, Sandoz submitted abbreviated new drug applications, or ANDAs, in its name to the FDA for M-Enoxaparin in syringe and vial forms seeking approval to market M-Enoxaparin in the United States. Both ANDAs currently include a Paragraph IV certification stating that Sanofi-Aventis' patents listed in the Orange Book for Lovenox are, among other things, invalid and unenforceable. The FDA is currently reviewing the M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. In November 2007, Sandoz received a letter from the FDA indicating that the ANDA for M-Enoxaparin syringe formulation was not approvable in its current form because the ANDA does not adequately address the potential for immunogenicity of the drug product. We and Sandoz are working together to address the FDA's questions and determine the information necessary to obtain approval of M-Enoxaparin. To date, the FDA has not requested human clinical studies to address the issue of immunogenicity, and, based on discussions to date with the FDA, we do not believe that such human clinical studies will be required to obtain approval of the M-Enoxaparin ANDA. However, there can be no assurances that the FDA will not require such studies in the future. We and Sandoz are working together to prepare for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives. However, we cannot predict the timing of any potential approval of the M-Enoxaparin ANDA by the FDA.

Under the Hatch-Waxman Act, the first applicant to submit an ANDA for review by the FDA that includes a paragraph IV certification may be eligible to receive a 180-day period of generic market exclusivity. Both Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, submitted ANDAs containing paragraph IV certifications prior to the submission of the first Sandoz ANDA for M-Enoxaparin. However, there may be uncertainty as to whether only Teva or Amphastar or both of Teva and Amphastar would have rights to the 180-day exclusivity period. Therefore, if one or both of their ANDAs are approved by the FDA, one or both of them may receive market exclusivity for 180 days, which, assuming that the M-Enoxaparin ANDA receives FDA approval, would potentially delay the commercial launch of M-Enoxaparin. Because the Teva and Amphastar ANDAs were filed prior to December 8, 2003, this 180-day exclusivity period would commence upon the earlier of (i) a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken or (ii) first commercial market of the product by the holder of the exclusivity period. Under other circumstances, the start of the exclusivity period may be delayed or may not be triggered and we may be delayed or prevented from commercially launching our M-Enoxaparin product.

Legal Matters

Currently, Sanofi-Aventis has two listed patents for Lovenox in the FDA's listing of approved drug products, the Orange Book. They are U.S. Patent No. 5,389,618, or the '618 Patent, and its counter-part, Reissue Patent No. 38,743, or the '743 Reissue Patent. Sanofi-Aventis has brought lawsuits for patent infringement: one against Amphastar and Teva, and a second, separate patent infringement lawsuit against Sandoz.

Amphastar/Teva Patent Infringement Lawsuit

In September 2003, prior to issuance of the '743 Reissue Patent, Sanofi-Aventis announced that it had received individual notices from Amphastar and Teva indicating that each had submitted its own ANDA for enoxaparin with a paragraph IV certification. Sanofi-Aventis sued Amphastar and Teva for patent infringement and in response Amphastar and Teva asserted claims of non-infringement, invalidity and/or unenforceability of the '618 Patent, as well as various counterclaims, and sought related declaratory judgment relief against Sanofi-Aventis. In September 2005, after issuance of the '743 Reissue Patent, Amphastar and Teva each subsequently amended their own ANDA to include a second paragraph IV certification for the '743 Reissue Patent.

In June 2005, the District Court granted summary judgment in the Amphastar/Teva case finding that both the '618 Patent and the '743 Reissue Patent were unenforceable due to Aventis' inequitable conduct before the United States Patent and Trademark Office, or USPTO. In April 2006, the Court of Appeals determined that, although there were no issues of material fact with respect to the materiality of certain information withheld from the USPTO, there remained genuine issues of material fact regarding the intent to deceive the USPTO. Accordingly, the Court of Appeals reversed the District Court's ruling and remanded the case to the District Court for further proceedings consistent with the Court of Appeals' decision. The District Court held a bench trial in December 2006 focused only on inequitable conduct and in February 2007 the District Court ruled in favor of Amphastar and Teva holding both the '618 Patent and the '743 Reissue Patent unenforceable by virtue of inequitable conduct before the USPTO. Sanofi-Aventis appealed this ruling and oral arguments were presented before the Court of Appeals in January 2008. If Sanofi-Aventis is successful in its appeal, all other remaining issues regarding invalidity, non-infringement and unenforceability could be subsequently tried by the District Court, if necessary. If Sanofi-Aventis is not successful, the '618 Patent and the '743 Reissue Patent will continue to be unenforceable.

Sandoz Patent Infringement Lawsuit

In response to the Paragraph IV certification contained in the ANDAs for M-Enoxaparin, Sanofi-Aventis brought patent infringement suits against Sandoz. Sandoz has moved for summary judgment finding unenforceability of the '618 Patent and '743 Reissue Patent in the patent suit related to the syringe ANDA and a motion to dismiss in the patent suit related to the vial ANDA. The District Court has stayed both cases against Sandoz until on or about April 4, 2008.

Neither Teva nor Amphastar are currently marketing a generic version of enoxaparin in the United States, nor can they market such product in the United States unless the FDA approves Amphastar's or Teva's respective ANDA filings.

M118

M118 is a novel anticoagulant that was rationally designed with the goal of providing improved clinical anticoagulant properties when used to support the treatment of patients diagnosed with ACS and stable angina. We believe that M118 has the potential to provide baseline anticoagulant therapy for patients with ACS or stable angina who require a coronary intervention, as well as those ACS patients who are medically managed, or do not require intervention in order to treat their condition. M118 is

designed to be a reversible and monitorable anticoagulant that can be administered intravenously or subcutaneously, and has a pharmacokinetic profile similar to a LMWH. We believe that the properties of M118 have the potential to provide greater flexibility than other therapies presently used to treat patients diagnosed with ACS and stable angina.

ACS includes several diseases ranging from unstable angina, which is characterized by chest pain at rest, to acute myocardial infarction, or heart attack, which is caused by a complete blockage of a coronary artery. While some patients are initially medically managed with anti-clotting agents such as unfractionated heparin, or UFH, or LMWH, an increasing proportion of ACS patients are proceeding to early intervention with procedures such as angioplasty or coronary artery bypass grafting, or CABG. Both angioplasty and CABG require anticoagulant therapy to prevent clot formation during and immediately following the procedure. UFH is currently the foundation anti-clotting agent used in both angioplasty and CABG. No LMWHs are currently approved for use in either angioplasty or CABG. M118 is designed to be a LMWH that could be used in multiple settings, including initial medical management, angioplasty or CABG.

Description of Our Program

M118 was designed utilizing our proprietary analytical methods and technology to identify the polysaccharide sequences in heparin responsible for specific desired clinical attributes. Using this information, the design of M118 was tailored to include specific attributes that address the unmet medical needs of anticoagulation therapy in ACS, including, among others, reversibility and the ability to be monitored. The results of our preclinical animal studies suggest potential benefits of M118 over UFH and other LMWHs, including:

- *Increased efficacy.* In animal studies directly comparing M118 with UFH and other LMWHs, M118 appeared to more effectively prevent clotting of injured arteries in a rat and canine thrombosis model. The results of *in vivo* and *in vitro* experiments suggest that M118 acts at multiple points in the coagulation cascade by inhibiting both factor Xa and factor IIa and through the release of tissue factor pathway inhibitor.
- *Reversibility.* Animal and human study results also suggest that the anti-clotting effects of M118 are reversible by administering protamine sulfate, the standard drug used to reverse anticoagulant activity. Other existing LMWHs are not fully reversible with protamine.
- *Ability to monitor.* Due to the presence of certain saccharide sequences in M118, we believe the anti-clotting activity of M118 can be monitored by standard, point-of-care laboratory tests that detect the presence of factor IIa, or thrombin. These assays, which include activated clotting time, or ACT, are routinely used during interventional procedures. Currently, existing marketed LMWHs cannot be monitored efficiently with routine laboratory tests.

Potential Commercial Market

The anticoagulant/antithrombotic market in which M118 will compete generated greater than \$4 billion in worldwide sales in 2007.

Regulatory Matters

In July 2006, we filed an Investigational New Drug Application, or IND, with the FDA for our M118 intravenous injection product and in October 2006 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In October 2007, we began a Phase 2a clinical trial to evaluate the feasibility of utilizing M118 intravenous injection formulation as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention.

In March 2007, we filed an IND for our M118 subcutaneous product, and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile.

We are not currently able to estimate the timing of commercialization of M118. Based on analysis of Phase 1 data, M118 has demonstrated anticoagulant activity in a dose-dependent manner that is monitorable with a rapid point-of-care assay, ACT, is reversible with protamine sulfate and can be concomitantly administered with other agents typically utilized to treat ACS, including aspirin, thienopyridines, and glycoprotein IIb/IIIa inhibitors. We expect the Phase 2 study to provide important information about the ability to use M118 as a procedural anticoagulant. Our Phase 2b studies will explore the use of M118 in patients diagnosed with ACS who are either managed medically or proceed to early intervention via percutaneous coronary intervention, or PCI.

M356

M356 is targeted to be a generic version of Copaxone (glatiramer acetate injection), a drug consisting of a complex mixture of polypeptide chains. Copaxone is indicated for the reduction of the frequency of relapses in patients with RRMS. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. Copaxone and several interferon beta products are among the leading products marketed for treating multiple sclerosis.

Description of Our Program

Under our 2006 Sandoz Collaboration, we and Sandoz agreed to jointly develop, manufacture and commercialize M356. Given its structure as a mixture of polypeptide chains of various lengths and sequences, there are significant technical challenges involved in thoroughly characterizing Copaxone and in manufacturing an equivalent version. We believe our technology can be applied to characterize glatiramer acetate and to develop a generic product that has the same active ingredients as Copaxone.

Potential Commercial Market

In North America, Copaxone is marketed through Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., and distributed by Sanofi-Aventis. Teva and Sanofi-Aventis have an additional collaborative arrangement for the marketing of Copaxone in Europe and other markets, under which Copaxone is either co-promoted with Teva or is marketed solely by Sanofi-Aventis. Teva reported worldwide sales of Copaxone of approximately \$1.7 billion in 2007, with approximately \$1.1 billion from the U.S. market. Several analysts project that annual worldwide sales of Copaxone will exceed \$2.0 billion in 2009.

Regulatory Matters

Copaxone was approved under the FDA's NDA regulations.

Legal Matters

Teva has listed six patents in the Orange Book for Copaxone, all of which expire in May 2014.

Glycoproteins

Glycoproteins are proteins to which sugar molecules are attached. Examples of glycoprotein drugs are erythropoietin, blood clotting factors and interferon beta. We are applying our technology to the development of generic or biosimilar glycoprotein drugs. We believe that this technology can further be used in assisting pharmaceutical and biotechnology companies in developing improved and next-generation versions of their branded products by analyzing and modifying the sugar structures contained in the branded products, and can also be used to engineer novel complex mixture drugs.

Description of Our Program

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to glycoproteins. The goal of the program is to facilitate the development of generic or biosimilar versions of major marketed glycoprotein drugs. Under our 2006 Sandoz Collaboration, we are currently applying our technology to develop two generic or biosimilar proteins in partnership with Sandoz. We refer to these two glycoprotein product candidates as M178 and M249.

Potential Commercial Market

Biologics represent a sizable segment of the U.S. drug industry, with sales expected to exceed \$60 billion by 2010. Most of these products are glycoprotein drugs, which contain branched sugars that vary from molecule to molecule. These sugars can impart specific biological properties to the glycoprotein drug and can often comprise a significant portion of the mass of the molecule. Given the inadequacies of standard technology, many of these glycoproteins have not been thoroughly characterized.

Regulatory Matters

Many glycoprotein drugs are complex mixture drugs that have been approved by the FDA under the Biologic License Application, or BLA, regulatory pathway. The BLA pathway was created to review and approve applications for biologic drugs that are typically produced from living systems. Presently, there is no abbreviated regulatory pathway for the approval of generic or biosimilar versions of BLA-approved products in the United States; however, there are emerging guidelines for biosimilar products in the EU. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in the creation of an appropriate U.S. regulatory pathway in the future.

Discovery Program

Our discovery program is focused on the role that complex sugars play in biological systems, including regulating the development and progression of disease. Our initial focus is in the area of cancer, a disease characterized by unregulated cell growth, where we are seeking to discover sugar sequences with anti-cancer properties for development as therapeutics. We are evaluating an oncology product candidate that is in the advanced discovery phase. Sugars play a part in the conversion of normal cells into cancerous cells, the regulation of tumor growth and tumor invasion and metastasis. We believe that our technology can provide us with a better understanding of the role of sugars in disease, enabling us to discover novel sugar therapeutics, as well as to discover new disease mechanisms that can be targeted with other small molecule and biologic drugs.

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, contract research and manufacturing, and the costs of laboratory equipment and facilities. Research and development expense for 2007 was \$69.9 million, compared with \$46.9 million in 2006 and \$23.7 million in 2005.

Collaborations and Licenses

Sandoz

2003 Sandoz Collaboration

Under the terms of the 2003 Sandoz Collaboration, we and Sandoz agreed to exclusively work with each other to develop and commercialize injectable enoxaparin for any and all medical indications within the United States. In addition, we granted Sandoz an exclusive license under our intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States.

Under this collaboration, Sandoz makes certain payments to us. As mutually agreed, we provide, and Sandoz pays us for internal expenses incurred in scientific, technical and/or management work. Sandoz is also responsible for funding substantially all of the other ongoing development and commercialization costs and legal expenses incurred with respect to injectable enoxaparin, subject to termination rights upon reaching agreed upon limits. In addition, Sandoz will, in the event there are no

third party competitors marketing a Lovenox-Equivalent Product, as defined in the agreement, provide to us a share of the profits from M-Enoxaparin. Alternatively, if there are one or more third party competitors marketing a Lovenox-Equivalent Product, Sandoz will either pay a royalty to us based on net sales of M-Enoxaparin or pay a combination of royalty payments and a share of profits, depending on certain circumstances. In addition, if certain milestones are achieved with respect to injectable enoxaparin under certain circumstances, Sandoz may also make milestone payments to us which would reach \$55.0 million if all such milestones are achieved. In all of these scenarios, a portion of the development expenses and certain legal expenses which have exceeded a specified amount will be offset against the profit-sharing amounts, the royalties and the milestone payments. Sandoz may also offset a portion of any product liability costs and certain other expenses arising from patent litigation against the profit-sharing amounts, the royalties and the milestone payments.

The collaboration is governed by a joint steering committee and a joint project team, each consisting of an equal number of Sandoz and Momenta representatives. Most decisions must be made unanimously, with Sandoz collectively having one vote and us having one vote. Sandoz has sole authority to make decisions with respect to any litigation claiming that the manufacture, use or sale of the injectable enoxaparin product infringes any patents listed in the Orange Book for Lovenox. In addition, Sandoz has the sole authority to determine whether or not to launch M-Enoxaparin prior to receipt of final legal clearance from any such infringement claims, as well as determine the price at which it will sell M-Enoxaparin. Sandoz has filed paragraph IV certifications in its ANDAs for both syringe and vial forms of M-Enoxaparin.

We and Sandoz will indemnify each other for losses resulting from the indemnifying party's misrepresentation or breach of its obligations under the agreement. We will indemnify Sandoz if we actually misappropriate the know-how or trade secrets of a third party. Sandoz will indemnify us and our collaborators involved in the enoxaparin program for any losses resulting from any litigation by third parties, including Sanofi-Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the Orange Book for Lovenox, any product liability claims with respect to injectable enoxaparin and any other claims relating to the development and commercialization of injectable enoxaparin. To the extent that any losses result from a third-party claim for which we are obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify us. After the expiration or termination of the agreement, these indemnification obligations will continue with respect to claims that arise before or after the termination of the agreement due to activities that occurred before or during the term of the agreement.

Unless terminated earlier, the agreement will expire upon the last sale of injectable enoxaparin by or on behalf of Sandoz in the United States. Either party may terminate the collaboration relationship for material uncured breaches or certain events of bankruptcy or insolvency by the other. Sandoz may also terminate the agreement if the 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 redress, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If Sandoz terminates the agreement (except due to our uncured breach) or if we terminate the agreement due to an uncured breach by Sandoz, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States and our obligation to indemnify Sandoz will survive with respect to claims that arise due to our exclusive development or commercialization of injectable enoxaparin after the term of the agreement. In the event of a termination by Sandoz due to the incurrence of costs beyond the agreed upon limits, we must pay certain royalties to Sandoz on our net sales of injectable enoxaparin. If Sandoz terminates the agreement due to our uncured breach, Sandoz retains the exclusive right to develop and commercialize injectable enoxaparin in the United States. Sandoz' profit sharing, royalty and milestone payment obligations survive and Sandoz' obligation to indemnify us will survive with respect to claims that arise due to Sandoz' exclusive development or commercialization of injectable enoxaparin after the term of

the agreement. In addition, if Sandoz terminates the agreement due to our uncured breach, Sandoz would retain its rights of first negotiation with respect to certain of our other products and its rights of first refusal outside the United States.

2006 Sandoz Collaboration

Under the 2006 Sandoz Collaboration, we expanded the geographic markets covered by the 2003 Sandoz Collaboration related to M-Enoxaparin to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world.

Pursuant to the terms of the Stock Purchase Agreement, we sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of \$15.93 for an aggregate purchase price of \$75.0 million. This resulted in a paid premium of \$13.6 million as the closing price of our common stock on the NASDAQ Global Market was \$13.05 on the date of the Stock Purchase Agreement. We recognize revenue from the \$13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. Under the 2006 Sandoz Collaboration, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. We have agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. We have the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market the products.

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz. Under the 2006 Sandoz Collaboration, we are paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG, or partly in proportion where development costs are shared between us and Sandoz AG. We are also paid for full-time equivalent employees performing development services where development activities are funded solely by Sandoz AG, or partly by proportion where development costs are shared between us and Sandoz AG. The parties will share profits in varying proportions, depending on the product. We are eligible to receive up to \$188.0 million in milestone payments if all milestones are achieved for the four product candidates. None of these payments, once received, are refundable and there are no general rights of return in the arrangement. Sandoz AG has agreed to indemnify us for various claims, and a certain portion of such costs may be offset against certain future payments received by us.

The term of the Definitive Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the Definitive Agreement. The Definitive Agreement may be terminated if either party breaches the Definitive Agreement or files for bankruptcy. In addition, the following termination rights apply to some of the products, on a product-by-product basis: (i) if clinical trials are required, (ii) at Sandoz' convenience within a certain time period, (iii) if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval, (iv) if Sandoz decides to permanently cease development and commercialization of a product or (v) by either party with respect to certain products if, following a change of control of the other party, such other party fails to perform its material obligation with respect to such product.

In addition, through the period ending July 24, 2011, we and Sandoz may negotiate additional collaboration agreements with respect to certain products, including expanded territories for certain products already part of the collaboration. If we and Sandoz do not execute a definitive agreement within a specified time frame, we are permitted to enter into a transaction for such opportunity with a third party, provided that the terms which we give to that third party can be no less favorable, taken as a whole, to us than the terms last offered to Sandoz. If we do not enter into a transaction with a third party in a specified time frame, then the negotiations between us and Sandoz with respect to such product will start again, with the corresponding rights and obligations if the parties do not execute a definitive agreement within the specified time frame.

Pursuant to the terms of the Investor Rights Agreement, we granted to Novartis Pharma AG certain registration rights and inspection rights, and Novartis Pharma AG agreed until the earliest of (i) the termination of the Definitive Agreement, (ii) the Termination Date (as defined in the Investor Rights Agreement) and (iii) 24 months from September 6, 2006, not to acquire any of our voting securities (other than an acquisition resulting in Novartis Pharma AG and its affiliates beneficially owning less than 13.5% of our total outstanding voting securities), make any public proposal for any merger, other business combination or other extraordinary transaction involving us, our securities or material assets or seek to control or influence our management, Board of Directors or policies, in each case subject to specified exceptions described in the Investor Rights Agreement. Specifically, Novartis Pharma AG is entitled to “piggyback” and demand registration rights under the Securities Act of 1933, as amended, with respect to the shares of common stock purchased under the Stock Purchase Agreement.

We also granted Novartis Pharma AG inspection rights whereby, subject to certain exceptions, Novartis Pharma AG may visit and inspect our properties and records, discuss our business and financial affairs with its officers, employees and other agents, and meet, at least twice a year, with the members of our Board of Directors.

Massachusetts Institute of Technology

In December 2001, we entered into a patent license agreement with the Massachusetts Institute of Technology, or M.I.T., pertaining to the characterization and synthesis of sugars for the purpose of researching, developing and commercializing products (other than sequencing machines) and processes under the licensed patents. This agreement was subsequently amended and restated in early November 2002 and has been subsequently further amended. We entered into an additional patent license agreement with M.I.T. in late October 2002, which gave us the right to develop and commercialize sequencing machines. Subject to typical retained rights of M.I.T. and the U.S. government, these two agreements grant us various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to (i) methods and technologies for characterizing sugars, (ii) certain heparins, heparinases and other enzymes and (iii) synthesis methods.

We must meet certain diligence requirements in order to maintain our licenses under the two agreements. Under the agreements, we must expend at least \$1.0 to \$1.2 million per year commencing in 2005 towards the research, development and commercialization of products and processes covered by the agreements. In addition, we are obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter, ranging from \$0.5 million to \$5.0 million annually. M.I.T. may convert the exclusive licenses granted to us under the amended and restated license agreement to non-exclusive licenses, as its sole remedy, if we fail to meet our diligence obligations. Under the license agreement covering sequencing machines, M.I.T. has the right to treat a failure by us to fulfill our diligence obligations as a material breach of the license agreement.

In exchange for the licenses granted in the two agreements, we have paid M.I.T. license issue fees and we pay annual license and maintenance fees ranging, in the aggregate, from \$82,500 to \$157,500. We are also required to pay M.I.T. royalties on certain products and services covered by the licenses and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from corporate partners and sublicensees, and certain patent prosecution and maintenance costs. We recorded \$82,500, \$487,500 and \$82,500 as expenses related to these agreements in the years ended December 31, 2007, 2006 and 2005, respectively.

We are obligated to indemnify M.I.T. and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements, unless the losses result from the indemnified parties' gross negligence or willful misconduct.

Each agreement expires upon the expiration or abandonment of all patents that issue and are licensed to us by M.I.T. under such agreement. The issued patents include 21 United States patents that expire between 2012 and 2023, and 39 foreign patents that expire between 2012 and 2013. We expect that additional patents will issue from presently pending patent applications. Any such patent will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate either or both agreements immediately if we cease to carry on our business, if any nonpayment by us is not cured within 60 days of written notice or if we commit a material breach that is not cured within 90 days of written notice. We may terminate either or both agreements for any reason upon six months notice to M.I.T., and, under one agreement, we can separately terminate the license under a certain subset of patent rights upon three months notice.

We have granted Sandoz a sublicense under the amended and restated license agreement to certain of the patents and patent applications licensed to us. If M.I.T. converts our exclusive licenses under this agreement to non-exclusive due to our failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense we granted to Sandoz so long as Sandoz continues to fulfill its obligations to us under the collaboration and license agreement we entered into with Sandoz and, if our agreement with M.I.T. is terminated, Sandoz agrees to assume our rights and obligations to M.I.T.

The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory

In November 2002, we entered into an agreement with The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory, or Lawrence Berkeley National Lab, under which we exclusively licensed certain patents and patent applications covering the metabolic synthesis of sugars and glycoconjugates. Subject to typical retained rights of Lawrence Berkeley National Lab and the United States government, we were granted an exclusive license, with the right to grant sublicenses, for the synthesis, production or modification of sugars and glycoconjugates in or on biological molecules for purposes of researching, developing and commercializing products, services and processes for all human therapeutic applications, excluding the sale of research reagents.

In connection with this agreement, we paid certain license fees and minimum royalties and recorded \$30,000, \$30,000 and \$130,000 as research and development expense in the years ended December 31, 2007, 2006 and 2005, respectively. License fees include \$100,000 expensed and paid to Lawrence Berkeley National Lab in 2005 for the election to retain the broader field. The research and development expenses include \$30,000, \$30,000 and \$30,000 in annual minimum royalties that we paid and recorded as expense during the years ended December 31, 2007, 2006 and 2005, respectively.

On January 23, 2008 we provided notice to Lawrence Berkeley National Lab that we were terminating the agreement pursuant to our option to terminate for any reason upon 180 days notice because we are not utilizing the technology as originally anticipated.

Patents and Proprietary Rights

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology and product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology and product candidates that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We license or own a patent portfolio of 41 patent families, which presently includes 25 United States patents and 60 United States patent applications as well as foreign counterparts to certain of the United States patents and patent applications. Our patent portfolio includes issued or pending claims covering: methods and technologies for characterizing sugars and other heterogeneous mixtures; the use of certain naturally occurring heparinases, heparinase variants and other enzymes which specifically recognize polysaccharides in the characterization of sugars; methods and technologies for synthesis of sugars; the composition of matter of certain novel LMWHs, including M118, and heparinase variants; methods to produce and identify sugars associated with glycoproteins; methods to analyze and monitor glycoprotein profiles for purposes associated with the diagnosis, staging, prognosis and monitoring of cancer; and methods for the *in vivo* non-invasive delivery of sugars.

A significant portion of our patent portfolio covering methods and technologies for characterizing sugars consists of patents and patent applications owned and licensed to us by M.I.T. In addition, a significant portion of the claims in our patent portfolio covering the composition of matter of naturally occurring heparinases, heparinase variants and other enzymes, the use of these heparinases and enzymes in the characterization of sugars, the methods and technologies for chemical synthesis of sugars, and the composition of matter of novel low molecular weight heparins consists of patents and patent applications that are owned and licensed to us by M.I.T.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents. Moreover, any issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of the term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our generic, biosimilar and novel products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our novel heparin or other products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by confidentiality agreements with our employees, consultants, advisors, contractors and collaborators. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Asset Purchase

In April 2007, we entered into an asset purchase agreement, or the Purchase Agreement, with Parivid, LLC, or Parivid, a provider of data integration and analysis services to us, and S. Raguram, the principal owner and Chief Technology Officer of Parivid. Pursuant to the Purchase Agreement, we acquired certain of the assets and assumed certain specified liabilities of Parivid related to the acquired assets for \$2.5 million in cash paid at closing and up to \$11.0 million in additional payments, payable in a combination of cash and/or stock, if certain milestones are achieved.

The contingent milestone payments include (i) potential cash payments of no more than \$2.0 million if certain milestones are achieved within two years from the date of the Purchase Agreement and (ii) the issuance of up to \$9.0 million 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.

As part of our acquisition of assets from Parivid, two previous collaboration agreements we had in place with Parivid were terminated. S. Raguram is the brother of Ram Sasisekharan, a member of our Board of Directors. Ram Sasisekharan received no consideration in connection with the execution of the Purchase Agreement. We recorded \$0.2 million, \$1.0 million and \$0.7 million as research and development expense related to work performed by Parivid in the years ended December 31, 2007, 2006 and 2005, respectively.

Manufacturing

We do not own facilities for manufacturing any products. Although we intend to rely on contract manufacturers, we have personnel with experience in manufacturing, as well as process development, analytical development, quality assurance and quality control. Under the 2003 Sandoz Collaboration and the 2006 Sandoz Collaboration, Sandoz is responsible for commercialization of the products covered by those agreements.

We have entered into various agreements with third party contractors for process development, analytical services and manufacturing. In each of our agreements with contractors, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contractor intellectual property for purposes of exploiting the products that are the subject of the agreement and in a few instances we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. The agreements also typically contain provisions for both parties to terminate for material breach, bankruptcy and insolvency.

The starting material for manufacture of both M118 and M-Enoxaparin is UFH. In early 2008, due to the occurrence of adverse events, including deaths, associated with the use of UFH, there have been recalls of UFH products in both the United States and Germany. Based on its investigation, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use a CE and NMR test to screen their UFH active pharmaceutical ingredient. As a result of these UFH product recalls and potential future recalls, the U.S. government may decide to place restrictions on the import of raw materials, including UFH, which could make it difficult for us to obtain our starting material, could increase costs significantly or make these materials unavailable.

Sales and Marketing

We do not currently have any sales and marketing capabilities, nor do we currently have any plans to build a sales and marketing force to support any of our products. In order to commercialize any products that are not encompassed by the 2003 Sandoz Collaboration or 2006 Sandoz Collaboration, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience, and we will review these options as our other product candidates move closer to commercialization.

Competition

The development and commercialization of pharmaceutical products is highly competitive. In the event that we were to receive approval for, market and sell M-Enoxaparin, we would face competition from Sanofi-Aventis, the company currently marketing Lovenox, and from other firms if they receive marketing approval for generic versions of Lovenox. Sanofi-Aventis may also choose to market a generic version of Lovenox itself or through an authorized third-party distributor. While there are no generic versions of Lovenox approved by the FDA to date, ANDAs have been submitted to the FDA by Amphastar and Teva, and other ANDAs or other regulatory applications may have been submitted or will be submitted in the future.

In addition, other anticoagulants used in the treatment of DVT and ACS will compete with our M-Enoxaparin product, should it be approved by the FDA. These competitive products include GlaxoSmithKline's factor Xa inhibitor, Arixtra[®], which is approved in multiple DVT indications and ACS, and other LMWH products. We are also aware of other anticoagulant drugs in development for the treatment of DVT, including next-generation LMWHs and several factor Xa inhibitors that are in clinical trials. These include AVE5026 and idrabiotaparinux which are being developed by Sanofi-Aventis, rivaroxaban which is being developed by Bayer AG, and dabigatran etexilate which is being developed by Boehringer Ingelheim.

Our M118 product is targeted to support treatment of patients with ACS. Potential competitive products to this product include: the Medicines Company's direct thrombin inhibitor, Angiomax[®], which is approved for use in angioplasty; GlaxoSmithKline's Arixtra, which recently received an approvable letter to treat patients with UA/NSTEMI and STEMI in ACS; and various other LMWH and unfractionated heparin products.

There are other anticoagulant drugs in development for ACS, including next-generation LMWHs and several factor Xa inhibitors and synthetic factor Xa and factor IIa inhibitors, which are in clinical trials. M118 also faces competition from products other than heparins, such as anti-platelet and direct thrombin inhibitors which may be used in the treatment of ACS.

In the field of complex mixtures, there are several competitors seeking to provide additional characterization or create biosimilar, generic, and/or improved versions of marketed complex products. GlycoFi, a wholly-owned subsidiary of Merck & Co., Inc., possesses selected analytical and engineering capabilities for complex sugars which could be applied to creating biosimilar, generic, or improved versions of complex protein-based products containing sugars. Companies such as Barr Pharmaceuticals, Inc., Teva, Sandoz, BioGenerix AG, Stada Arzneimittel, Cangene Corporation and GeneMedix Ltd., a wholly-owned subsidiary of Reliance Life Sciences, also have disclosed intentions to develop and commercialize generic and/or improved versions of marketed protein products in the U.S. or Europe. Most of these companies have experience with manufacturing complex protein products or with commercializing generic products. There has been substantial growth in recent years in the number of generic companies looking to develop biosimilar or generic versions of protein-based products. Biotechnology and pharmaceutical companies also continue to invest significantly in better understanding their own products or creating improved versions of marketed products.

Similarly, our discovery work in oncology faces substantial competition from major pharmaceutical and other biotechnology companies that are actively working on improved and novel therapeutics. Companies competing most directly with our approach of developing sugar-based therapeutics for oncology include Progen Industries Limited. Pfizer has also conducted investigative clinical trials using Fragmin as a therapeutic drug for cancer; while there are no approved indications, selected trials are ongoing.

The field of glycobiology generally is a growing field with increased competition. However, the capabilities of the field can generally be segmented into those companies using sugars as therapeutics, companies focused on engineering or modifying sugars, including pegylation technologies, and companies focused on analytics. Among those in analytics, we are not aware of others that have similar capabilities for detailed chemical characterization of complex sugars. Procognia Limited's technology is largely focused on analyzing proteins and their glycosylation. In addition, many major pharmaceutical and biotechnology companies such as Amgen and Biogen Idec Inc. have successfully improved products through sugar modification. Potential competitors with broad glycobiology capabilities include Neose Technologies, Inc., Keryx Pharmaceuticals and Pro-Pharmaceuticals, Inc. as well as many private, start-up pharmaceutical organizations. Many of these companies are focused on providing services to pharmaceutical companies rather than focused on drug discovery and product development.

Regulatory and Legal Matters

Government authorities in the United States, at the federal, state and local level, the European Union, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and exporting and importing of products such as those we are developing.

United States Government Regulation

In the United States, the information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans, or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. Drugs follow either the NDA or BLA routes, and a drug that claims to be the same as an already approved NDA drug may be able to follow the ANDA route.

NDA and BLA Approval Processes

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. The steps required before a drug or biologic may be marketed in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's current good laboratory practices;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin and must include independent Institutional Review Board, or IRB, approval at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity or to meet standards designed to ensure the biologic's continued safety, purity and potency; and
- FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects or patients in accordance with specific protocols and under the supervision of qualified investigators. Each clinical trial protocol must be submitted to the FDA as part of the IND, and an IRB at each site where the study is conducted must also approve the study. Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase 1 trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance and pharmacokinetics, pharmacodynamics. If feasible, Phase 1 studies also attempt to detect any early indication of a drug's potential effectiveness. Phase 2 trials usually involve controlled trials in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks and evaluate the preliminary efficacy of the drug for specific indications. Phase 3 trials usually test a specific hypothesis to evaluate clinical efficacy and test further for safety in an expanded patient population. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or a sponsor may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the chemistry, manufacture and control of the product, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may refuse to accept and review insufficiently complete applications.

Before approving an NDA or BLA, the FDA will inspect the facility or the facilities at which the product is manufactured. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental

approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

ANDA Process

FDA approval is required before a generic equivalent of an existing brand name drug can be marketed. Such approval for products is typically obtained by submitting an ANDA to the FDA and demonstrating therapeutic equivalence. However, it is within the FDA's regulatory discretion to determine the kind and amount of evidence required to approve a product for marketing. Although the FDA has accepted ANDAs for generic versions of Lovenox for review, the FDA could determine that therapeutic equivalence cannot be shown for M-Enoxaparin and require instead that an NDA be submitted for approval. An ANDA may be submitted for a drug on the basis that it is the same as a previously approved branded drug, also known as a reference listed drug. Specifically, the generic drug that is the subject of the ANDA must have the same active ingredient(s), route of administration, dosage form, and strength, as well as the same labeling, with certain exceptions, and the labeling must prescribe conditions of use that have been previously approved for the listed drug. If the generic drug product has a different route of administration, dosage form, or strength, the FDA must grant a suitability petition approving the differences(s) from the listed drug before the ANDA may be filed. The ANDA must also contain data and information demonstrating that the generic drug is bioequivalent to the listed drug, or if the application is submitted pursuant to an approved suitability petition, information to show that the listed drug and the generic drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a proposed condition of use.

Generic drug applications are termed "abbreviated" because they are not required to duplicate the clinical (human) testing or, generally, preclinical testing necessary to establish the underlying safety and effectiveness of the branded product. However, the FDA may refuse to approve an ANDA if there is insufficient information to show that the active ingredients are the same and to demonstrate that any impurities or differences in active ingredients do not affect the safety or efficacy of the generic product. In addition, like NDAs, an ANDA will not be approved unless the product is manufactured in cGMP-compliant facilities to assure and preserve the drug's identity, strength, quality and purity. As is the case for NDAs and BLAs, the FDA may refuse to accept and review insufficiently complete ANDAs.

In an ANDA submission, determination of the "sameness" of the active ingredients to those in the reference listed drug is based on the demonstration of the chemical equivalence of the components of the generic version to those of the branded product. While the standard for demonstrating chemical equivalence is relatively straightforward for small molecule drugs, it is inherently more difficult to define sameness for the active ingredients of complex drugs. Under the NDA pathway, these types of drugs include such products as heparins and recombinant versions of certain hormones, among others. Due to the limited number of ANDA submissions for generic complex drugs, the FDA has not reached a final position for demonstrating chemical equivalence for many of these products specifically, nor provided broad guidance for achieving "sameness" for complex drugs in general. In many cases, the criteria the FDA may apply are still evolving. Additionally, there is currently no abbreviated approval mechanism for products which are approved under the BLA pathway. Most glycoprotein drugs are approved under the BLA pathway. Although, to our knowledge, the FDA has not provided official guidance on the legal and scientific aspects of follow-on protein regulation, legislation has been proposed in both 2006 and 2007, and we anticipate this issue will be the subject of significant

Congressional debate in the near future, as well as lobbying efforts by both generic and branded pharmaceutical companies.

To demonstrate bioequivalence, ANDAs generally must also contain *in vivo* bioavailability data for the generic and branded drugs. “Bioavailability” indicates the rate and extent of absorption and levels of concentration of a drug product in the bloodstream needed to produce a therapeutic effect. “Bioequivalence” compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body are the same as the previously approved branded drug. The studies required to demonstrate *in vivo* bioequivalence are generally very small, quick to complete, and involve relatively few subjects. Under current regulations, the FDA may waive requirements for *in vivo* bioequivalence data for certain drug products, including where bioequivalence is self evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the reference listed drug. The FDA, however, does not always waive requirements for *in vivo* bioequivalence data. For example, bioequivalence data was required for the M-Enoxaparin ANDA submission.

Generic drug products that are found to be therapeutically equivalent by the FDA receive an “A” rating in FDA’s Orange Book, which lists all approved drug products and therapeutic equivalence evaluations. Products that are therapeutically equivalent can be expected in the FDA’s judgment to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling. Products with “A” ratings are generally substitutable for the innovator drug by both in-hospital and retail pharmacies. Many health insurance plans require automatic substitution for “A” rated generic versions of products when they are available, although physicians may still prescribe the branded drug for individual patients.

The timing of final FDA approval of a generic drug for commercial distribution depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and/or its use and whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from accepting or approving generic product applications. For example, submission of an ANDA for a drug that was approved under an NDA as a new chemical entity will be blocked for five years after the pioneer’s approval, or for four years after approval if the application includes a paragraph IV certification of non-infringement or invalidity against a patent applicable to the branded drug. This does not apply to M-Enoxaparin but may apply to future generic products that we pursue. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on or after the patent expiration date. For example, a three-year exclusivity period may be granted for new uses or versions of previously approved drugs, if approval of such changes required the sponsor to conduct new clinical studies. In addition, the FDA may extend the exclusivity of a product by six months past the date of patent expiry or other regulatory exclusivity if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

Post-Approval Requirements

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing and surveillance to monitor the product’s safety or efficacy. Proposed legislation, if enacted, could expand our post-approval regulatory obligations, and the cost of complying with such obligations.

In addition, holders of an approved NDA, BLA, or ANDA are required to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The

FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We use, and will continue to use in at least the near term, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct.

Discovery of problems with a product or failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include a clinical hold on or termination of studies, the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, restriction on marketing, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Patent Challenge Process Regarding ANDAs

The Hatch-Waxman Act provides incentives for generic pharmaceutical manufacturers to challenge patents on branded pharmaceutical products and/or their methods of use, as well as to develop products comprising non-infringing forms of the patented drugs. The Hatch-Waxman legislation places significant burdens on the ANDA filer to ensure that such challenges are not frivolous, but also offers the opportunity for significant financial reward if the challenge is successful.

If there is a patent listed for the branded drug in the FDA's Orange Book at the time of submission of the ANDA, or at any time before the ANDA is approved, the generic company's ANDA must include one of four types of patent certification with respect to each listed patent. If the applicant seeks approval to market the generic equivalent prior to the expiration of a listed patent, the generic company includes a certification asserting that the patent is invalid, unenforceable and/or not infringed, a so-called "paragraph IV certification." Within 20 days after receiving notice from the FDA that its application is acceptable for review, or immediately if the ANDA has been amended to include a paragraph IV certification after the application was submitted to the FDA, the generic applicant is required to send the patent owner and the holder of the NDA for the brand-name drug notice explaining why it believes that the listed patents in question are invalid, unenforceable or not infringed. If the patent holder commences a patent infringement lawsuit within 45 days of receipt of such notice, the Hatch-Waxman Act provides for an automatic stay on the FDA's ability to grant final approval of the ANDA for the generic product, generally for a period of 30 months. A 30-month stay may be shortened or lengthened by a court order if the district court finds that a party has failed to reasonably cooperate in expediting the action. Moreover, the district court may, before expiration of the stay, issue a preliminary injunction prohibiting the commercial sale of the generic drug until the court rules on the issues of validity, infringement, and enforceability. If the district court finds that the relevant patent is invalid, unenforceable, or not infringed, such ruling terminates the 30-month stay on the date of the judgment. If it is finally determined that the patent is valid, enforceable, and infringed, approval of the ANDA may not be granted prior to the expiration of the patent. In addition, if the challenged patent expires during the 30-month period, the FDA may grant final approval for the generic drug for marketing, if the FDA has determined that the application meets all technical and regulatory requirements for approval and there are no other obstacles to approval.

In most cases, patent holders may only obtain one 30 month stay with respect to patents listed in the Orange Book. Specifically, for ANDAs with paragraph IV certifications to a patent listed for the branded drug in the Orange Book on or after August 18, 2003, a single 30-month stay is available for

litigation related to that patent only if the patent was submitted to the FDA before the date that the ANDA (excluding an amendment or supplement) was submitted. In other words, 30-month stays are not triggered by later listed patents submitted to the FDA on or after the date the ANDA application was submitted. Because of this limitation, in most cases ANDAs will be subject to no more than one 30-month stay.

Under the Hatch-Waxman Act, the first ANDA applicant to have submitted a substantially complete ANDA that includes a paragraph IV certification may be eligible to receive a 180-day period of generic market exclusivity during which the FDA may not approve any other ANDA for the same drug product. However, this exclusivity does not prevent the sponsor of the innovator drug from selling an unbranded “authorized generic” version of its own product during the 180-day exclusivity period. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs and to build its market share before other generic competitors can enter the market. Under the Hatch-Waxman law, as amended by the Medicare Modernization Act of 2003, or MMA, there are a number of ways an applicant who has filed an ANDA after the date of the MMA may forfeit its 180-day exclusivity, including if the ANDA is withdrawn or if the applicant fails to market its product within the specified statutory timeframe. In addition, for ANDAs filed after the MMA was enacted, it is possible for more than one ANDA applicant to be eligible for 180-day exclusivity. This occurs when multiple “first” applicants submit substantially complete ANDAs with paragraph IV certifications on the same day.

Follow-on Biologics

The BLA regulatory pathway was created to review and approve new applications for biologic drugs that are typically produced from living systems. Presently, there is no abbreviated regulatory pathway for the approval of generic or biosimilar versions of BLA-approved products in the United States; however, there are emerging biosimilar guidelines in the EU. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in the creation of such a U.S. regulatory pathway in the future.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products when we enter those markets. Whether or not we obtain FDA approval for a product, we must obtain approval of a clinical trial application or product from the applicable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization from one EU member state (the reference member state) may submit an application to the remaining member states. Generally, each member state decides whether to recognize the reference member state’s approval in its own country.

Related Matters

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products

regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, or what the impact of such changes, if any, may be.

Hazardous Materials

Our research and development processes involve the controlled use of certain hazardous materials and chemicals, including radioactive materials and equipment. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2007, we had 163 employees, including a total of 54 employees who hold M.D. or Ph.D. degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

Item 1A. RISK FACTORS

Statements contained or incorporated by reference in this Annual Report on Form 10-K that are not based on historical fact are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, clinical trial results and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as “anticipate,” “believe,” “could,” “could increase the likelihood,” “hope,” “target,” “project,” “goals,” “potential,” “predict,” “might,” “estimate,” “expect,” “intend,” “is planned,” “may,” “should,” “will,” “will enable,” “would be expected,” “look forward,” “may provide,” “would” or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

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 December 31, 2007, our accumulated deficit was approximately \$194.4 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; and manufacturing, 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, depends on the successful development and commercialization of M-Enoxaparin.

In accordance with our 2003 Sandoz Collaboration, Sandoz has submitted ANDAs to the FDA seeking approval to market M-Enoxaparin in the United States. FDA approval of an ANDA is required before marketing of a generic equivalent of a drug previously approved under an NDA. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin is not approvable, because the ANDA did not adequately address the potential for immunogenicity of the drug product. If we are unable to satisfactorily demonstrate therapeutic equivalence, if the FDA disagrees with our characterization approach or does not agree that M-Enoxaparin is equivalent to Lovenox, if we fail to resolve questions raised in FDA's correspondence regarding the M-Enoxaparin ANDA or if we otherwise fail to meet FDA requirements for the ANDA (including but not limited to manufacturing and bioequivalence requirements) or obtain FDA approval for, and successfully commercialize, M-Enoxaparin, we may never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

Patent litigation with Sanofi-Aventis, the innovator of Lovenox, may cause delays and additional expense in the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, our business would be materially harmed, which could include without limitation the curtailment of our other development programs.

Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA's listing of approved drug products, the Orange Book, often bring patent infringement litigation against applicants seeking FDA approval to manufacture and market generic forms of the branded products before patent expiration. Litigation against Sandoz, us or others with respect to Lovenox may cause delays and additional expense in the commercialization of M-Enoxaparin.

Currently, Sanofi-Aventis has two listed patents for Lovenox in the Orange Book, the '618 Patent and the '743 Reissue Patent. Sanofi-Aventis has reported that the claims of the '618 Patent are identical or substantially identical to the corresponding claims of the '743 Reissue Patent. According to Sanofi-Aventis, by operation of law, the '618 Patent ceases to exist and has been replaced by the '743 Reissue Patent. According to the Orange Book, the '743 Reissue Patent expires February 14, 2012.

Sanofi-Aventis has brought lawsuits for patent infringement; one against Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., and two separate patent infringement lawsuits against Sandoz.

Amphastar/Teva Patent Infringement Lawsuit

In September 2003, prior to issuance of the '743 Reissue Patent, Sanofi-Aventis announced that it received individual notices from Amphastar and Teva indicating that each had submitted with the FDA its own ANDA for enoxaparin with a paragraph IV certification. Sanofi-Aventis sued Amphastar and Teva for patent infringement, and in response Amphastar and Teva asserted claims of non-infringement, invalidity and/or unenforceability of the '618 Patent, as well as various counterclaims, and sought related declaratory judgment relief against Sanofi-Aventis. In September 2005, after issuance of the '743 Reissue Patent, Amphastar and Teva each subsequently amended its own ANDA to include a second paragraph IV certification for the '743 Reissue Patent.

In June 2005, the District Court granted summary judgment in the Amphastar/Teva case, finding that both the '618 Patent and the '743 Reissue Patent were unenforceable due to Aventis' inequitable conduct before the United States Patent and Trademark Office, or USPTO. Thereafter, Sanofi-Aventis appealed the decision to the U.S. Court of Appeals for the Federal Circuit, or the Court of Appeals. In April 2006, the Court of Appeals determined that, although there were no issues of material fact with respect to the materiality of certain information withheld from the USPTO, there remained genuine issues of material fact regarding the intent to deceive the USPTO. Accordingly, the Court of Appeals reversed the District Court's ruling and remanded the case to the District Court for further proceedings.

consistent with the Court of Appeals' decision. The District Court held a bench trial in December 2006 focused only on inequitable conduct and in February 2007 the District Court ruled in favor of Amphastar and Teva holding both the '618 Patent and the '743 Reissue Patent unenforceable by virtue of inequitable conduct before the USPTO. Sanofi-Aventis appealed this ruling and oral arguments were presented before the Court of Appeals in January 2008. If Sanofi-Aventis is successful in its appeal, all other remaining issues regarding invalidity, non-infringement and unenforceability could be subsequently tried by the District Court.

Sandoz Patent Infringement Lawsuit

In August 2005, Sandoz filed an ANDA with the FDA to obtain approval for the commercial manufacture, use and sale of the syringe formulation of enoxaparin and in 2006 Sandoz amended its ANDA by filing a paragraph IV certification stating, among other things, that the '618 Patent and '743 Reissue Patent are invalid and unenforceable. In response, Sanofi-Aventis brought a patent infringement suit against Sandoz in August 2006. Sandoz has moved for summary judgment finding unenforceability of the '618 Patent and '743 Reissue Patent based upon the decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until on or about April 4, 2008.

In December 2006, Sandoz filed an ANDA with the FDA to obtain approval for the commercial manufacture, use and sale of the vial formulation of enoxaparin and included a paragraph IV certification, stating, among other things, that the '618 Patent and '743 Reissue Patent are invalid and unenforceable. Sanofi-Aventis brought a patent infringement suit against Sandoz in June 2007. Sandoz has moved to dismiss the suit based upon the decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until on or about April 4, 2008.

Continuing litigation could delay or prevent the introduction of M-Enoxaparin. Moreover, Sanofi-Aventis' efforts to litigate against potential generic challengers to enforce its intellectual property related to Lovenox may not be limited to enforcement of the '618 Patent and '743 Reissue Patent. Pharmaceutical companies frequently sue generic challengers over potential infringement of patents that are not listed in the Orange Book. Presently, we are not aware of any enoxaparin litigation relating to non-Orange Book patents, but it is possible that Sanofi-Aventis will initiate such litigation against us, Sandoz, Teva, Amphastar, or others in the future. If Sanofi-Aventis were to initiate litigation relating to non-Orange Book patents, this litigation could significantly delay, impair or prevent our ability to commercialize M-Enoxaparin and our business would be materially harmed.

Under our 2003 Sandoz Collaboration, the decision as to when to begin marketing M-Enoxaparin will be determined jointly by us and Sandoz in most circumstances. However, Sandoz does have sole discretion over the decision as to when to begin marketing M-Enoxaparin under certain circumstances. Sandoz could decide to market M-Enoxaparin prior to final resolution of either the Teva and Amphastar or Sandoz litigation matters, which could result in significant damages, including possibly treble damages, in the event Sanofi-Aventis is successful in either patent litigation case. Although Sandoz has agreed to indemnify us for patent liability damages, Sandoz has the right to offset certain of these liabilities against the profit-sharing amounts, the royalties and the milestone payments otherwise due to us from the marketing of M-Enoxaparin.

Litigation involves many risks and uncertainties, and there is no assurance that Amphastar, Teva, Sandoz or we will prevail in any lawsuit with Sanofi-Aventis. In addition, Sanofi-Aventis has significant resources and any litigation with Sanofi-Aventis could last a number of years, potentially delaying or prohibiting the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, we may have to curtail our other product development programs and our business would be materially harmed.

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

In March 2003, Amphastar and Teva each submitted 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 obtains licenses from Sanofi-Aventis to market an authorized generic, the resulting financial returns to us 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. Under the Hatch-Waxman Act, any developer of a generic drug that is first to have its ANDA accepted for review by the FDA, and whose submission includes a paragraph IV certification, is eligible to receive a 180-day period of generic market exclusivity. Sandoz was not the first applicant to file an enoxaparin ANDA with a paragraph IV certification, so we will be forced to wait until the expiration of Teva and/or Amphastar's exclusivity period before the FDA will be able to finally approve our application. As a result, Teva and/or Amphastar may have the opportunity to establish long term supply agreements with institutional customers before we can enter the market, which would hinder our ability to penetrate the market for generic enoxaparin products.

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 would be triggered. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues for 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.

If other generic versions of our generic and novel drug products are approved and successfully commercialized, our business would suffer.

We expect that certain of our generic 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, 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 basis for approval of some of our products in current or future development, including M-Enoxaparin and M356, is new technologies that have not previously been formally reviewed or accepted by the FDA or other regulatory authorities. The FDA's review and acceptance of our technologies may take time and resources, require independent third-party analysis or 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 we are unable to obtain sufficient quantities of raw materials, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our product candidates, including M-Enoxaparin, 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 third parties to provide raw materials, manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our product candidates, including M-Enoxaparin. We 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, we or our third party contractors may have difficulty producing products in the quantities necessary to meet anticipated market demand. If we are unable to satisfy the FDA 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.

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

We and our partners and vendors obtain certain starting materials, including UFH, from suppliers who in turn source the materials from other countries. In early 2008, due to the occurrence of adverse events, including deaths, associated with the use of UFH, there have been recalls of UFH products in both the United States and Germany. Based on investigation by the FDA into those adverse events, the FDA has identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use a CE and NMR test to screen their UFH active pharmaceutical ingredient. The U.S. government may place additional restrictions or testing requirements on the use of raw materials, including UFH, in products intended for sale in the U.S., including our M-Enoxaparin, M118 and other products. The U.S. government could also place restrictions on the import of such raw materials into 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 may be unable to produce our products in sufficient quantities to meet the requirement for the commercial launch of the product or to meet future demand, which would have a material adverse impact on our business.

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 December 31, 2007, we had cash, cash equivalents and marketable securities totaling \$135.9 million. For the twelve months ended December 31, 2007, we had a net loss of \$68.9 million and used cash in operating activities of \$56.3 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;
- the timing of FDA approval of the products of our competitors;

- the cost of litigation, including potential patent litigation with Sanofi-Aventis relating to Lovenox 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. 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.

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 in 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 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;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the effectiveness of our marketing 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.

If we are unable to establish and maintain key customer 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 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 of our physician education and marketing programs;
- the sales 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 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, 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. Such 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;
- 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 as therapeutic equivalents to their corresponding reference listed drugs, including M-Enoxaparin, 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, including M-Enoxaparin. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products (i) contain the same active ingredients as the branded products upon which they are based, (ii) are of the same dosage form, strength and route of administration as the branded products upon which they are based, and (iii) meet compendial or other applicable standards for strength, quality, purity and identity, including potency. In addition, we may be required to conduct *in vivo* studies to demonstrate that our generic versions of complex drugs are bioequivalent to the branded products upon which they

are based, meaning typically 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.

Determination of therapeutic equivalence of our generic versions of complex drugs to the reference listed drugs will be based on our demonstration of chemical equivalence to the 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 determine 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 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 other lengthy processes, the commercialization of some of our development candidates could be delayed or prevented. 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 U.S. Congress does not take action to create an abbreviated regulatory pathway for follow-on versions of complex protein products, and if the FDA is not able to establish specific guidelines regarding the scientific analyses required for characterizing follow-on versions of complex protein drugs, then the uncertainty about the value of our glycoprotein program will be increased.

The regulatory climate for follow-on versions of protein products in the U.S. 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 most protein drugs. The FDA has approved the majority of new protein products under the Public Health Service Act, or PHS Act, through the use of BLAs. Unlike drugs approved through the submission of NDAs, under section 505 of the Federal Food, Drug, and Cosmetic Act, or the FDCA, there is no provision in the PHS Act for an abbreviated BLA approval pathway, 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, there is uncertainty as to what data the FDA may deem is necessary to demonstrate the sameness required for approval of an ANDA under section 505(j) of the FDCA. 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 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 U.S. Congress to enact legislation establishing an abbreviated pathway for approval for follow-on products to approved BLA products could reduce the value of, or render obsolete, our glycoprotein program.

If our preclinical studies and clinical trials for our development candidates, including M118, 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 or improved 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 the clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize M118 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 the 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 or our product candidates beyond those that we currently contemplate, 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 varies 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

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 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. In addition, neither we, nor any of our third-party collaborators, are permitted to employ in any capacity, any individual who has been debarred under the FDA's Application Integrity Policy, and if such person is or has been so employed, the FDA may delay its review and approval of some or all of our applications, reject certain studies, withdraw approval of our applications, and take other adverse administrative action against us.

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. 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, 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 structure. Teva, Amphastar, and others have filed comments opposing the Petition, and Aventis has filed numerous supplements and reply comments in support of its Petition. The FDA has yet to rule on

the Petition, and if the FDA ultimately grants the Petition, we and Sandoz may be unable to obtain approval of our ANDA for M-Enoxaparin, 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.

New 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 Medicare Prescription Drug Improvement and Modernization Act of 2003, or 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 considered separate 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 remove 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 amount of reimbursement we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

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

In some foreign countries, particularly the countries of the European Union, the pricing 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, 2007, 2006 and 2005, we spent approximately \$64,000, \$31,000 and \$19,000, 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 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 USPTO 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 their intellectual property rights or that our creation or use of proprietary technology infringes upon their 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. 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 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 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.

Under our 2003 Sandoz Collaboration, we and Sandoz agree to exclusively work with each other in the development and commercialization of injectable enoxaparin within the United States. We also granted to Sandoz the right to negotiate additional rights for certain products under certain circumstances. Under our 2006 Sandoz Collaboration, we and Sandoz agree to exclusively work with each other in the development and commercialization of four follow-on and complex generic products for sale in specified regions of the world, including M356 and the expansion of M-Enoxaparin activity into the European Union.

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 redress, 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 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 Definitive Agreement 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: (i) if clinical trials are required, (ii) at Sandoz' convenience within a certain time period, (iii) if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval, (iv) if Sandoz decides to permanently cease development and commercialization of a product, or (v) 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 collaboration 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 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 a 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 depend on third-parties for the manufacture of products. If in the future we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely affected.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any 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 partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. As a result, we expect generally to rely on contract manufacturers for regulatory compliance. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or 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 our 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. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term 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 cGMP regulations. Any failure by us 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 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 sales, marketing and 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 and 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 40.1% of our outstanding common stock as of December 31, 2007. As a result, these stockholders, if acting together, may have the ability to determine the outcome of or 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;
- 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;
- a “poison pill” in accordance with the Company’s Shareholders Rights Plan that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- limitations on the removal of directors.

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 have 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. 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 ANDA or other adverse FDA decisions relating to M-Enoxaparin, including the FDA requiring clinical trials as a condition to M-Enoxaparin approval;
- FDA approval of other ANDAs for generic versions of Lovenox;
- litigation involving our company or our general industry or both;
- a decision in favor of Sanofi-Aventis in any of the current patent litigation matters, or a settlement related to any of those cases;
- 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;
- failure to demonstrate the safety and efficacy for our novel development product candidates;
- our inability to manufacture any products to commercial standards;
- 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;
- termination of any of our strategic partnerships;

- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; and
- investors' general perception of our company, our products, the economy and general market conditions.

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.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

As of March 1, 2008, pursuant to our sublease agreements, we are leasing a total of approximately 78,500 square feet of office and laboratory space in one building in Cambridge, Massachusetts:

<u>Property Location</u>	<u>Approximate Square Footage</u>	<u>Use</u>	<u>Lease Expiration Date</u>
675 West Kendall Street Cambridge, Massachusetts 02142	78,500	Laboratory & Office	04/30/2011

Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded publicly on the NASDAQ Global Market under the symbol "MNTA." The following table sets forth the high and low last sale prices of our common stock for the periods indicated, as reported on the NASDAQ Global Market:

<u>Quarter ended</u>	<u>High</u>	<u>Low</u>
March 31, 2006	\$25.05	\$18.78
June 30, 2006	19.09	11.76
September 30, 2006	18.02	10.76
December 31, 2006	18.18	13.05
March 31, 2007	20.13	11.42
June 30, 2007	16.10	10.08
September 30, 2007	12.02	9.49
December 31, 2007	13.38	4.87

Holdings

On February 29, 2008, the approximate number of holders of record of our common stock was 63 and the approximate number of beneficial holders of our common stock was 4,085.

Dividends

We have never declared or paid any cash dividends on our common stock. We anticipate that, in the foreseeable future, we will continue to retain any earnings for use in the operation of our business and will not pay any cash dividends.

Equity Compensation Plan Information

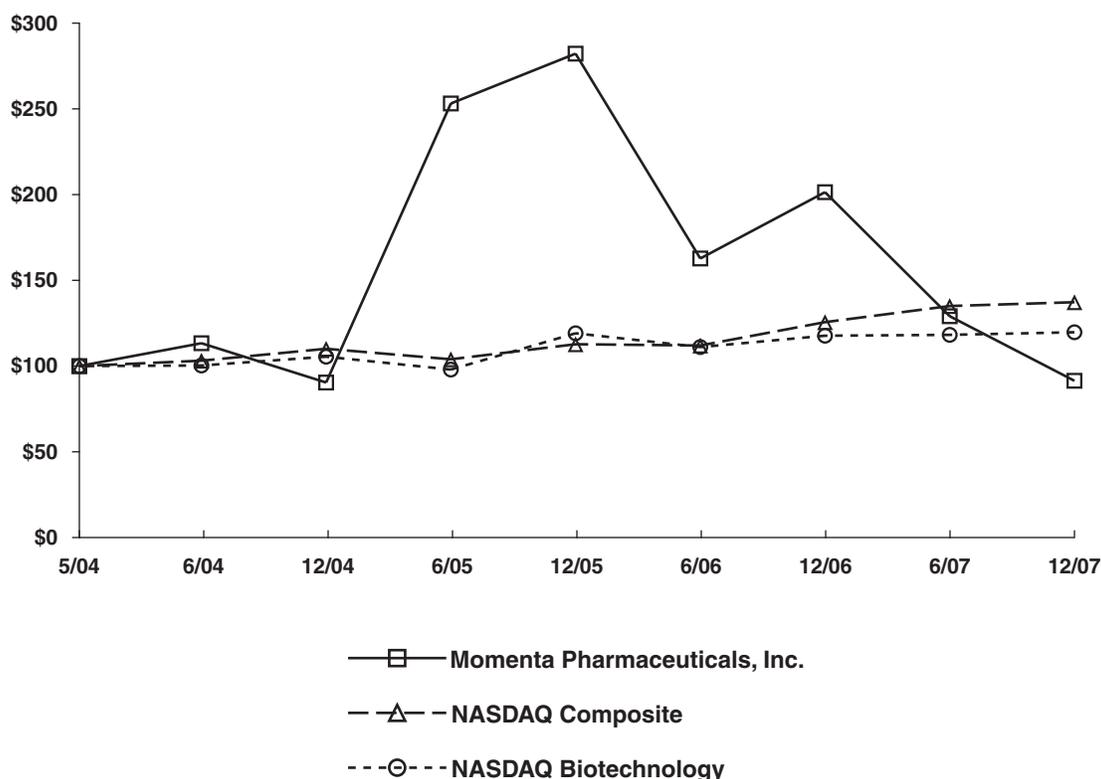
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth under "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for our 2008 Annual Meeting of Stockholders.

Stock Performance Graph

The comparative stock performance graph below compares the cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing \$100 on June 22, 2004, the date on which our common stock was first publicly traded, through December 31, 2007, in each of (i) our common

stock, (ii) The NASDAQ Composite Index and (iii) The NASDAQ Biotechnology Index (capitalization weighted).

COMPARISON OF 42 MONTH CUMULATIVE TOTAL RETURN*
Among Momenta Pharmaceuticals, Inc., The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



* \$100 invested on 6/22/04 in our common stock and \$100 invested on 5/31/04 in each of the NASDAQ Composite Index and the NASDAQ Biotechnology Index, including reinvestment of dividends.
Fiscal year ending December 31.

	Base Period*	6/30/04	12/31/04	6/30/05	12/31/05	6/30/06	12/31/06	6/30/07	12/31/07
Momenta Pharmaceuticals, Inc.	100.00	113.32	90.40	253.14	282.20	162.74	201.41	129.07	91.42
NASDAQ Composite	100.00	103.14	110.09	103.96	112.74	111.99	125.61	135.01	137.24
NASDAQ Biotechnology	100.00	100.33	105.47	97.96	119.12	111.08	117.70	118.20	119.72

The information included under the heading “Stock Performance Graph” in Item 5 of this Annual Report on Form 10-K is “furnished” and not “filed” and shall not be deemed to be “soliciting material” or subject to Regulation 14A, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the balance sheet data as

of December 31, 2007 and 2006 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2004 and 2003 and the balance sheet data as of December 31, 2005, 2004 and 2003 are derived from our audited financial statements, which are not included herein. Historical results are not necessarily indicative of future results. See the notes to the consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per common share. The selected consolidated financial data set forth below should be read in conjunction with and is qualified in its entirety by our audited consolidated financial statements and related notes thereto found at “Item 8. Financial Statements and Supplementary Data” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations,” which are included elsewhere in this Annual Report on Form 10-K.

Momenta Pharmaceuticals, Inc.
Selected Financial Data

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue	\$ 21,561	\$ 15,999	\$ 13,011	\$ 7,832	\$ 1,454
Operating expenses:					
Research and development	69,899	46,916	23,710	15,722	5,347
General and administrative	28,219	28,466	14,059	6,751	4,083
Total operating expenses	98,118	75,382	37,769	22,473	9,430
Loss from operations	(76,557)	(59,383)	(24,758)	(14,641)	(7,976)
Interest income	8,484	7,974	3,353	605	74
Interest expense	(808)	(504)	(257)	(39)	(43)
Net loss	\$(68,881)	\$(51,913)	\$(21,662)	\$(14,075)	\$(7,945)
Net loss attributable to common stockholders . . .	\$(68,881)	\$(51,913)	\$(21,662)	\$(36,316)	\$(9,843)
Basic and diluted net loss per share attributable to common stockholders	\$ (1.93)	\$ (1.62)	\$ (0.79)	\$ (2.56)	\$ (5.02)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	35,639	32,103	27,283	14,177	1,961

	As of December 31,				
	2007	2006	2005	2004	2003
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	\$ 33,038	\$ 22,351	\$ 25,890	\$ 11,678	\$ 4,613
Marketable securities	102,899	168,914	130,364	41,943	7,994
Working capital	125,293	185,299	155,661	54,154	13,044
Total assets	168,298	216,385	171,101	64,330	16,084
Total long-term obligations	7,971	7,057	2,996	1,105	372
Total liabilities	40,758	33,794	10,946	7,337	2,638
Redeemable convertible preferred stock	—	—	—	—	27,225
Accumulated deficit	(194,400)	(125,519)	(73,606)	(51,944)	(15,628)
Total stockholders’ equity (deficit)	\$ 127,540	\$ 182,591	\$160,155	\$ 56,993	\$(13,779)

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Our Management's Discussion and Analysis of Financial Condition and Results of Operations includes the identification of certain trends and other statements that may predict or anticipate future business or financial results. There are important factors that could cause our actual results to differ materially from those indicated. See "Risk Factors" in Item 1A of this Annual Report on Form 10-K.

Business Overview

Momenta is a biotechnology company with a product pipeline of both novel and complex generic drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixture drugs. 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, resulting in our product pipeline of both complex generic and novel drugs.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox®, a widely prescribed low molecular weight heparin, or LMWH. In 2003, we formed a collaboration, the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc., collectively Sandoz, affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin in the U.S. In August 2005, Sandoz submitted an Abbreviated New Drug Application, or ANDA, to the FDA for the syringe formulation of M-Enoxaparin. The ANDA was amended in 2006 to include a paragraph IV certification stating that Sanofi-Aventis' patents for Lovenox listed in the FDA's listing of approved drug products, the Orange Book, are, among other things, invalid or unenforceable.

In July 2006, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG and a Memorandum of Understanding, or MOU, with Sandoz AG, an affiliate of Novartis Pharma AG. In June 2007, we and Sandoz AG executed a definitive collaboration and license agreement, or the Definitive Agreement, which superseded the MOU. We refer to this series of agreements collectively as the 2006 Sandoz Collaboration. Under the 2006 Sandoz Collaboration, we expanded the geographic markets covered by the 2003 Sandoz Collaboration related to M-Enoxaparin to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world.

Since our inception in May 2001, we have incurred annual net losses. As of December 31, 2007, we had an accumulated deficit of \$194.4 million. We recognized net losses of \$68.9 million, \$51.9 million and \$21.7 million for the years ended December 31, 2007, 2006 and 2005, respectively. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our research and development activities and prepare for the commercial launch of our product candidates. Additionally, we plan to continue to evaluate possible acquisitions or licensing of rights to additional technologies, products or assets that fit within our growth strategy. Accordingly, we will need to generate significant revenues to achieve and then maintain profitability.

Since our inception, we have had no revenues from product sales. Our revenues for the years ended December 31, 2007, 2006 and 2005 of \$21.6 million, \$16.0 million and \$13.0 million, respectively, have been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and primarily consist of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for certain programs. In June 2004, we completed an initial public offering of 6,152,500 shares of common stock, the net proceeds of which were \$35.3 million after deducting underwriters' discounts and expenses. In July 2005, we raised \$122.3 million in a follow-on public offering, net of expenses, from the sale and issuance of 4,827,300 shares of our common stock. In September 2006, in connection with the 2006 Sandoz Collaboration, we sold 4,708,679 shares of

common stock to Novartis Pharma AG for an aggregate purchase price of \$75.0 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates.

Financial Operations Overview

Revenue

We have not yet generated any revenue from product sales and are uncertain whether or not we will generate any revenue from the sale of products over the next several years. We have recognized, in the aggregate, \$59.9 million of revenue from our inception through December 31, 2007. This revenue was derived entirely from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. We will seek to generate revenue from a combination of research and development payments, profit sharing payments, milestone payments and royalties in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and similar future collaborative or strategic relationships. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of research and development and other payments received under our collaborative or strategic relationships, and the amount and timing of payments we receive upon the sale of our products, to the extent any are successfully commercialized.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, contract research and manufacturing, and the costs of laboratory equipment and facilities. We expense research and development costs as incurred. Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

The following summarizes our primary research and development programs:

Development Programs

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and commercialize M-Enoxaparin in the U.S. and Sandoz is responsible for funding substantially all of the U.S.-related M-Enoxaparin development, regulatory, legal and commercialization costs. The total cost of development and commercialization, and the timing of M-Enoxaparin product launch, are subject to uncertainties relating to the development, regulatory approval and legal processes. In accordance with our 2003 Sandoz Collaboration, Sandoz submitted ANDAs in its name to the FDA for M-Enoxaparin in syringe and vial forms seeking approval to market M-Enoxaparin in the United States. Both ANDAs currently include a paragraph IV certification stating that Sanofi-Aventis' patents listed in the Orange Book for Lovenox are, among other things, invalid and unenforceable.

The FDA is currently reviewing both M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable in its current form because the ANDA does not adequately address the potential for immunogenicity of the drug product. We and Sandoz are working together to address the FDA's questions and determine the information

necessary to obtain approval of M-Enoxaparin. Based on our work to date, we believe that we will not need to conduct clinical trials to address the FDA's questions, but we cannot be assured of this yet. We are preparing for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives. However, we cannot predict the timing of any action by the FDA related to the M-Enoxaparin ANDA.

Our 2006 Sandoz Collaboration expanded our collaboration efforts related to M-Enoxaparin to include the European Union. Under the 2006 Sandoz Collaboration, we will share certain development, regulatory, legal and commercialization costs as well as a portion of the profits, if any.

M118

M118 is a novel anticoagulant that was rationally designed with the goal of providing improved clinical anticoagulant properties to support the treatment of patients diagnosed with ACS and stable angina. We believe that M118 has the potential to provide baseline anticoagulant therapy to treat coronary artery disease and patients with ACS or stable angina who require invasive treatment, as well as those ACS patients who are medically managed, or do not require invasive treatment. M118 is designed to be a reversible and monitorable anticoagulant that can be administered intravenously or subcutaneously and have a pharmacokinetic profile similar to other LMWHs. We believe that these properties of M118 have the potential to provide greater flexibility than other therapies presently used to treat patients diagnosed with ACS and stable angina.

In July 2006, we filed our Investigational New Drug Application, or IND, with the FDA for our M118 intravenous injection formulation, and in October 2006 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In October 2007, we began a Phase 2a clinical trial to evaluate the feasibility of utilizing M118 intravenous injection formulation as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention.

In March 2007, we filed our IND for our M118 subcutaneous formulation, and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile.

M356

M356 is designed to be a technology-enabled generic version of Copaxone®, a complex drug consisting of a mixture of polypeptide chains. Copaxone is indicated for reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed through Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., and distributed by Sanofi-Aventis. Teva and Sanofi-Aventis have an additional collaborative arrangement for the marketing of Copaxone in Europe and other markets, under which Copaxone is either co-promoted with Teva or is marketed solely by Sanofi-Aventis. Under the Definitive Agreement, we and Sandoz jointly develop, manufacture and commercialize M356. We are responsible for funding substantially all of the U.S.-related M356 development costs, with Sandoz responsible for legal and commercialization costs. Outside of the U.S., we and Sandoz share equally the development costs, with Sandoz responsible for commercialization and legal costs.

Glycoproteins

Glycoproteins are proteins to which sugar molecules are attached. Examples of glycoprotein drugs are erythropoietin, blood clotting factors and interferon beta. We are applying our technology to the development of generic or biosimilar glycoprotein drugs. We believe that this technology can further be used in assisting pharmaceutical and biotechnology companies in developing improved and

next-generation versions of their branded products by analyzing and modifying the sugar structures contained in the branded products, and can also be used to engineer novel complex mixture drugs.

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to glycoproteins. The goal of the program is to facilitate the development of generic or biosimilar versions of major marketed glycoprotein drugs.

Under our 2006 Sandoz Collaboration, we are currently applying our technology to develop two follow-on proteins in partnership with Sandoz AG. We refer to these two product candidates as M178 and M249.

Discovery Program

We are also applying our analytical capabilities to drug discovery. Our discovery program is focused on the role that complex sugars play in biological systems, including regulating the development and progression of disease. Our initial focus is in the area of cancer, where we are seeking to discover sugar sequences with anti-cancer properties for development as therapeutics, and we are advancing an oncology product candidate that is in the advanced discovery phase. Sugars play a part in the conversion of normal cells into cancerous cells, the regulation of tumor growth and tumor invasion and metastasis. We believe that our technology can provide us with a better understanding of the role of sugars in disease, enabling us to discover novel sugar therapeutics, as well as to discover new disease mechanisms that can be targeted with other small molecule and biologic drugs.

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, legal, accounting, investor relations, business development and human resource functions. Other costs include facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services and other general expenses.

Results of Operations

Years Ended December 31, 2007, 2006 and 2005

Revenue

Revenue for 2007 was \$21.6 million, compared with \$16.0 million for 2006 and \$13.0 million for 2005. Revenue for the year ended December 31, 2007 consists of (i) amounts earned by us under our 2003 Sandoz Collaboration for reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received and (ii) amounts earned by us under our 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs. Revenue increased \$5.6 million from 2006 to 2007 due primarily to \$2.7 million of reimbursable expenditures associated with the first year of the 2006 Sandoz Collaboration, a \$1.7 million increase in reimbursable development expenditures associated with preparing for the potential commercial launch of M-Enoxaparin in the U.S., and \$1.2 million of the first year of amortization related to the equity premium.

The increase of \$3.0 million from 2005 to 2006 is entirely attributable to our 2003 Sandoz Collaboration. These revenues consist of amounts earned by us for payment by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin and amortization of the initial payment received under our 2003 Sandoz Collaboration. The increase in revenues was the result of increased reimbursable expenditures associated with preparing for the potential commercial launch of M-Enoxaparin in the U.S.

Research and Development

Research and development expense for 2007 was \$69.9 million, compared with \$46.9 million in 2006 and \$23.7 million in 2005. The increase of \$23.0 million from 2006 to 2007 principally resulted from an increase of \$8.5 million in manufacturing and process development costs and research conducted by third parties in support of our M356, M-Enoxaparin and glycoprotein programs, \$5.6 million in clinical trial costs for our M118 program, \$5.2 million in personnel and related costs associated with the growth in our research and development organization, \$1.4 million in laboratory supplies and a \$0.7 million in-process research and development charge related to the Parivid asset purchase. The increase of \$23.2 million from 2005 to 2006 principally resulted from an increase of \$6.0 million in manufacturing and process development costs and research conducted by third parties, \$4.7 million in personnel and related costs, \$3.7 million in stock-based compensation, of which \$2.2 million was related to the adoption of SFAS 123R, \$3.4 million in laboratory expenses, \$2.6 million in facilities costs, \$1.0 million in consultant costs and \$0.9 million in depreciation expense.

The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate when, if ever, our product candidates will generate revenues and cash flows. We expect future research and development expenses to increase in support of our product candidates.

The following table summarizes the primary components of our research and development expenditures for our principal research and development programs for the years ended December 31, 2007, 2006 and 2005. Certain prior year amounts have been reclassified due to a current year change in the allocation method for indirect costs.

<u>Research and Development Expense (in thousands)</u>	<u>2007</u>	<u>2006</u>	<u>2005</u>
Development programs	\$65,277	\$39,728	\$16,606
Discovery programs	4,436	5,333	3,472
Other research	186	1,855	3,632
Total research and development expense	<u>\$69,899</u>	<u>\$46,916</u>	<u>\$23,710</u>

Development programs

The increase in expenditures on development programs of \$25.5 million from 2006 to 2007 was primarily related to increases in the expenses of our M356, M118, M-Enoxaparin and glycoprotein programs. Our M356 program manufacturing and research costs have increased as we continue to advance the program. M118 clinical costs have increased as we have progressed from preclinical to Phase 2 studies. M-Enoxaparin manufacturing costs have increased as we prepare for potential commercial launch. Our glycoprotein program expenditures have increased as we devote additional headcount resources to facilitate the development of follow-on versions of glycoprotein drugs.

The increase in expenditures on development programs of \$23.1 million from 2005 to 2006 was primarily related to preclinical and toxicology work to support the M118 IND filing, commencement of our Phase 1 clinical studies for M118, manufacturing and professional fees related to our M-Enoxaparin program and the development expenses of our M356 program.

Discovery programs

The discovery program expenditures from 2006 to 2007 include a decrease of approximately \$2.5 million due to the termination of the drug delivery program in late 2006, offset by increased oncology program expenditures of approximately \$1.6 million representing additional resources dedicated to applying our analytical capabilities to drug discovery. The \$1.9 million increase in expenses in our discovery programs from 2005 to 2006 was primarily related to increased expenditures to support our disease biology and drug delivery programs.

Other research

The decrease in both years in other research expense was primarily due to a decrease in headcount and headcount related costs relating to general technology development and support activities as resources are allocated to development programs.

General and Administrative

General and administrative expense for the year ended December 31, 2007 was \$28.2 million, compared to \$28.5 million in 2006 and \$14.1 million in 2005. General and administrative expense decreased by \$0.3 million from 2006 to 2007 primarily due to a decrease of \$1.8 million in professional fees due to a reduction in legal activities, offset by an increase of \$1.5 million in personnel and related costs due to increased headcount. General and administrative expense increased by \$14.4 million from 2005 to 2006 due primarily to an increase of \$5.4 million in stock-based compensation, of which \$3.9 million was related to the adoption of SFAS 123R, increases of \$4.6 million in professional fees and other legal expenses and \$3.8 million in personnel and related costs.

We anticipate increases in general and administrative expenses to support our research and development programs. These increases will likely include the hiring of additional personnel. We expect to incur increased internal and external legal and business development costs to support our various product development efforts, which can vary from period to period.

Interest Income

Interest income was \$8.5 million, \$8.0 million and \$3.4 million for the years ended December 31, 2007, 2006 and 2005, respectively. The increase of \$0.5 million from 2006 to 2007 was primarily due to higher average investment balances as a result of the proceeds from the issuance of common stock to Novartis Pharma AG in September 2006. The increase of \$4.6 million from 2005 to 2006 was primarily due to higher average investment balances as a result of the proceeds from the issuance of common stock to Novartis Pharma AG in September 2006 and from our follow-on public offering in July 2005.

Interest Expense

Interest expense was \$0.8 million, \$0.5 million and \$0.3 million for the years ended December 31, 2007, 2006 and 2005, respectively. The increase of \$0.3 million from 2006 to 2007 and \$0.2 million from 2005 to 2006 was primarily due to additional amounts drawn from our equipment line of credit during 2006 and 2007.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, borrowings from our lines of credit, and capital lease obligations. Since our inception, we have received net proceeds of \$45.4 million from the issuance of redeemable convertible preferred stock. In June 2004, we completed our initial public offering and raised net proceeds of \$35.3 million. In July 2005, we completed a

follow-on public offering and raised net proceeds of \$122.3 million. In September 2006, we received net proceeds of \$74.9 million from Novartis Pharma AG's purchase of 4,708,679 shares of our common stock in connection with the 2006 Sandoz Collaboration. As of December 31, 2007, we have received a cumulative total of \$51.7 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, \$4.0 million from debt financing, \$9.2 million from capital lease obligations, \$3.2 million from our landlord for leasehold improvements related to our corporate facility, and additional funds from interest income.

At December 31, 2007, we had \$135.9 million in cash, cash equivalents and marketable securities. In addition, we also hold \$1.8 million in restricted cash, which serves as collateral for a letter of credit related to our facility lease. During the years ended December 31, 2007, 2006 and 2005, our operating activities used \$56.3 million, \$25.2 million and \$17.0 million, respectively. The use of cash for operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities. Our net losses have increased year over year as we increase our headcount and continue to develop our product candidates. For the year ended December 31, 2007, our net loss adjusted for non-cash items was \$57.7 million. In addition, the net change in our operating assets and liabilities provided \$1.4 million and resulted from: increases in accounts receivable of \$0.7 million and unbilled collaboration revenue of \$4.3 million due to timing of cash receipts from our sole customer and an increase in billable activities; a decrease in restricted cash of \$2.9 million due to the cancellation of a letter of credit for the Third Street sublease; an increase in accounts payable of \$4.8 million resulting from increased manufacturing and research costs for our programs; and a decrease in deferred revenue of \$1.3 million representing amortization of the \$13.6 million equity investment premium paid by Novartis in connection with the 2006 Sandoz Collaboration.

For the year ended December 31, 2006, our net loss adjusted for non-cash items was \$40.1 million. In addition, the net change in our operating assets and liabilities provided \$14.9 million, primarily due to an increase in deferred revenue of \$13.4 million relating to the equity investment premium paid by Novartis in connection with the 2006 Sandoz Collaboration offset by the restriction of \$2.9 million in conjunction with a letter of credit for the Third Street sublease. Remaining increases of approximately \$3.7 million in accounts payable and accrued expenses were due to general increases in our business activities as a result of greater headcount and increased product development costs. For the year ended December 31, 2005, our net loss adjusted for non-cash items was \$17.3 million, and the net change in our operating assets and liabilities provided \$0.3 million. Increases in operating assets and liabilities were due to the collection of \$2.2 million in 2005 for receivables from 2004 and an increase in accrued expenses of \$1.7 million due to increases in headcount related expenses and product development costs. These increases were offset by the effects of increases in unbilled collaboration revenue and prepaid expenses of \$3.0 million due to greater reimbursable development spend over the prior year and an increase in interest receivable due to higher average investment balances.

Net cash provided by investing activities was \$60.9 million for the year ended December 31, 2007. During 2007, we used \$242.5 million of cash to purchase marketable securities, offset by cash provided of \$314.7 million in maturities of marketable securities. Net cash used in investing activities was \$46.3 million and \$93.3 million for the years ended December 31, 2006 and 2005, respectively. During 2006, we used \$243.2 million of cash to purchase marketable securities, offset by cash provided of \$206.6 million in maturities of marketable securities. During 2005, we used \$151.6 million of cash to purchase marketable securities, offset by cash provided of \$62.0 million in maturities of marketable securities. During the years ended December 31, 2007, 2006 and 2005, we used \$8.8 million, \$9.8 million and \$3.7 million, to purchase laboratory equipment and leasehold improvements.

Net cash provided by financing activities for the year ended December 31, 2007 was \$6.1 million. We borrowed \$4.2 million on an equipment lease agreement entered into in December 2005, recovered \$3.7 million in property and equipment from the assignment of the Third Street sublease, received proceeds of \$0.9 million from stock option exercises and purchases of common shares through our

Employee Stock Purchase Plan, offset by principal payments of \$2.1 million on our line of credit and lease agreement obligations and payments of \$0.6 million on financed leasehold improvements. Net cash provided by financing activities for the year ended December 31, 2006 was \$68.0 million. We received net proceeds of \$74.9 million from the sale of 4,708,679 shares of common stock to Novartis Pharma AG of which \$13.6 million is included in deferred revenue in our consolidated balance sheet as of December 31, 2006. Additionally, we borrowed \$3.7 million on an equipment lease agreement entered into in December 2005, received \$3.2 million in financing from our landlord for leasehold improvements related to our corporate facility, and received proceeds of \$1.3 million from stock option exercises and purchases of common shares through our Employee Stock Purchase Plan, offset by principal payments of \$1.3 million on our line of credit and lease agreement obligations and payments of \$0.3 million on financed leasehold improvements. Net cash provided by financing activities for the year ended December 31, 2005 was \$124.5 million. We received proceeds of \$122.3 million from our follow-on public offering of common stock in July 2005, \$1.6 million from our line of credit obligation, \$1.2 million from our equipment lease agreement entered into in December 2005, \$0.3 million from stock option exercises, purchases of common shares through our Employee Stock Purchase Plan and a payment related to restricted stock. The total proceeds of \$125.4 million were offset by \$0.9 million in principal payments on our line of credit obligation.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2007:

Contractual Obligations (in thousands)	Payments Due by Period		2009 through 2010	2011 through 2012	After 2012
	Total	2008			
License maintenance obligations	\$ 983	\$ 138	\$ 410	\$ 435	*
Short and long-term line of credit obligation	769	752	17	—	\$ —
Capital lease obligations	9,432	2,318	5,297	1,817	—
Operating lease obligations	11,886	3,578	7,123	1,185	—
Total contractual obligations	\$23,070	\$6,786	\$12,847	\$3,437	\$ —

* After 2012, the annual obligations, which extend indefinitely, are approximately \$0.2 million per year.

We anticipate that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations through at least 2009. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue, accrued expenses and certain equity instruments. Prior to our initial public offering, we also evaluated our estimates and judgments regarding the fair valuation assigned to our common stock. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities

that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue

We record revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues received in advance of performance obligations or in cases where we have a continuing obligation to perform services are deferred and recognized over the performance period. When we are required to defer revenue, the period over which such revenue is recognized is based on estimates by management and may change over the course of the performance period. At the inception of a collaboration agreement, we estimate the term of our performance obligation based on our development plans and our estimate of the regulatory review period. The development plans generally include designing a manufacturing process to make the drug product, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale and related development of intellectual property. Each reporting period we reassess our remaining performance obligations under the applicable collaboration arrangement by considering the time period over which any remaining development and related services to be provided prior to obtaining regulatory approval are expected to be completed. Changes in our estimate could occur due to changes in our development plans or due to changes in regulatory or legal requirements. We have deferred upfront payments of \$0.6 million and \$13.6 million in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, respectively. Such upfront payments are being recognized over our estimated period of performance obligation, which is approximately five and six years, respectively, from the applicable collaboration inception date. In December 2007, we revised our estimate of the development period under the 2003 Sandoz Collaboration agreement due to a change in the projected timing of certain activities required for the completion of the FDA's review of the ANDA for M-Enoxaparin. The change in estimate did not have a material impact on the Company's net loss or net loss per share for the year ended December 31, 2007.

Revenue from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and then estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include contract service fees paid to contract manufacturers in conjunction with the production of clinical drug supplies and to contract research organizations. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

Stock-Based Compensation

We adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, effective January 1, 2006 under the modified prospective transition method. SFAS 123R requires the recognition of the fair value of stock-based compensation expense in our operations, and accordingly the adoption of SFAS 123R fair value method has had and will continue to have a significant impact on our results of operations, although it will have no impact on our overall financial position.

Prior to January 1, 2006, we accounted for employee stock options under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and provided pro forma disclosures of net loss attributable and net loss per share allocable to common stockholders as if we had adopted the fair value based method of accounting in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123*, or SFAS 148.

We determine the fair value of each option award on the date of grant using the Black-Scholes-Merton option pricing model. Option valuation models require the input of highly subjective assumptions, including stock price volatility and expected term of an option. In determining our volatility, we have considered implied volatilities of currently traded options to provide an estimate of volatility based upon current trading activity in addition to our historical volatility. After considering other such factors as our stage of development and the length of time we have been public, we believe a blended volatility rate based upon historical performance, as well as the implied volatilities of currently traded options, best reflects the expected volatility of our stock going forward. Changes in market price directly affect volatility and could cause stock-based compensation expense to vary significantly in future reporting periods.

The expected term of awards represents the period of time that the awards are expected to be outstanding. We use a blend of our own historical employee exercise and post-vest termination behavior and expected term data from our peer group to arrive at the estimated expected life of an option. For purposes of identifying similar entities, we considered characteristics such as industry, stage of life cycle and financial leverage. We update these assumptions on a quarterly basis to reflect recent historical data. Additionally, we are required to estimate forfeiture rates to approximate the number of shares that will vest in a period to which the fair value is applied. We will continually monitor employee exercise behavior and may further adjust the estimated term and forfeiture rates in future periods. Increasing the estimated life would result in an increase in the fair value to be recognized over the requisite service period, generally the vesting period. Estimated forfeitures will be adjusted to actual forfeitures upon the vest date of the cancelled options as a cumulative adjustment on a quarterly basis. The risk-free interest rates used in the Black-Scholes-Merton option pricing model are based on the United States Treasury yield curve in effect for periods corresponding with the expected term of the stock option.

The value of our restricted stock awards is recognized as compensation cost in our consolidated statements of operations over each award's explicit or implicit service periods. We estimate an award's implicit service period based on our best estimate of the period over which an award's vesting conditions will be achieved. We reevaluate these estimates on a quarterly basis and will recognize any remaining unrecognized compensation as of the date of an estimate revision over the revised remaining implicit service period. In December 2007, we revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, our net loss and net loss per share for the year ended December 31, 2007 was \$2.6 million and \$0.07 per share, respectively, less than had the estimate remained unchanged.

For the years ended December 31, 2007 and 2006, we recognized total stock-based compensation expense under SFAS 123R of \$12.7 million and \$11.4 million, respectively. As of December 31, 2007, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to \$13.4 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of 2.5 years. As of December 31, 2007, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to \$5.2 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of approximately 1.7 years.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 provides a common definition of fair value and establishes a framework to make measurement of fair value in generally accepted accounting principles more consistent and comparable. SFAS 157 also requires expanded disclosures to provide information about the extent to which fair value is used to measure assets and liabilities, the methods and the assumptions used to measure fair value, and the effect of fair value measures on earnings. SFAS 157 will be effective for our 2008 fiscal year, although early adoption is permitted. We do not currently believe the adoption of SFAS 157 will have a material impact on results of operations, financial position or cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, or SFAS 159, which allows an entity to elect to record financial assets and liabilities at fair value upon their initial recognition on a contract-by-contract basis. Subsequent changes in fair value would be recognized in earnings as the changes occur. SFAS 159 also establishes additional disclosure requirements for these items stated at fair value. SFAS 159 is effective for our 2008 fiscal year, with early adoption permitted, provided that we also adopt SFAS 157. We do not currently believe the adoption of SFAS 159 will have a material impact on results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141 (R), *Business Combinations*, a replacement for SFAS No. 141, *Business Combinations*. The Statement retains the fundamental requirements of SFAS No. 141, but requires the recognition of all assets acquired and liabilities assumed in a business combination at their fair values as of the acquisition date. It also requires the recognition of assets acquired and liabilities assumed arising from contractual contingencies at their acquisition date fair values. Additionally, SFAS No. 141(R) supersedes FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, which required research and development assets acquired in a business combination that have no alternative future use to be measured at their fair values and expensed at the acquisition date. SFAS No. 141(R) now requires that purchased research and development be recognized as an intangible asset. We are required to adopt SFAS No. 141(R) prospectively for any acquisitions on or after January 1, 2009 and are currently evaluating the impact this new standard will have on our future results of operations and financial position.

In December 2007, the FASB issued EITF issued 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for us beginning on January 1, 2009. We do not currently believe

the adoption of EITF 07-1 will have a material impact on our results of operations, financial position or cash flows.

In July 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The task forces reached a consensus that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may not be applied to earlier periods. Early adoption of the provisions is not permitted. We do not currently believe the adoption of EITF 07-3 will have a material impact on the results of operations, financial position or cash flows.

In December 2007, the FASB issued FASB Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires that noncontrolling interests be reported as a separate component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the consolidated statement of operations, that changes in a parent's ownership interest be accounted for as equity transactions, and that, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary and the gain or loss on the deconsolidation of the subsidiary be measured at fair value. SFAS 160 will be applied prospectively, except for presentation and disclosure requirements which will be applied retrospectively, as of the beginning of the Company's fiscal year 2010. We do not currently have any noncontrolling interests, and therefore the adoption of SFAS 160 is not expected to have an impact on our financial position, results of operations or cash flows.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of U.S. money market and high-grade corporate securities, directly or through managed funds, with maturities of twenty-four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short effective maturities of debt instruments, interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at December 31, 2007 or 2006, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**Momenta Pharmaceuticals, Inc.
Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of Momenta Pharmaceuticals, Inc.

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

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

As discussed in Note 12 to the consolidated financial statements, effective January 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*. As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, using the modified prospective transition method.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Momenta Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts
March 6, 2008

Momenta Pharmaceuticals, Inc.
Consolidated Balance Sheets

	December 31,	
	2007	2006
	(In thousands, except per share amounts)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,038	\$ 22,351
Marketable securities	102,899	168,914
Accounts receivable	747	—
Unbilled collaboration revenue	9,037	4,727
Prepaid expenses and other current assets	1,984	2,069
Total current assets	147,705	198,061
Property and equipment, net of accumulated depreciation	15,296	13,603
Intangible assets, net	3,495	—
Restricted cash	1,778	4,685
Other assets	24	36
Total assets	\$ 168,298	\$ 216,385
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 9,132	\$ 4,311
Accrued expenses	5,973	5,786
Deferred revenue	2,180	123
Line of credit obligations	721	883
Capital lease obligations	1,696	941
Lease financing liability	640	596
Deferred rent	70	122
Other current liabilities	2,000	—
Total current liabilities	22,412	12,762
Deferred revenue, net of current portion	10,212	13,552
Line of credit obligations, net of current portion	17	738
Capital lease obligations, net of current portion	6,273	3,998
Lease financing liability, net of current portion	1,681	2,321
Deferred rent, net of current portion	163	423
Total liabilities	40,758	33,794
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, \$0.01 par value; 5,000 shares authorized at December 31, 2007 and 2006, 100 shares of Series A Junior Participating Preferred Stock, \$0.01 par value designated and no shares issued and outstanding	—	—
Common stock, \$0.0001 par value; 100,000 shares authorized at December 31, 2007 and 2006, 36,489 and 36,098 shares issued and outstanding at December 31, 2007 and 2006, respectively	4	4
Additional paid-in capital	321,604	308,061
Accumulated other comprehensive income	332	45
Accumulated deficit	(194,400)	(125,519)
Total stockholders' equity	127,540	182,591
Total liabilities and stockholders' equity	\$ 168,298	\$ 216,385

The accompanying notes are an integral part of these consolidated financial statements.

Momenta Pharmaceuticals, Inc.
Consolidated Statements of Operations

	Year Ended December 31,		
	2007	2006	2005
	(In thousands, except per share amounts)		
Collaboration revenue	\$ 21,561	\$ 15,999	\$ 13,011
Operating expenses:			
Research and development*	69,899	46,916	23,710
General and administrative*	28,219	28,466	14,059
Total operating expenses	98,118	75,382	37,769
Loss from operations	(76,557)	(59,383)	(24,758)
Other income (expense):			
Interest income	8,484	7,974	3,353
Interest expense	(808)	(504)	(257)
Net loss	\$(68,881)	\$(51,913)	\$(21,662)
Basic and diluted net loss per share	\$ (1.93)	\$ (1.62)	\$ (0.79)
Shares used in computing basic and diluted net loss per share	35,639	32,103	27,283
* Includes stock-based compensation as follows:			
Research and development	\$ 4,792	\$ 4,367	\$ 634
General and administrative	\$ 7,895	\$ 7,035	\$ 1,659

The accompanying notes are an integral part of these consolidated financial statements.

Momenta Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Due from Officer	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value						
Balances at December 31, 2004	25,409	\$3	\$112,510	\$(159)	\$(36)	\$(3,381)	\$ (51,944)	\$ 56,993
Issuance of common stock in follow-on public offering	4,827	—	122,327	—	—	—	—	122,327
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	229	—	248	—	—	—	—	248
Payment of officer obligation	—	—	—	—	36	—	—	36
Deferred stock compensation expense associated with stock options	—	—	213	—	—	(213)	—	—
Amortization of deferred stock compensation	—	—	—	—	—	1,401	—	1,401
Compensation expense associated with options issued to non-employees	—	—	783	—	—	—	—	783
Compensation expense associated with the modification of stock options	—	—	109	—	—	—	—	109
Unrealized loss on marketable securities	—	—	—	(80)	—	—	—	(80)
Net loss	—	—	—	—	—	—	(21,662)	(21,662)
Comprehensive loss	—	—	—	—	—	—	—	(21,742)
Balances at December 31, 2005	30,465	\$3	\$236,190	\$(239)	\$ —	\$(2,193)	\$ (73,606)	\$160,155
Issuance of common stock to Sandoz	4,709	1	61,383	—	—	—	—	61,384
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	379	—	1,279	—	—	—	—	1,279
Issuance of restricted stock	745	—	—	—	—	—	—	—
Cancellation of restricted stock	(200)	—	—	—	—	—	—	—
Reclassification of unearned compensation on non-vested share awards upon adoption of SFAS 123R	—	—	(2,193)	—	—	2,193	—	—
Stock-based compensation expense for employees	—	—	11,130	—	—	—	—	11,130
Stock-based compensation expense for non-employees	—	—	272	—	—	—	—	272
Unrealized gain on marketable securities	—	—	—	284	—	—	—	284
Net loss	—	—	—	—	—	—	(51,913)	(51,913)
Comprehensive loss	—	—	—	—	—	—	—	(51,629)
Balances at December 31, 2006	36,098	\$4	\$308,061	\$ 45	\$ —	\$ —	\$(125,519)	\$182,591
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	143	—	856	—	—	—	—	856
Issuance of restricted stock	248	—	—	—	—	—	—	—
Stock-based compensation expense for employees	—	—	12,682	—	—	—	—	12,682
Stock-based compensation expense for non-employees	—	—	5	—	—	—	—	5
Unrealized gain on marketable securities	—	—	—	287	—	—	—	287
Net loss	—	—	—	—	—	—	(68,881)	(68,881)
Comprehensive loss	—	—	—	—	—	—	—	(68,594)
Balances at December 31, 2007	36,489	\$4	\$321,604	\$ 332	\$ —	\$ —	\$(194,400)	\$127,540

The accompanying notes are an integral part of these consolidated financial statements

Momenta Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2007	2006	2005
	(In Thousands)		
Cash Flows from Operating activities:			
Net loss	\$ (68,881)	\$ (51,913)	\$ (21,662)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,308	1,947	967
Stock-based compensation expense	12,687	11,402	2,293
Noncash interest expense	—	—	10
Loss on disposal of assets	92	147	62
(Accretion of discount)/amortization of premium on investments	(5,907)	(1,702)	1,050
Charge for in-process research and development	737	—	—
Amortization of intangibles	268	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(747)	—	2,238
Unbilled collaboration revenue	(4,310)	(380)	(1,546)
Prepaid expenses and other current assets	85	730	(1,442)
Restricted cash	2,907	(2,907)	(293)
Other assets	12	(30)	—
Accounts payable	4,821	1,231	(409)
Accrued expenses	187	2,431	1,744
Deferred rent	(312)	429	116
Deferred revenue	(1,283)	13,405	(147)
Net cash used in operating activities	(56,336)	(25,210)	(17,019)
Cash Flows from Investing activities:			
Purchase of intangible assets	(2,500)	—	—
Purchases of marketable securities	(242,526)	(243,176)	(151,554)
Proceeds from maturities of marketable securities	314,735	206,612	62,003
Purchase of property and equipment	(8,817)	(9,780)	(3,726)
Net cash provided by (used in) investing activities	60,892	(46,344)	(93,277)
Cash Flows from Financing activities:			
Proceeds from public offering of common stock, net of issuance costs	—	—	122,327
Proceeds from issuance of common stock to Sandoz, net of issuance costs	—	61,384	—
Proceeds from issuance of common stock under stock plans	856	1,279	248
Proceeds from financing of leasehold improvements	—	3,199	—
Payments on financed leasehold improvements	(596)	(282)	—
Proceeds from line of credit	—	—	1,551
Principal payments on line of credit	(883)	(845)	(896)
Proceeds from capital lease obligations	4,199	3,735	1,242
Principal payments on capital lease obligations	(1,169)	(455)	—
Payment of officer obligation	—	—	36
Proceeds from assignment of sublease, net of recovery of rent expense	3,724	—	—
Net cash provided by financing activities	6,131	68,015	124,508
Increase (decrease) in cash and cash equivalents	10,687	(3,539)	14,212
Cash and cash equivalents, beginning of period	22,351	25,890	11,678
Cash and cash equivalents, end of period	\$ 33,038	\$ 22,351	\$ 25,890
Supplemental Cash Flow Information:			
Cash paid for interest	\$ 808	\$ 504	\$ 163
Non Cash Transactions:			
Acquisition of assets under capital lease	\$ —	\$ —	\$ 398
Accrued milestone payments to Parivid	\$ 2,000	\$ —	\$ —

The accompanying notes are an integral part of these consolidated financial statements.

Momenta Pharmaceuticals, Inc.
Notes to Consolidated Financial Statements December 31, 2007

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the “Company” or “Momenta”) was incorporated in the state of Delaware on May 17, 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs, applying its technology to the development of generic or follow-on versions of complex drug products as well as to the discovery and development of novel drugs. The Company presently derives all of its revenue from research collaborations with pharmaceutical companies.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The Company’s consolidated financial statements include the Company’s accounts and the accounts of the Company’s wholly-owned subsidiary, Momenta Pharmaceuticals Securities Corporation. All intercompany transactions have been eliminated.

Reclassifications

Certain prior year amounts in the reconciliation of federal statutory income tax provision to the Company’s actual provision have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash, Cash Equivalents, and Marketable Securities

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities and U.S. government obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions. All marketable securities, which primarily represent marketable debt securities, have been classified as “available-for-sale.” Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. Management determines the appropriate classification of its investments in marketable securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive income (loss), which is reported as a separate component of stockholders’ equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on marketable securities is included in interest income.

Credit Risks and Concentrations

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and marketable securities. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, which include cash equivalents and other accrued expenses, approximate their fair values due to their short maturities. The carrying amount of the Company's line of credit and capital lease obligations approximate their fair values due to their variable interest rates.

Unbilled Collaboration Revenue

Unbilled collaboration revenue represents amounts owed from one collaborative partner at December 31, 2007 and December 31, 2006. The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

Property and Equipment

Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets are charged to expense. Upon disposal, the related cost and accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leased assets meeting certain capital lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under capital lease arrangements are depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter.

Long-Lived Assets

The Company evaluates the recoverability of its property, equipment and intangible assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, which provides that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the undiscounted future cash flows of such assets or businesses. In addition, SFAS 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. No impairment charges have been required to be recognized through December 31, 2007.

Revenue Recognition

The Company recognizes revenue from research and development collaboration agreements in accordance with the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") No. 00-21, *Revenue Arrangements With Multiple Deliverables*, or EITF 00-21.

Under the terms of collaboration agreements entered into by the Company, the Company may receive non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is then allocated among the separate units based on either their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

Revenues from non-refundable, up-front license fees are recognized on a straight-line basis over the contracted or estimated period of performance, which is typically the development term. Research and development funding is recognized as earned over the period of effort.

Any milestone payments are recognized as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payment is deferred and recognized as revenue over the estimated remaining period of performance under the contract as the Company completes its performance obligations. Royalty and/or profit-share revenue, if any, is recognized based upon actual and estimated net sales of licensed products in licensed territories as provided by the licensee and in the period the sales occur. The Company has not recognized any milestone, royalty or profit-share revenue to date.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include wages, benefits, facility and other research-related overhead expenses, as well as license fees and contracted research and development activities.

Stock-Based Compensation Expense

As discussed more fully in Note 4, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R, effective January 1, 2006 under the modified prospective method of adoption. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, is being recognized in the Company's statements of operations in the periods after the date of adoption. Stock-based compensation expense primarily relates to stock options, restricted stock and stock issued under the Company's employee stock purchase plans.

Prior to January 1, 2006, the Company followed Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employee*, or APB 25, and related interpretations, in accounting for its stock-based compensation plan. Under APB 25, when the exercise price of the employee stock options equaled the market price of the underlying stock on the date of grant, no compensation expense was recognized. For stock options granted prior to January 1, 2006, the Company calculated stock-based compensation expense on a straight-line basis over the requisite service period. For restricted stock granted prior to January 1, 2006, the Company calculated stock-based compensation expense on a straight-line basis over the requisite service period based on the market value on the date of grant.

SFAS 123 and 123R require the presentation of pro forma information for periods prior to adoption as if the Company had accounted for all stock-based employee compensation expense under the fair value method of those statements. The Company accounted for forfeitures as they occurred.

The following table illustrates the effect on net loss and net loss per share as if the Company had applied the fair value recognition provisions to stock-based employee compensation expense:

	<u>2005</u>
	(In thousands, except per share data)
Net loss as reported	\$(21,662)
Add: Stock-based employee compensation expense included in reported net loss	1,510
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	<u>(3,119)</u>
Pro forma net loss	<u>\$(23,271)</u>
Basic and diluted net loss per share:	
As reported	<u>\$ (0.79)</u>
Pro forma net loss	<u>\$ (0.85)</u>

Unvested stock options held by consultants have been revalued using the Company’s estimate of fair value at each balance sheet date pursuant to EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18. Stock-based compensation expense is recorded in accordance with Financial Accounting Standards Board (“FASB”) Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*.

Income Taxes

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—An Interpretation of FASB Statement No. 109*, or FIN 48, the accounting for income tax positions by prescribing a minimum recognition threshold that a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on the derecognition of previously recognized deferred tax items, measurement, classification, interest and penalties, disclosure and transition. Under FIN 48, the Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained upon examination by the taxing authorities, based on the technical merits of the tax position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

Comprehensive Loss

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, or SFAS 130. SFAS 130 establishes rules for the reporting and display of comprehensive income (loss) and its components. Accumulated other comprehensive income as of December 31, 2007 and December 31, 2006 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the years ended December 31, 2007, 2006 and 2005 was \$68.6 million, \$51.6 million and \$21.7 million, respectively.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings per Share*, or SFAS 128. Under the provisions of SFAS 128, basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares consist of the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per common share is the same. The total number of shares excluded from the calculations of historical diluted net loss per share, due to their antidilutive effect, was 3,981,601, 3,273,386 and 1,783,611 for the years ended December 31, 2007, 2006 and 2005, respectively.

Segment Reporting

SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, requires companies to report selected information about operating segments, as well as enterprise-wide disclosures about products, services, geographical areas, and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the discovery, development and commercialization of drug products. All of the Company's revenue through December 31, 2007 has come from one collaborative partner.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. SFAS 157 provides a common definition of fair value and establishes a framework to make measurement of fair value in generally accepted accounting principles more consistent and comparable. SFAS 157 also requires expanded disclosures to provide information about the extent to which fair value is used to measure assets and liabilities, the methods and the assumptions used to measure fair value, and the effect of fair value measures on earnings. SFAS 157 will be effective for the Company's 2008 fiscal year, although early adoption is permitted. The Company does not currently believe the adoption of SFAS 157 will have a material impact on the results of operations, financial position or cash flows.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities, including an amendment of FASB Statement No. 115*, or SFAS 159, which allows an entity to elect to record financial assets and liabilities at fair value upon their initial recognition on a contract-by-contract basis. Subsequent changes in fair value would be recognized in earnings as the changes occur. SFAS 159 also establishes additional disclosure requirements for these items stated at fair value. SFAS 159 is effective for the Company's 2008 fiscal year, with early adoption permitted, provided that the Company also adopts SFAS 157. The Company does not currently believe the adoption of SFAS 159 will have a material impact on the results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, a replacement for SFAS No. 141, *Business Combinations*. The Statement retains the fundamental requirements of SFAS No. 141, but requires the recognition of all assets acquired and liabilities assumed in a business combination at their fair values as of the acquisition date. It also requires the recognition of assets acquired and liabilities assumed arising from contractual contingencies at their acquisition date fair values. Additionally, SFAS No. 141(R) supersedes FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, which required

research and development assets acquired in a business combination that have no alternative future use to be measured at their fair values and expensed at the acquisition date. Statement No. 141(R) now requires that purchased research and development be recognized as an intangible asset. The Company is required to adopt SFAS No. 141(R) prospectively for any acquisitions on or after January 1, 2009 and is currently evaluating the impact this new standard will have on the future results of operations and financial position.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products)*. EITF 07-1 will be effective for us beginning on January 1, 2009. The Company does not currently believe the adoption of EITF 07-1 will have a material impact on its results of operations, financial position or cash flows.

In July 2007, the FASB ratified EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. The task forces reached a consensus that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The consensus may not be applied to earlier periods. Early adoption of the provisions is not permitted. The Company does not currently believe that the adoption of EITF 07-3 it will have a material impact on the financial position or results of operations.

In December 2007, the FASB issued FASB Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires that noncontrolling interests be reported as a separate component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the consolidated statement of operations, that changes in a parent's ownership interest be accounted for as equity transactions, and that, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary and the gain or loss on the deconsolidation of the subsidiary be measured at fair value. SFAS 160 will be applied prospectively, except for presentation and disclosure requirements which will be applied retrospectively, as of the beginning of the Company's fiscal year 2010. The Company does not currently have noncontrolling interests, and therefore the adoption of SFAS 160 is not expected to have an impact on the Company's financial position, results of operations or cash flows.

3. Asset Purchase

In April, 2007, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Parivid, LLC ("Parivid"), a data integration and analysis services provider to the Company, and S. Raguram, the principal owner and Chief Technology Officer of Parivid, pursuant to which the Company acquired patent rights, software, know-how and other intangible assets, and assumed certain specified liabilities of Parivid related to the acquired assets, for \$2.5 million in cash paid at closing and up to \$11.0 million in additional payments, which, if certain milestones are achieved, will be paid in a combination of cash and/or stock.

The milestone payments include (i) potential cash payments of no more than \$2.0 million if certain milestones are achieved within two years from the date of the Purchase Agreement and (ii) the issuance of up to \$9.0 million of the Company's 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 the Company's common stock, the Company has granted Parivid certain registration rights under the Securities Act of 1933, as amended, with respect to such shares. The Company also entered into an employment agreement with S. Raguram.

As part of the acquisition of assets from Parivid, two previous collaboration agreements that had been in place with Parivid were terminated. S. Raguram is the brother of a member of the Company's Board of Directors, who received no consideration in connection with the execution of the Purchase Agreement.

The Company has recorded a total purchase price of \$4.5 million that includes \$2.5 million paid in cash at the closing and \$2.0 million in milestone payments, which are probable. The total purchase price was allocated to the assets acquired based on their estimated relative fair values at the date of acquisition. The fair values of the acquired assets were determined using a combination of the income approach and the comparative business valuation method. At the date of acquisition, the Company recorded an acquired in-process research and development charge of \$0.7 million, which is included in research and development expense in the consolidated statement of operations for the year ended December 31, 2007.

As of December 31, 2007, intangible assets, net of accumulated amortization, are as follows (in thousands):

	Estimated Life	December 31, 2007	
		Gross Carrying Amount	Accumulated Amortization
Core technology	12 years	\$3,593	\$(209)
Non-compete agreement	2 years	170	(59)
Total intangible assets		<u>\$3,763</u>	<u>\$(268)</u>

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. Amortization expense was \$0.3 million during year ended December 31, 2007.

The Company expects to incur amortization expense ranging from \$0.3 million to \$0.4 million per year for each of the next five years.

4. Stock-Based Compensation

SFAS 123R Compensation Expense

As discussed in Note 2, the Company adopted SFAS 123R effective January 1, 2006. SFAS 123R requires the recognition of the fair value of stock-based compensation in its statements of operations. Stock-based compensation expense primarily relates to stock options, restricted stock and stock issued under the Company's employee stock purchase plan. The Company recognizes stock-based compensation expense equal to the fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are recorded as compensation cost, based on the market value on the date of the grant, on a straight-line basis over the requisite service period. The Company issues new shares to satisfy stock option exercises, the issuance of restricted stock and stock issued under the Company's employee stock purchase plan.

Total compensation cost for all share-based payment arrangements including employee, director, consultant and advisor stock options, restricted stock and the Company's employee stock purchase plan for the years ended December 31, 2007, 2006 and 2005 was \$12.7 million, \$11.4 million and \$2.3 million, respectively.

In accordance with SFAS 123R, the fair value of each option award was estimated on the date of grant using the Black-Scholes- Merton option-pricing model that uses the assumptions noted in the table below. In the fourth quarter of 2007, the Company considered implied volatilities of its own currently traded options to provide an estimate of volatility based upon current trading activity. After considering other factors such as its stage of development and the length of time the Company has been public, the Company concluded that a blended volatility rate based upon the most recent three-and-one-half year period of its own historical performance, as well as the implied volatilities of its own currently traded options, better reflects the expected volatility of its stock going forward. The Company uses a blend of its own historical data and peer data to estimate option exercise and employee termination behavior, adjusted for known trends, to arrive at the estimated expected life of an option. For purposes of identifying peer entities, the Company considered characteristics such as industry, stage of life cycle and financial leverage. The Company updates these assumptions on a quarterly basis to reflect recent historical data. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

The following table summarizes the weighted average assumptions the Company used in its fair value calculations at the date of grant:

	Stock Options			Stock Purchase Plan		
	2007	2006	2005	2007	2006	2005
Expected volatility	76%	72%	80%	74%	68%	80%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6	6	6	0.5	0.5	1.0
Risk-free interest rate	4.7%	4.8%	4.0%	4.8%	5.2%	4%

SFAS 123R requires the application of an estimated forfeiture rate to current period expense to recognize stock-based compensation expense only for those awards expected to vest. The Company estimates forfeitures based upon historical data, adjusted for known trends, and will adjust its estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods.

2004 Stock Incentive Plan

The Company's 2004 Stock Incentive Plan, as amended (the "Incentive Plan"), allows for the granting of incentive and nonstatutory stock options, restricted stock awards, stock appreciation rights and other stock-based awards to employees, officers, directors, consultants and advisors. At December 31, 2007, the Company was authorized to issue up to 5,750,838 shares of common stock with annual increases (to be added on the first day of the Company's fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) equal to the lowest of (i) 1,974,393 shares, (ii) 5% of the then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. Effective January 1, 2008, the Company's Board of Directors increased the number of authorized shares by 1,823,491.

Incentive stock options are granted only to employees of the Company. Incentive stock options granted to employees who own more than 10% of the total combined voting power of all classes of stock will be granted at no less than 110% of the fair market value of the Company's common stock on

the date of grant. Incentive stock options generally vest ratably over four years. Non-statutory stock options may be granted to employees, officers, directors, consultants and advisors. Non-statutory stock options granted have varying vesting schedules. Incentive and non-statutory stock options generally expire ten years after the date of grant.

Under the 2004 Employee Stock Purchase Plan, participating employees purchase common stock through payroll deductions. An employee may withdraw from an offering before the purchase date and obtain a refund of the amounts withheld through payroll deductions. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on the first business day and the last business day of the relevant plan period. The plan periods begin on February 1 and August 1 of each year. The Company issued 42,689 shares of common stock to employees under the plan during the year ended December 31, 2007. During the years ended December 31, 2007 and 2006, the Company recorded stock-based compensation expense of \$0.2 million. The Company did not record stock-based compensation expense during the year ended December 31, 2005. At December 31, 2007, subscriptions were outstanding for an estimated 21,430 shares at approximately \$8.35 per share. The weighted average grant date fair value of the offerings during 2007, 2006 and 2005 was \$4.88, \$6.27 and \$14.95, respectively.

Shares of common stock reserved for future issuance at December 31, 2007 are as follows (in thousands):

Shares available for grant under stock option plans	2,076
Shares available for exercise of stock options	1,739
Shares available for grant under employee stock purchase plan	435
Total	<u>4,250</u>

The following table presents stock option activity of the Company's stock plan for the year ended December 31, 2007:

	Number of Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2007	2,730	\$12.38		
Granted	831	11.47		
Exercised	(101)	4.09		
Forfeited	(189)	15.26		
Expired	<u>(77)</u>	21.07		
Outstanding at December 31, 2007	<u>3,194</u>	<u>\$12.02</u>	<u>7.67</u>	<u>\$3,097</u>
Exercisable at December 31, 2007	<u>1,739</u>	<u>\$10.28</u>	<u>6.95</u>	<u>\$2,927</u>
Vested or expected to vest at December 31, 2007 . .	<u>3,016</u>	<u>\$11.89</u>	<u>7.61</u>	<u>\$3,077</u>

The weighted average grant date fair value of options granted during 2007, 2006 and 2005 was \$7.90, \$11.50 and \$10.54 per option, respectively. The total intrinsic value of options exercised during 2007, 2006 and 2005 was \$1.0 million, \$4.9 million and \$3.5 million, respectively. At December 31, 2007, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to \$13.4 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.5 years. The total fair value of shares vested during 2007, 2006 and 2005 was \$7.3 million, \$7.0 million and \$1.5 million, respectively.

Cash received from option exercises for 2007, 2006 and 2005 was \$0.4 million, \$1.0 million and \$0.2 million, respectively. Due to the Company's net loss position, the tax benefit related to the tax deductions from option exercises was not realized in any of the periods presented.

Restricted Stock Awards

A summary of the status of nonvested shares of restricted stock as of December 31, 2007, and the changes during the year then ended, is presented below:

	<u>Number of Shares</u>	<u>Weighted-Average Grant Date Fair Value</u>
	(in thousands)	
Nonvested at January 1, 2007	545	\$22.07
Granted	248	14.39
Vested	(4)	16.94
Forfeited	—	—
Nonvested at December 31, 2007	<u>789</u>	<u>\$19.68</u>

Awards of restricted stock have been granted to certain employees, officers and directors and generally fully vest four years from the grant date, although certain awards have performance conditions such as the commercial launch of M-Enoxaparin in the U.S.

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2007 are summarized below:

<u>Vesting Schedule</u>	<u>Nonvested Shares</u>
	(in thousands)
Time-based	144
Performance-based	<u>645</u>
Nonvested at December 31, 2007	<u>789</u>

In December 2007, the Company revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, the Company's net loss and net loss per share was \$2.6 million and \$0.07 per share, respectively, less than had the estimate remained unchanged for the year ended December 31, 2007. The total fair value of shares of restricted stock vested during 2007, 2006 and 2005 was \$64,000, \$0 and \$0.4 million, respectively. The Company recorded stock-based compensation expense of \$5.4 million, \$5.0 million and \$0.4 million related to outstanding restricted stock awards during 2007, 2006 and 2005, respectively. As of December 31, 2007, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to \$5.2 million, including estimated forfeitures, which is expected to be recognized over the weighted average remaining requisite service period of 1.7 years.

Stock Options Granted to Non-Employee Consultants

As of December 31, 2007, the Company had granted stock options to purchase 154,162 shares of common stock to consultants. These stock options were granted in exchange for consulting services to be rendered and vest over periods of up to four years. During 2007, 7,812 stock options were cancelled due to the termination of certain consulting agreements. As of December 31, 2007, all outstanding options are fully vested. The Company recorded a stock-based compensation expense, using the accelerated method under FIN 28, of \$5,000, \$0.3 million and \$0.8 million during 2007, 2006 and 2005, respectively. The fair value of the options is estimated on the date of grant and subsequently revalued

at each reporting period over their vesting period using the Black-Scholes-Merton option pricing model and assumptions including an expected life ranging from three to ten years, volatility of approximately 72% to 76% and risk free interest rates ranging from 4.2% to 5.0%.

5. Collaborations and License Agreements

2003 Sandoz Collaboration

In November 2003, the Company entered into a collaboration and license agreement (the “2003 Sandoz Collaboration”) with Sandoz N.V. and Sandoz Inc. to jointly develop and commercialize M-Enoxaparin, a generic version of Lovenox[®], a low molecular weight heparin. Sandoz N.V. later assigned its rights and obligations under the 2003 Sandoz Collaboration to Sandoz AG. Sandoz AG and Sandoz Inc. are collectively referred to as “Sandoz.” Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell M-Enoxaparin in the United States. The Company agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make M-Enoxaparin, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz’ name to be filed with the Food & Drug Administration, or FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is responsible for overseeing development, legal and commercial activities and approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product.

As compensation under the 2003 Sandoz Collaboration, the Company received a \$588,000 non-refundable up-front payment as reimbursement for certain specified vendor costs that were incurred prior to the effective date of the 2003 Sandoz Collaboration. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents (“FTEs”) performing development and related services. In addition, Sandoz will, in the event there are no third party competitors marketing a Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration) share profits with the Company. Alternatively, in certain circumstances, if there are third party competitors marketing a Lovenox-Equivalent Product, Sandoz will pay royalties to the Company on net sales of injectable M-Enoxaparin. If certain milestones are achieved with respect to injectable M-Enoxaparin under certain circumstances, Sandoz will make payments to the Company, which would reach \$55 million if all such milestones are achieved. A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, will be offset against profit-sharing amounts, royalties and milestone payments. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments. The Company has not earned any milestones, royalties or profit-share to date.

The Company recognizes the \$588,000 non-refundable up-front payment as revenue on a straight line basis over the estimated M-Enoxaparin development period. In December 2007, the Company revised its estimate of the development period from 4 years to approximately 5 years due to a change in the projected timing of regulatory activities. The change in estimate is not material to the Company’s net loss or net loss per share for the year ended December 31, 2007. The Company recognized revenue relating to this up-front payment of approximately \$0.1 million for the year ended December 31, 2007.

The Company recognizes revenue from FTE services and revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenues from external development costs are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third party vendors for such development and related services, except with respect to any amounts due

Sandoz for manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense pursuant to the provisions of EITF No. 02-16, *Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor*. The Company purchased \$3.3 million and \$1.5 million of manufacturing raw material in 2006 and 2005, respectively. There were no such manufacturing raw material purchases during 2007.

2006 Sandoz Collaboration

In July 2006, the Company entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, each with Novartis Pharma AG, and a Memorandum of Understanding (the "MOU") with Sandoz AG, an affiliate of Novartis Pharma AG. On June 13, 2007, the Company and Sandoz AG executed a definitive collaboration and license agreement (the "Definitive Agreement"), which superseded the MOU. Together, this series of agreements is referred to as the "2006 Sandoz Collaboration."

Pursuant to the terms of the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of \$15.93 (the closing price of the Company's common stock on the NASDAQ Global Market was \$13.05 on the date of the Stock Purchase Agreement) for an aggregate purchase price of \$75.0 million, resulting in a paid premium of \$13.6 million. The Company recognizes revenue from the \$13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. The Company recognized revenue relating to this paid premium of approximately \$1.2 million for the year ended December 31, 2007. Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the M-Enoxaparin geographic markets covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. The Company has agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market the products.

The term of the Definitive Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the Definitive Agreement. Sandoz AG has agreed to indemnify the Company for various claims, and a certain portion of such costs may be offset against certain future payments received by the Company.

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG, or partly in proportion where development costs are shared between the Company and Sandoz AG. The Company also is paid for FTEs performing development services where development activities are funded solely by Sandoz AG, or partly by proportion where development costs are shared between the Company and Sandoz AG. The parties will share profits in varying proportions, depending on the product. The Company is eligible to receive up to \$188.0 million in milestone payments if all milestones are achieved for the four product candidates. None of these payments, once received, are refundable and there are no general rights of return in the arrangement.

The Company recognizes revenue from FTE services and revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third party vendors for such development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis.

Massachusetts Institute of Technology

The Company has two patent license agreements with the Massachusetts Institute of Technology (“M.I.T.”) that grant the Company various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars and certain heparins, heparinases and other enzymes and synthesis methods. Subject to typical retained rights of M.I.T. and the United States government, the Company was granted exclusive rights under certain of these patents and applications in certain fields.

In exchange for these rights, the Company paid M.I.T. a license issue fee, and pays annual license maintenance fees. The Company, upon commercialization, is also required to pay M.I.T. royalties on products and services covered by the licenses and sold by the Company or its affiliates or sublicensees, a percentage of certain other income received by the Company from corporate partners and sublicensees, and certain patent prosecution and maintenance costs. M.I.T. and certain contributing individuals were also issued shares of the Company’s common stock. The Company recorded license fee expense of \$82,500, \$487,500 and \$82,500 related to these agreements in the years ended December 31, 2007, 2006 and 2005, respectively.

The Company must meet certain diligence requirements in order to maintain its licenses under the two agreements. Under the agreements, the Company must expend at least \$1.0 to \$1.2 million per year commencing in 2005 towards the research, development and commercialization of products and processes covered by the agreements. In addition, the Company is obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter, ranging from \$0.5 million to \$5.0 million annually. If the Company fails to meet its diligence obligations, M.I.T. may, as its sole remedy, convert the exclusive licenses granted to the Company under the amended and restated license agreement to non-exclusive licenses. Under the license agreement covering sequencing machines, M.I.T. has the right to treat the Company’s failure to fulfill its diligence obligations as a material breach of the license agreement.

If, due to the Company’s failure to meet diligence obligations, M.I.T. converts certain of the Company’s exclusive licenses to non-exclusive, or if M.I.T. terminates one of the agreements, M.I.T. will honor the exclusive nature of the sublicense the Company granted to Sandoz so long as Sandoz both continues to fulfill its obligations to the Company under the 2003 Sandoz Collaboration, 2006 Sandoz Collaboration and license agreement and agrees to assume the Company’s rights and obligations to M.I.T.

6. Cash, Cash Equivalents, and Marketable Securities

The following is a summary of cash, cash equivalents, and marketable securities as of December 31, 2007 and 2006 (in thousands):

<u>December 31, 2007</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash and money market funds	\$ 24,070	\$ —	\$ —	\$ 24,070
Corporate debt securities due in one year or less	111,535	335	(3)	111,867
Total	<u>\$135,605</u>	<u>\$335</u>	<u>\$ (3)</u>	<u>\$135,937</u>
Reported as:				
Cash and cash equivalents	\$ 33,025	\$ 13	\$ —	\$ 33,038
Marketable securities	102,580	322	(3)	102,899
Total	<u>\$135,605</u>	<u>\$335</u>	<u>\$ (3)</u>	<u>\$135,937</u>
<u>December 31, 2006</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash and money market funds	\$ 19,444	\$—	\$ —	\$ 19,444
Corporate debt securities due in one year or less	171,776	58	(13)	171,821
Total	<u>\$191,220</u>	<u>\$58</u>	<u>\$(13)</u>	<u>\$191,265</u>
Reported as:				
Cash and cash equivalents	\$ 22,351	\$—	\$ —	\$ 22,351
Marketable securities	168,869	58	(13)	168,914
Total	<u>\$191,220</u>	<u>\$58</u>	<u>\$(13)</u>	<u>\$191,265</u>

The following table summarizes the aggregate fair value of corporate debt securities in an unrealized loss position for less than one year at December 31, 2007 and 2006. There are no unrealized loss positions for any corporate debt securities due in greater than one year. The Company reviews its investments for other than temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying value is not recoverable within a reasonable period of time. At December 31, 2007 and 2006, there were three and four marketable securities in an unrealized loss position, respectively. Investments in an unrealized loss position at December 31, 2007 and 2006 were caused by fluctuations in interest rates. The Company reviewed its investments with unrealized losses and has concluded that no other-than-temporary impairment existed at December 31, 2007 and 2006 as the Company has the ability and intent to hold these investments to maturity. The Company had no realized gains or losses during the years ended December 31, 2007, 2006 or 2005.

(in thousands)	<u>2007</u>		<u>2006</u>	
	<u>Aggregate Fair Value</u>	<u>Unrealized Losses</u>	<u>Aggregate Fair Value</u>	<u>Unrealized Losses</u>
Corporate debt securities due in one year or less	<u>\$4,508</u>	<u>\$(3)</u>	<u>\$18,676</u>	<u>\$(13)</u>

7. Property and Equipment

At December 31, 2007 and 2006, property and equipment, net consists of the following (in thousands):

	<u>2007</u>	<u>2006</u>	<u>Depreciable Lives</u>
Computer equipment	\$ 250	\$ 171	3 years
Software	2,223	935	3 years
Office furniture and equipment	877	920	5 to 6 years
Laboratory equipment	3,722	4,991	7 years
Leasehold improvements	4,384	4,022	Shorter of asset life or lease term
Equipment purchased under capital lease obligations	10,061	5,570	3 to 7 years
Less: accumulated depreciation	<u>(6,221)</u>	<u>(3,006)</u>	
	<u>\$15,296</u>	<u>\$13,603</u>	

Depreciation and amortization expense, including amortization of assets recorded under capital leases, amounted to \$3.3 million, \$1.9 million and \$1.0 million for the years ended December 31, 2007, 2006 and 2005.

8. Restricted Cash

In September 2004, \$1.5 million of the Company's cash was designated as collateral for a letter of credit related to the lease of office and laboratory space. This balance will remain restricted during the 80-month lease term and the Company will continue to earn interest on the balance. In December 2005, this balance was increased to \$1.8 million due to an increase in leased space.

In October 2006, an additional \$2.9 million of the Company's cash was designated as collateral for a letter of credit related to the lease of additional office and laboratory space. In July of 2007, as a result of an evaluation of its space needs the Company determined the additional office and laboratory space leased, but not yet occupied, was in excess of the Company's present requirements. In October 2007, the Company cancelled the letter of credit associated with the additional office and laboratory space, in connection with the assumption of the related lease agreement by a third party as discussed in Note 14, and reclassified \$2.9 million from restricted cash to cash and cash equivalents.

9. Accrued Expenses

At December 31, 2007 and 2006, accrued expenses consisted of the following (in thousands):

	<u>2007</u>	<u>2006</u>
Accrued compensation	\$2,923	\$2,661
Accrued contracted research costs	2,205	2,152
Accrued professional fees	548	680
Other	297	293
	<u>\$5,973</u>	<u>\$5,786</u>

10. Preferred Stock

Shareholders' Rights Agreement

Effective November 7, 2005, the Board of Directors of the Company declared a dividend of one right (collectively, the "Rights") to buy one one-thousandth of a share of newly designated Series A

Junior Participating Preferred Stock (“Series A Junior Preferred Stock”) for each outstanding share of the Company’s common stock to stockholders of record at the close of business on November 18, 2005. Initially, the Rights are not exercisable and will be attached to all certificates representing outstanding shares of common stock, and no separate Rights Certificates will be distributed. The Rights will expire at the close of business on November 6, 2008 unless earlier redeemed or exchanged. Until a right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including the right to vote or to receive dividends. The rights are not immediately exercisable. Subject to the terms and conditions of the Rights Agreement entered into by the Company with American Stock Transfer & Trust Company, as Rights Agent (the “Rights Agreement”), the Rights will become exercisable upon the earlier of (1) 10 business days following the later of (a) the first date of a public announcement that a person or group (an “Acquiring Person”) acquires, or obtained the right to acquire, beneficial ownership of 20 percent or more of the outstanding shares of common stock of the Company or (b) the first date on which an executive officer of the Company has actual knowledge that an Acquiring Person has become such or (2) 10 business days following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning more than 20 percent of the outstanding shares of common stock of the Company.

Each right entitles the holder to purchase one one-thousandth of a share of Series A Junior Preferred Stock at an initial purchase price of \$125.00 in cash, subject to adjustment. In the event that any person or group becomes an Acquiring Person, unless the event causing the 20% threshold to be crossed is an offer permitted pursuant to the Rights Agreement, each Right not owned by the Acquiring Person will entitle its holder to receive, upon exercise, that number of shares of common stock of the Company (or in certain circumstances, cash, property or other securities of the Company), which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of such common stock at the date of the occurrence of the event. In the event that, at any time after any person or group becomes an Acquiring Person, (i) the Company is consolidated with, or merged with and into, another entity and the Company is not the surviving entity of such consolidation or merger (other than a consolidation or merger which follows a Permitted Offer) or if the Company is the surviving entity, but shares of its outstanding Common Stock are changed or exchanged for stock or securities (of any other person) or cash or any other property, or (ii) more than 50% of the Company’s assets or earning power is sold or transferred, each holder of a Right (except Rights which previously have been voided as set forth in the Rights Agreement) shall thereafter have the right to receive, upon exercise, that number of shares of common stock of the acquiring company which equals the exercise price of the Right divided by 50% of the current market price of such common stock at the date of the occurrence of the event.

11. Common Stock

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

In July 2005, the Company raised \$122.3 million in a follow-on public offering, net of expenses, from the sale and issuance of 4,827,300 shares of common stock. The price to the public was \$27.02 per share.

In connection with the 2006 Sandoz Collaboration, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG for an aggregate purchase price of \$75.0 million.

12. Income Taxes

On January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—An Interpretation of FASB Statement No. 109*, or FIN 48.

The adoption of FIN 48 did not result in any adjustments to the Company's financial statements. Certain amounts have been reclassified in the deferred tax disclosures in order to comply with FIN 48.

As of January 1, 2007, the Company recorded a reduction in its deferred tax asset valuation allowance of approximately \$3.1 million for unrecognized tax benefits related to research and development tax credit and net operating losses. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance, January 1, 2007	\$3,318
Additions for tax positions related to 2007	1,107
Additions for tax positions related to pre 2007	—
Reductions for tax positions related to pre 2007	—
Balance, December 31, 2007	<u>\$4,425</u>

Of the unrecognized tax benefit of approximately \$4.4 million at December 31, 2007, the amount that would impact the Company's effective tax rate, if recognized, is approximately \$4.1 million. The difference between the total amount of the unrecognized tax benefits and the amount that would affect the effective tax rate consists of the federal tax benefit of research and development credits and net operating losses and the federal tax benefit of state research and development credits.

The Company recognizes both accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company did not recognize any interest and penalties in the year ended December 31, 2007, or since the adoption of FIN 48.

At December 31, 2007, the Company had federal and state net operating loss ("NOL") carryforwards of \$127.3 million and \$139.6 million available, respectively, to reduce future taxable income and which will expire at various dates through 2027. Of this amount, approximately \$4.3 million of federal and state net operating loss carryforwards relate to stock option deductions and the related tax benefit will be recognized in equity when realized. At December 31, 2007, federal and state research and development and other credit carryforwards were \$2.9 million and \$2.1 million, respectively, available to reduce future tax liabilities, and, which will expire at various dates beginning in 2016 through 2027.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2007	2006
Deferred tax assets:		
Federal and state net operating losses	\$ 50,302	\$ 29,277
Research credits	4,341	4,040
Deferred compensation	7,881	480
Deferred revenue	4,990	5,507
Accrued expenses	150	116
Intangibles	360	—
Capital leases	4,144	3,164
Total deferred tax assets	<u>72,168</u>	<u>42,584</u>
Deferred tax liabilities:		
Depreciation	(4,856)	(3,702)
Unrealized gain on marketable securities	(116)	(16)
Total deferred tax liabilities	<u>(4,972)</u>	<u>(3,718)</u>
Valuation allowance	<u>(67,196)</u>	<u>(38,866)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$28.3 million for the year ended December 31, 2007, primarily as a result of the current period loss.

A reconciliation of federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2007, 2006 and 2005 is as follows:

	2007	2006	2005
Benefit at federal statutory tax rate	\$(23,381)	\$(17,651)	\$(7,365)
Change in valuation allowance	23,573	15,318	7,597
Stock-based compensation	810	3,669	470
Tax credits	(1,021)	(1,354)	(713)
Other	19	18	11
Income tax provision	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

13. Line of Credit

In December 2004, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank (the "Bank"). Under the terms of the Loan Agreement, the Company was eligible to borrow up to an aggregate of \$3.0 million solely for reimbursement of purchases of Eligible Equipment, as defined under the Loan Agreement. As of December 31, 2005, the Company had drawn \$3.0 million against the Loan Agreement. The Company was not obligated to draw down any amounts under the Loan Agreement and any borrowings bear interest at the per annum rate of the U.S. Treasury note yield to maturity for a term equal to forty-two months plus 5%, which rate was fixed on the funding date for each advance under the Loan Agreement. Advances under the Loan Agreement are to be repaid over a forty-two month period commencing on the applicable funding date. To secure the payment and performance in full of the Company's obligations under the

Loan Agreement, the Company granted to the Bank a continuing security interest in the Collateral, as such term is defined under the Loan Agreement and which essentially includes all Eligible Equipment and records relating thereto. As of December 31, 2007, the Company had approximately \$0.7 million in borrowings outstanding under the Loan Agreement subject to interest rates ranging from 8.46% to 9.18%.

The following schedule sets forth the principal payments due as of December 31, 2007 (in thousands):

2008	\$721
2009	<u>17</u>
Total	<u>\$738</u>

14. Commitments and Contingencies

Capital and Operating Leases

In December 2005, the Company entered into a Master Lease Agreement (the “Agreement”) with General Electric Capital Corporation (“GECC”). Under the Agreement, the Company may lease office, laboratory, computer and other equipment from GECC by executing specified equipment schedules with GECC. Each equipment schedule will specify the lease term with respect to the underlying leased equipment. As of December 31, 2007, the Company had drawn \$9.6 million against the Agreement. Borrowings under the agreement are payable over a 54-month period at effective annual interest rates of 7.51% to 9.39%. In accordance with the Agreement, should the effective corporate income tax rate for calendar-year taxpayers increase above 35%, GECC will have the right to increase rent payments by requiring payment of a single additional sum, calculated in accordance with the Agreement. The Agreement also provides the Company an early purchase option after 48 months at a predetermined fair market value, which the Company intends to exercise. As a result, the Agreement is considered a capital lease for accounting purposes and the equipment is included in property and equipment. Under the Agreement, if any material adverse change in the Company or its business occurs, as solely determined by GECC, the total unpaid principal would become immediately due and payable. There have been no events of default under this agreement. As of December 31, 2007, the Company had approximately \$8.0 million in outstanding borrowings under the agreement.

The Company leases office space and equipment under various operating lease agreements. Rent expense for office space under operating leases amounted to \$4.9 million, \$5.4 million and \$2.7 million for the years ended December 31, 2007, 2006 and 2005, respectively.

In September 2004, the Company entered into an agreement to lease 53,323 square feet of office and laboratory space located at 675 West Kendall Street, Cambridge, Massachusetts, for a term of 80 months (the “West Kendall Sublease”). The Company has an option to extend the West Kendall Sublease for one additional term of 48 months, ending April 2015, or on such other earlier date as provided in accordance with the West Kendall Sublease. In November 2005, the Company amended the West Kendall Sublease to lease an additional 25,131 square feet in its current premises through April 2011. Under the lease amendment, the landlord agreed to finance the leasehold improvements. In accordance with FASB Staff Position (FSP) 13-1, *Accounting for Rental Costs Incurred during a Construction Period*, the Company commenced expensing the applicable rent on a straight line basis beginning with the commencement of the construction period. The construction period was completed in June 2006. In accordance with EITF 97-10, *The Effect of Lessee Involvement in Asset Construction*, the Company was the owner of the leasehold assets during the construction period, and as of December 31, 2007, the Company has recorded \$3.2 million in leasehold improvements offset by \$2.3 million as a related lease financing liability.

In October 2006, the Company entered into an agreement to lease approximately 22,300 square feet of office and research space located in Cambridge, Massachusetts (the “Third Street Sublease”). In July of 2007, as a result of an evaluation of its space needs the Company determined that the office and laboratory space leased, but not yet occupied, under the Third Street Sublease was in excess of the Company’s present requirements. Accordingly, in October 2007, the Company executed an agreement pursuant to which a third party agreed to assume the Company’s rights and obligations under the Third Street Sublease. Under the agreement the third party paid the Company approximately \$4.4 million to offset certain rent payments and fees paid by the Company to architects, contractors, brokers and other vendors engaged to build out the space. The effect of this transaction was a reduction in the Company’s property and equipment of approximately \$3.7 million and a recovery of operating expenses of approximately \$0.7 million. In addition, upon the cancellation of the letter of credit associated with the Third Street Sublease, \$2.9 million was reclassified from restricted cash to cash and cash equivalents.

Future minimum capital and total operating lease commitments as of December 31, 2007 are as follows (in thousands):

	<u>Operating Lease</u>	<u>Capital Lease</u>
2008	\$ 3,578	\$ 2,318
2009	3,567	2,671
2010	3,556	2,626
2011	<u>1,185</u>	<u>1,817</u>
Total future minimum lease payments	<u>\$11,886</u>	9,432
Less—Amounts representing interest		<u>(1,463)</u>
Capital lease obligation at December 31, 2007		7,969
Less—Current maturities		<u>(1,696)</u>
Capital lease obligation, net of current maturities		<u>\$ 6,273</u>

License Agreements

In connection with license arrangements with the research universities discussed in Note 5, the Company has certain annual fixed obligations to pay these institutions fees for the technology licensed. At December 31, 2007, financial obligations under these agreements for 2008 and 2009 amounted to \$0.1 million and \$0.2 million, respectively. After 2010, the annual obligations, which extend indefinitely, are approximately \$0.2 million per year. The Company may terminate the agreements at any time without further annual obligations. Annual payments may be applied towards royalties payable to the licensors for that year for product sales, sublicensing of the patent rights or joint development revenue.

Legal Contingencies

Companies that seek to market a generic version of a branded product can be sued for infringing patents that purportedly cover the branded product and/or methods of using the product if the proposed marketing is to occur before the branded product’s patents expire. The Company is not currently engaged in any actual or threatened material litigation; however, in August 2006, Sanofi-Aventis brought a patent infringement suit against Sandoz in connection with regulatory filings seeking approval to market M-Enoxaparin in the U.S. This case has been stayed through March 2008, pending the outcome in a similar lawsuit between Sanofi-Aventis and third parties unrelated to the Company. The Company believes that its product development plans will likely cause patent infringement litigation in the future. The accompanying consolidated financial statements do not include any provision for such potential litigation.

15. 401(k) Plan

The Company has a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company has discretion to make contributions to the plan. In March 2005, the Company's Board of Directors approved a match of 50% of the first 6% contributed by employees, effective for the 2004 plan year and thereafter. The Company recorded \$0.4 million, \$0.2 million and \$0.2 million of such match expense in the years ended December 31, 2007, 2006 and 2005, respectively.

16. Related Party Transactions

The Company purchased \$3.3 million and \$1.5 million of heparin in 2006 and 2005, respectively, from Sandoz GmbH, which in turn was reimbursed under the Company's collaboration agreement with Sandoz N.V. and Sandoz, Inc. The Company did not purchase any heparin from Sandoz GmbH in 2007. The Company did not have any material outstanding payables to Sandoz at December 31, 2007 and 2006.

Parivid, LLC, a company that provided data integration and analysis services to the Company, was considered to be a related party as a co-founder and member of the Company's Board of Directors is the brother of the former chief technology officer of Parivid. The Company recorded \$0.2 million, \$1.0 million and \$0.7 million as research and development expense related to work performed by Parivid in the years ended December 31, 2007, 2006 and 2005, respectively. As described in Note 3, the Company entered into a Purchase Agreement with Parivid and has recorded a total purchase price of \$4.5 million that includes \$2.5 million paid in cash at the closing and \$2.0 million in milestone payments which are probable and accrued at December 31, 2007.

17. Selected Quarterly Financial Data (Unaudited) (in thousands, except per share data)

	Quarter Ended			
	March 31	June 30	September 30	December 31
2007				
Collaboration revenues	\$ 2,242	\$ 4,175	\$ 5,145	\$ 9,999
Net loss	(16,963)	(18,759)	(18,868)	(14,291)
Basic and diluted net loss per common share	\$ (0.48)	\$ (0.53)	\$ (0.53)	\$ (0.40)
Shares used in computing basic and diluted net loss per share	35,584	35,613	35,664	35,695
2006				
Collaboration revenues	\$ 2,506	\$ 5,397	\$ 4,058	\$ 4,038
Net loss	(11,331)	(12,584)	(12,015)	(15,983)
Basic and diluted net loss per common share	\$ (0.37)	\$ (0.41)	\$ (0.37)	\$ (0.45)
Shares used in computing basic and diluted net loss per share	30,444	30,532	32,334	35,518

Per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts may not add to the annual amount because of differences in the weighted average common shares outstanding during each period principally due to the effect of the Company's issuing shares of its common stock during the year.

Diluted and basic net loss per common share is identical since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

1. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2007, our disclosure controls and procedures were effective at the reasonable assurance level.

2. Internal Control Over Financial Reporting

(a) Management’s Annual Report on Internal Control Over Financial Reporting

The management of Momenta is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company’s principal executive and principal financial officers and effected by the company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the

risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Momenta's management, including the supervision and participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework."

Based on our assessment, management has concluded that, as of December 31, 2007, the Company's internal control over financial reporting is effective based on those criteria.

The Company's independent registered public accounting firm has issued its report on the effectiveness of the Company's internal control over financial reporting. This report appears below.

(b) Attestation Report of the Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Momenta Pharmaceuticals, Inc.

We have audited Momenta Pharmaceuticals, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Momenta Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weaknesses exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Momenta Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2007 of Momenta Pharmaceuticals, Inc. and our report dated March 6, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 6, 2008

(c) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information relating to our directors, nominees for election as directors and executive officers under the headings “Election of Directors”, “Corporate Governance—Our Executive Officers”, “Corporate Governance—Section 16(a) Beneficial Ownership Reporting Compliance” and “Corporate Governance—Board Committees” in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We make available our code of business conduct and ethics free of charge through our website which is located at www.momentapharma.com. We intend to disclose any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the NASDAQ Global Market by filing such amendment or waiver with the Securities and Exchange Commission and by posting it on our website.

Item 11. EXECUTIVE COMPENSATION

The discussion under the headings “Executive Compensation”, “Compensation of Directors”, “Compensation Committee Report” and “Compensation Committee Interlocks and Insider Participation” in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. The information specified in Item 407(e)(5) of Regulation S-K and set forth in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is not incorporated by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The discussion under the heading “Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters” in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The discussion under the headings “Certain Relationships and Related Transactions” and “Corporate Governance—Board Determination of Independence” in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The discussion under the heading “Ratification of Selection of Independent Registered Public Accounting Firm” in our definitive proxy statement for the 2008 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements:

	<u>Page number in this report</u>
Report of Independent Registered Public Accounting Firm	62
Consolidated Balance Sheets at December 31, 2007 and 2006	63
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005	64
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the years ended December 31, 2007, 2006 and 2005	65
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	66
Notes to Consolidated Financial Statements	67

2. All schedules are omitted as the information required is either inapplicable or is presented in the financial statements and/or the related notes.

3. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 10th day of March, 2008.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ CRAIG A. WHEELER

Craig A. Wheeler
Chief Executive Officer

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ CRAIG A. WHEELER Craig A. Wheeler	President and Chief Executive Officer; Director (Principal Executive Officer)	March 10, 2008
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2008
/s/ PETER BARRETT Peter Barrett	Chairman of the Board and Director	March 10, 2008
/s/ JOHN K. CLARKE John K. Clarke	Director	March 10, 2008
/s/ ALAN L. CRANE Alan L. Crane	Director	March 10, 2008
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	March 10, 2008
/s/ PETER BARTON HUTT Peter Barton Hutt	Director	March 10, 2008
/s/ ROBERT S. LANGER, JR. Robert S. Langer, Jr.	Director	March 10, 2008
/s/ STEPHEN T. REEDERS Stephen T. Reeders	Director	March 10, 2008
/s/ RAM SASISEKHARAN Ram Sasisekharan	Director	March 10, 2008
/s/ BENNETT M. SHAPIRO Bennett M. Shapiro	Director	March 10, 2008
/s/ ELIZABETH STONER Elizabeth Stoner	Director	March 10, 2008

EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
<i>Articles of Incorporation and By-Laws</i>					
3.1	Third Amended and Restated Certificate of Incorporation	S-1	3.3	3/11/2004	333-113522
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant	8-K	3.1	11/8/2005	000-50797
3.3	Second Amended and Restated By-Laws	S-1	3.4	3/11/2004	333-113522
<i>Instruments Defining the Rights of Security Holders</i>					
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	6/15/2004	333-113522
4.2	Second Amended and Restated Investors' Rights Agreement, dated as of February 27, 2004, by and among the Purchasers listed therein, the Founders listed therein and the Registrant; Amendment No. 1 to Second Amended and Restated Investors' Rights Agreement dated June 10, 2004, by and among the Registrant and the Investors set forth therein	S-1/A	4.3	6/15/2004	333-113522
4.3	Rights Agreement, dated as of November 7, 2005, between American Stock Transfer & Trust Company, as Rights Agent, and the Registrant	8-K	4.1	11/8/2005	000-50797
4.4	Investor Rights Agreement, dated as of July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.2	11/8/2006	000-50797
<i>Material Contracts—License Agreements</i>					
10.1†	Collaboration and License Agreement, dated November 1, 2003, by and among Biochemie West Indies, N.V., Geneva Pharmaceuticals, Inc. and the Registrant	S-1/A	10.4	5/11/2004	333-113522

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.2†	Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the “November 1, 2002 M.I.T. License”); First Amendment to the November 1, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated September 12, 2003, between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated October 22, 2003, between the Massachusetts Institute of Technology and the Registrant; Second Amendment to the November 1, 2002 M.I.T. License, dated November 19, 2003, by and between the Massachusetts Institute of Technology and the Registrant; Third Amendment to the November 1, 2002 M.I.T. License, dated April 2, 2004, by and between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797
10.3†	Letter Agreement Regarding November 1, 2002 M.I.T. License, dated August 4, 2006, between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797
10.4†	Letter Agreement Regarding November 1, 2002 M.I.T. License, dated October 18, 2006, between the Massachusetts Institute of Technology and the Registrant	10-Q	10.6	11/8/2006	000-50797
10.5†	Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the “October 31, 2002 M.I.T. License”); First Amendment to the October 31, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant	S-1/A	10.6	5/11/2004	333-113522
10.6†	Fourth Amendment to the Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.3	8/16/2004	000-50797

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.7†	Fifth Amendment to the Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.5	11/8/2006	000-50797
10.8	Sixth Amendment to the Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-K	10.8	3/15/2007	000-50797
10.9†	Second Amendment to the Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.4	8/16/2004	000-50797
10.10†	Third Amendment to the Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.4	11/8/2006	000-50797
10.11	Fourth Amendment to the Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Registrant	10-K	10.11	3/15/2007	000-50797
10.12†	Collaboration and License Agreement, dated June 13, 2007, by and between Sandoz AG and the Registrant	10-Q	10.1	8/9/2007	000-50797
10.13	Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant	10-K	10.16	3/15/2007	000-50797
	<i>Material Contracts—Management Contracts and Compensation Plans</i>				
10.14#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.15#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.16#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.17#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.18#	Form of Restricted Stock Agreement under 2004 Stock Incentive Plan	8-K	10.2	2/28/08	000-50797
10.19#	2004 Employee Stock Purchase Plan	S-1/A	10.3	4/16/2004	333-113522
*10.20#	Executive Officer Compensation Summary				
*10.21#	Non-Employee Director Compensation Summary				
10.22#	First Amended and Restated Employment Agreement, dated April 10, 2002, by and between Ganesh Venkataraman and the Registrant	S-1	10.12	3/11/2004	333-113522

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.23#	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Ganesh Venkataraman and the Registrant	S-1	10.13	3/11/2004	333-113522
10.24#	Reallocation of Founder Shares Agreement, dated April 10, 2002, by and among Ganesh Venkataraman, Ram Sasisekharan, Robert S. Langer, Jr., Polaris Venture Partners III, L.P. and the Registrant	S-1	10.14	3/11/2004	333-113522
10.25#	Restricted Stock Agreement, dated March 7, 2006, between Ganesh Venkataraman and the Registrant	10-Q	10.14	11/8/2006	000-50797
10.26#	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Robert S. Langer, Jr. and the Registrant	S-1	10.18	3/11/2004	333-113522
10.27#	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Ram Sasisekharan and the Registrant	S-1	10.20	3/11/2004	333-113522
10.28#	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Peter Barton Hutt and the Registrant	S-1	10.22	3/11/2004	333-113522
10.29#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.30#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.31#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797
10.32#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.33#	Restricted Stock Agreement, dated March 7, 2006, between Steven B. Brugger and the Registrant	10-Q	10.13	11/8/2006	000-50797
10.34#	Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
*10.35#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant				
10.36#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.37#	Restricted Stock Agreement, dated January 17, 2007, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.38#	Form of Executive Retention Agreement between the Registrant and each of John E. Bishop, Steven B. Brugger, Richard P. Shea and Ganesh Venkataraman	10-K	10.57	3/15/2007	000-50797
	<i>Material Contracts—Credit Agreements</i>				
10.39	Loan and Security Agreement, dated December 27, 2002, by and between Silicon Valley Bank and the Registrant	S-1	10.23	3/11/2004	333-113522
10.40	First Loan Modification Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.37	3/31/2005	000-50797
10.41	Loan and Security Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.38	3/31/2005	000-50797
10.42	Master Lease Agreement, dated December 30, 2005, between General Electric Capital Corporation and the Registrant	10-K	10.44	3/16/2006	000-50797
	<i>Material Contracts—Leases</i>				
10.43†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.44	First Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004), dated September 7, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.3	11/14/2005	000-50797
10.45	Second Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of November 21, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.47	3/16/2006	000-50797
10.46	Third Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of January 27, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.48	3/16/2006	000-50797
10.47	Letter Agreement (regarding Sublease Agreement, dated September 14, 2004, as amended), dated June 29, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.01	8/9/2006	000-50797
10.48	Purchase Agreement, dated October 31, 2007, between Alnylam Pharmaceuticals, Inc. and the Registrant	10-Q	10.2	11/8/2007	000-50797

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.49	<i>Material Contracts—Stock Purchase Agreement</i> Stock Purchase Agreement, dated July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.1	11/8/2006	000-50797
	<i>Additional Exhibits</i>				
*21	List of Subsidiaries				
*23.1	Consent of Ernst & Young LLP				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				

* Filed herewith.

† Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement filed as an Exhibit to this report pursuant to 15(a) and 15(c) of Form 10-K.



Exhibit C

Kotlikoff Article



Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity

by **Laurence J. Kotlikoff**

Professor of Economics
Boston University

September 2008



Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity¹

Executive Summary

New and improved medications are critical to Americans' health and welfare. Today, the most significant, but also most expensive, advances in medications come in *biologics*. Biologics are protein-based, rather than chemical-based, medicines. The new drugs can be of tremendous help in alleviating, if not curing, a wide range of heartbreaking diseases. At the same time, their prices are remarkably high, leaving millions of uninsured and underinsured Americans unable to access their use.

As policymakers in Congress debate legislation to create an approval pathway for affordable biologic medicines, a strong case has been made regarding the potential savings and increased access that will result. These savings could run in the tens of billions of dollars annually and have a significant impact on access for patients. They would also dramatically lower costs to health care purchasers, be they payors from private industry or the government — the single largest purchaser of prescription medications.

The key issue in providing affordable access to biologic wonder drugs is doing so without limiting their development. This paper focuses on how best to encourage continued innovation in this sector by providing the appropriate degree of monopoly protection. Four bills pending in Congress propose to do for biologic medications what the 1984 landmark Hatch-Waxman bill did for chemical medications, namely, promote a competitive marketplace that would dramatically lower prices while also ensuring strong incentives to innovate. Yet three of the four bills contain *exclusivity* provisions that run the danger of overextending monopoly protection. Doing so would, paradoxically, undermine innovation and the bills' own objectives.

Bestowing lengthy monopolies by statute on brand biologic companies not only greatly delays entry by competitors with low-cost alternatives, but also excludes other innovators from building — in a timely manner — on the stock of prior knowledge — much of which was accumulated at public expense.

New medications that alleviate or cure terrible disease are such remarkable gifts that we all want to do everything possible to continue their discovery. But the new drugs of today are not those of tomorrow. The reason is clear. Today's inventors have strong incentives to protect their discoveries, not to make new ones whose arrival on the market would undermine their existing profits.

Numerous papers in the economics literature on invention and monopoly protection stress that competition, not protection, is the true source of innovation and that overextending monopoly protection can be counterproductive. It may do little or nothing to incentivize new discovery, and may simply delay when the next discovery comes on board. Thus, rights to exclusive marketing periods can lead to less, not more, innovation over time. This is particularly true given the potential to use exclusivity periods to "evergreen" one's products — to secure additional long periods of monopoly based on minor product modifications.

Hatch-Waxman has proved remarkably successful in balancing incentives to innovate with the need for access to new medicines. Given this success and the absence of any material differences between the biologics and chemical medical industries arguing for longer monopoly protection, Congress should consider the Hatch-Waxman model for exclusivity rather than proposals that would distort the market and undercut innovation.

¹ I was asked by Teva Pharmaceuticals USA, which provided the funding for this study, to assess the impact of varying lengths of market exclusivity on innovation in the context of the biotechnology sector. The views expressed here are those of mine and not necessarily those of Teva Pharmaceuticals USA.





Introduction

New and improved medications are a vital and growing part of America's \$2 trillion healthcare system.² Today, one of every 10 healthcare dollars is spent on prescription drugs, compared to one of every 20 in 1980.³ The nature of medicines is also changing. The most significant, but also most expensive, advances are coming in *biologics*.

Biologics are protein-based, rather than chemical-based, medicines.⁴ When Americans take pills, capsules, and liquid medications, they are taking chemical compounds. But for many serious illnesses, they increasingly rely on injections and infusions of biologics.

The new drugs can be of tremendous help in relieving pain and suffering. In some cases they represent miracle cures. But their prices are staggering. Biologics cost, on average, 22 times more per daily dose than chemical medications;⁵ the most expensive biologics cost over \$100,000 a year. The public's annual bill for biologics has been growing at a 15 percent rate, with this year's total exceeding \$40 billion.⁶

For those lucky enough to gain access to these new super-expensive but often highly effective medications, there is real hope. Biologics are now fighting arthritis, asthma, Alzheimer's, heart disease, Crohn's disease, several cancers, psoriasis, multiple sclerosis, Lou Gehrig's disease, and AIDS. And *if* innovation continues, new biologics will be developed to battle the full range of cancers as well as a host of other diseases.

The *if* here is a big one. Innovation in biologics is now threatened, ironically, by specific exclusivity provisions in what is otherwise

long-overdue legislation to provide Americans with accessible alternatives to extraordinarily high-priced brand biologic medicines.⁷

The exclusivity provisions come in two forms — *data exclusivity* and *approval exclusivity* (often referred to as market exclusivity). Both extend the duration of monopoly protection afforded brand drug products; i.e., both convey *marketing exclusivity*. And both depart very sharply from longstanding U.S. policies in balancing intellectual property protection and the U.S. economy's lifeblood — competition.

The proposed legislation comprises four bills before Congress. Each bill authorizes the Food and Drug Administration (FDA) to do for biologic medicines what it's been doing under the Hatch-Waxman Act of 1984 for chemical-based medicines, namely expedite approval of generic alternatives to drive down prescription costs.⁸

Biologics cost, on average, 22 times more per daily dose than chemical medications;⁵ the most expensive biologics cost over \$100,000 a year.

The bills are *Access to Life Saving Medicine Act* (S623/HR1038), introduced by Congressman Henry Waxman and Senator Charles Schumer; *The Biologics Price Competition and Innovation Act of 2007* (S1695), introduced by Senator Edward Kennedy; *The Pathway for Biosimilars Act* (HR 5629), introduced by Congresswoman Anna Eshoo and Congressman Joseph Barton; and *The Patient Protection and Innovative Biologic Medicines Act of 2007* (HR1956), introduced by Congressman Jay Inslee.

The stated goal of each bill is to foster a robust generic biologics industry. But provisions in the Kennedy bill conveying four years

2 Centers for Medicare and Medicaid Website. http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp, accessed on 27 June 2008.

3 Ibid.

4 Epogen, which treats anemia, is an example. It's produced by extracting proteins from animal cells and replicating them in vitro. Nexium, which targets heartburn and acid reflux, is produced by combining chemical compounds with no reliance on animal tissue.

5 Ibid., p. 7.

6 <http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf> This expenditure is being made primarily via third-party insurers or the government.

7 The European Union created a new regulatory pathway for follow-on biologics in 2005. By 2010, when a number of brand biologics go off patent in the EU, we should see significant biologic generic entry.

8 The European Union passed such legislation in 2005. As a result, Europeans can now access low-cost generic versions of a number of leading biologics, including Epogen.

of data exclusivity followed by eight years of approval exclusivity, provisions in the Eshoo-Barton bill conveying 12 years of data exclusivity followed by two years of approval exclusivity, and provisions in the Inslee bill also conveying 12 years of data exclusivity followed by two years of approval exclusivity could delay by years the advent of low-cost generic alternatives.

Ongoing evergreening of biologics can extend their monopoly protection far into the future. Such “innovation” blocks true discoveries that would materially improve the public’s health, and undermine existing product sales.

Most importantly, the exclusivity provisions could stifle the discovery of new biologic treatments for the terrible afflictions just mentioned. This is particularly true in light of the industry’s ability to *evergreen* its drugs – to spend the time afforded by initial monopoly protection to make minor modifications to the biologic’s formulation and, thereby, garner extra periods of statutory exclusivity. Ongoing evergreening of biologics can extend their monopoly protection far into the future. Such “innovation” blocks true discoveries that would materially improve the public’s health, and undermine existing product sales.

Given the medical and economic stakes involved, it’s important for Congress to consider carefully the potential for exclusivity provisions to significantly retard innovation in biologics by undermining the ability of competitors to offer low-cost, competing products in a meaningful time frame.

This paper pursues this objective. It begins by briefly questioning two presumptions when it comes to monopoly protection policy and the drug industry. The first is that longer periods of monopoly protection necessarily promote innovation. The second is that extending the duration of monopoly protection, while it may have winners and losers, causes no overall economic loss, i.e., no economic inefficiency.

These questions provide the context for the next task – assessing the exclusivity provisions specially designed for the brand biologic companies and explaining how exclusivity provisions in three of four biogenerics bills would dramatically extend monopoly protection afforded to brand biologics.

But my main focus will be to amplify the point raised immediately below, namely, that extended periods of exclusivity pose a

threat to sustaining a rapid rate of innovation. This analysis forms the basis for my recommendation that when it comes to promoting biologic competition Congress should stick with what works, namely Hatch-Waxman, with its very limited exclusivity.

Economic theory speaks clearly here. So does the evidence. There are, quite simply, no compelling differences between the chemical-based and protein-based medication industries to justify deviating from a policy that has succeeded for over a quarter of a century in both dramatically reducing drug prices and stimulating innovation.

Indeed, to the extent there are differences, they generally favor less exclusivity. A key example here is the likelihood that obtaining FDA approval of generic biologics will take considerably longer than obtaining FDA approval of a chemical entity.⁹ If this proves true, it will automatically provide brand companies with an extended period of effective exclusivity even absent any legislated exclusivity.

Can Extended Periods of Exclusivity Threaten Innovation?

Raising this question may sound surprising given that some period of exclusive marketing rights is required to incentivize discovery. But starting a train is not the same as keeping it moving, let alone getting it to run at the proper speed. When it comes to innovation, each “discovery” builds on prior knowledge, with progress measured by the next innovation, not the last, and by how fast the next innovation gets to market.¹⁰

Policies that lengthen the time between innovations may do little to stimulate more innovation; instead, they may simply reduce the pace of innovation (the number of discoveries per unit of time) on which the economy’s growth so critically depends.

The key problem with providing excessive monopoly protection is that once an invention has been made, the inventor faces different incentives. The main goal becomes marketing and protecting one’s intellectual property, not developing a dramatically different and better version of the product. Doing so would diminish, if not vitiate, the value of the initial invention, which may have been undertaken at considerable cost. Hence, at least within a given product line, yesterday’s inventors are much less likely to be either today’s innovators or tomorrow’s.

This point comes across clearly in the economics literature starting with the seminal 1959 paper on intellectual property by Nobel

9 Shapiro, Robert, *op. cit.*, p.4.

10 Isaac Newton paid deference to this process in his famous statement: “If I have seen further it is by standing on ye shoulders of Giants.”

laureate Kenneth Arrow.¹¹ In the years since Arrow showed that “the incentive to invent is less under monopolistic than under competitive conditions,” numerous economists have developed alternative models of the innovation process, but they invariably reach the same conclusion — *monopolists don't innovate*. The reason is simple: bringing new products to the market undercuts a monopolist's revenues on his existing products.

Distorting the Economy via Excessive Monopoly Protection

Prolonged monopoly protection raises additional concerns. It distorts consumer choice by maintaining artificially high prices of those final goods and services that are being protected. The same point applies to all the monopoly-protected inputs purchased by businesses. If their prices remain too high for too long, too few of the inputs will be used in production. The result will be a production distortion.

Distortion arising from excessively long monopoly protection is called *rent seeking*. In the context of inventing, the rent seekers are the inventors and the rent they seek is the monopoly profits from their discoveries. For those winning the race to discovery, the rewards are great. But all those losing the race have expended resources, potentially very large amounts of resources, for naught. To be clear, some losers and losses are inevitable. The issue is how many would-be inventors, with what size losses, monopoly-protection policy will create.

Another distortion, which arises in the context of biologics, involves access. Because biologics are so expensive and because America has so many uninsured and underinsured people with limited access to these medications, those with access to these medicines may not have the most need for them. There is clearly an equity issue here. But there is also a separate issue of efficiency. Markets in which some people face one set of prices for goods and services and other people face another set are inefficient for a simple reason — there are beneficial economic trades between the two sets of people that are not occurring.

These economic and other distortions discussed in this paper are important. Economists reference them as *excess burdens*, *dead-weight losses*, or *economic inefficiencies*. But no matter they are called, these distortions entail real economic costs to society. Concern about these efficiency costs explains why we restrict monopolies, why we have patent limits, why we have free domestic trade, and why we form free trade agreements.

Data Exclusivity, Approval Exclusivity, and Marketing Exclusivity

As introduced in part of Hatch-Waxman, *data exclusivity* refers to a period of time during which a potential generic supplier of a brand drug is prohibited from filing for an ANDA (Abbreviated New Drug Application).¹² This prohibition is a type of gag order. It is effectively conveyed by preventing potential generic suppliers from using publicly available clinical trial and related data to substantiate the safety of their medically equivalent/similar medicines.

Approval exclusivity, sometimes referred to as *market exclusivity*, is a period of time during which a generic drug supplier can file for FDA approval, but cannot receive approval. In other words, FDA approval is exclusively limited to brand companies during this period even if all prerequisites for FDA approval of generic alternatives have been established.

Since data exclusivity prevents even seeking FDA approval and approval exclusivity prevents receiving FDA approval, even if one has sought it by substantiating medical equivalence/similarity, both data exclusivity and approval exclusivity constitute *marketing exclusivity* — periods during which brand companies are exclusively permitted to market the medication in question.

Prolonged monopoly protection raises additional concerns. It distorts consumer choice by maintaining artificially high prices of those final goods and services that have been patented.

Being able to file for FDA approval, even during periods when the FDA is precluded from granting approval, is important. Generic drug suppliers may not be able to contest the patents of a brand provider *unless* the generic supplier has filed with the FDA. Consequently, data exclusivity represents absolute monopoly protection for brand suppliers — monopolies that are granted even if a brand's patents are found to be invalid following judicial review.

Using data exclusivity periods to prevent the courts from adjudicating patent challenges goes well beyond standard patent protection policy provided under GATT. Indeed, providing data exclusivity is tantamount to the government simply doing away with patents altogether and conveying exclusive product marketing rights to favored companies by fiat. Such a policy is at considerable odds with the principles of free markets.

¹¹ Arrow, Kenneth J., “Economic Welfare and the Allocation of Resources for Invention,” Rand Corporation working paper P-1856-RC, December 15, 1959.

¹² To be precise, the FDA is prohibited during the period from using the brand company's safety and effectiveness findings (data) as a basis for approving medically equivalent generic alternatives.

As indicated, approval exclusivity comes into play after data exclusivity expires. Although approval exclusivity permits competing drug companies to file their product applications with the FDA and, in the process, potentially contest the validity of patents of drugs already on the market, it tells competitors that no matter whether they win their patent fights or not, they will not get to market until this extra protection period has run its course.

Given Hatch-Waxman's significant patent restoration provision, its exclusivity will rarely extend the total length of monopoly protection.¹⁴

The clock on the total period of data plus approval exclusivity starts with FDA approval of the brand drug. The reason is that the exclusion is determined with respect to the filing and approval of ANDAs. But an ANDA presupposes an NDA (a New Drug Application); the government's exclusivity clock doesn't start until the government approves the new brand drug and allows it to go on the market.

The upshot here is that if the total period of exclusivity exceeds the amount of patent protection left at the time of FDA NDA approval, monopoly protection will be expanded by the number of years that exclusivity exceeds remaining patent life.

Take, for example, a new biologic that receives FDA approval 12 years after initial patent filing. Under GATT, the biologic should receive eight more years of patent protection (20 years total less the 12 years already elapsed). But were the Eshoo-Barton or Inslee bills passed, the biologic would qualify for 14 years of exclusivity beyond the date of FDA approval. Since 14 exceeds eight, the biologic would receive 14 years of protection post-FDA approval rather than eight. And since 14 plus 12 equals 26, the biologic ends up with 26 years, rather than 20 years, of monopoly protection. This represents a 30 percent increase in monopoly protection relative to the GATT norm – the standard protection being provided to inventions of all other goods and services apart from drugs!

Exclusivity, Patent Restoration, and Marketing Stays under Hatch-Waxman

The Hatch-Waxman Act does provide for data and approval exclusivity for chemical entities, but on a much more limited basis than that proposed in the Kennedy, Eshoo-Barton, and Inslee generic biologics bills. Instead of the combined data plus approval exclusivity periods of 12 years (four data plus eight

approval) years proposed in the Kennedy bill and 14 years (12 data and two approval) proposed in both the Eshoo-Barton and Inslee biogenerics bills, Hatch-Waxman offers five years of exclusivity generally, with four years of data exclusivity followed by one year of approval exclusivity if an applicant files a patent challenge in the fourth year. The Waxman biogenerics bill does not address data or approval exclusivity whatsoever.

The Hatch-Waxman Act also provides for *patent restoration*; the Act restores to a new chemical entity's patent life half of the time spent in clinical testing and all of the time spent securing FDA approval, up to a maximum of five years. The amount of patent restoration is also subject to a ceiling; total patent life beyond FDA approval cannot exceed 14 years. Thus, a new chemical drug that receives FDA approval after 12 years from initial patent application, having spent four years in clinical trials and two years undergoing FDA review, has three years of patent restoration time tacked onto the standard 20-year patent term provided under GATT. This provides the drug with 24 years of patent life, of which 12 is post-FDA approval.

In contrast, if FDA approval had occurred eight years from patent application, six of which again had been spent in trials and FDA review, the patent would be extended by only two years – to 22 years total – because any longer extension would mean more than 14 years of patent life beyond the date of FDA approval.¹³

Given Hatch-Waxman's significant patent restoration provision, its exclusivity will rarely extend the total length of monopoly protection.¹⁴ But it does delay by at least four years the ability of competitors to contest the patents of brand companies. Another feature of Hatch-Waxman that delays competitors in overturning invalid patents and quickly getting to market is the ability of brand companies to have the courts automatically stay FDA approval of an ANDA for two and a half years if the brand company sues the competitor for patent infringement.

Hatch-Waxman's Applicability to Biogenerics

It's important to realize that one portion of Hatch-Waxman, namely patent-term restoration, applies to biologic medications as well as chemical medications, even though there is currently no pathway for generic biologics to receive FDA approval and reach market. And since none of the biologics bills abrogate Hatch-Waxman's provisions, brand biologics, under all of the bills, will still retain patent restoration. Hence, under all but the Waxman biogenerics bills, brand biologics will enjoy four legislated types of monopoly protection – GATT, data exclusivity, approval exclusivity,

¹³ As these two illustrations indicate, drugs brought to market early are being penalized by these provisions relative to those brought to market late. Providing incentives to delay the introduction of new medications seems a significant deficiency in the Hatch-Waxman Act.

¹⁴ Grabowski, Henry G., and John M. Vernon. "Effective Patent Life in Pharmaceuticals," *International Journal of Technology Management*, Vol. 19, 2000, p. 116, states that "The effects of Waxman-Hatch and GATT on EPL (effective patent life) have been modest to date."

Table 1: Years of Monopoly Protection from Date of Patent Application

Years between Patent Application and FDA Approval of Brand Drug	GATT – Non-Drugs	Hatch-Waxman Chemical Drugs	Waxman Biologics Bill	Kennedy Biologics Bill	Eshoo-Barton Bill	Inslee Biologics Bill
6	20	20	20	20	23	23
8	20	22	22	22	25	25
12	20	23	23	24	29	29
16	20	23	23	28	33	33
20	20	25	25	32	37	37

Table assumes no evergreening, incorporates exclusivities, and assumes five years for testing and approval of biosimilars (see Shapiro, 2008) commencing at ANDA filing and a three-year patent restoration period.

and patent restoration. Each of these protections can impact the total length of monopoly protection depending on the particular circumstances involved. Under the Waxman bill, brand biologics would enjoy GATT and patent restoration protections.

The Proposed Expansion of Monopoly Protection for Biologics

Table 1 examines the duration of monopoly protection that each of the biogenerics bills would extend to brand biologics companies under different assumptions about the amount of time brand companies spend between submitting a patent and achieving FDA approval of their product.

The table takes into account GATT's 20-year patent duration rule, exclusivity provisions, patent restoration, and the time required for biologic generic companies to receive FDA approval of their medically similar alternatives. I assume that, starting from the end of the period of data exclusivity, it would take biologic generic companies five years to develop a generic biologic, file for FDA approval, and receive FDA approval.¹⁵

For purposes of comparison, the table shows the duration of monopoly protection under pure GATT treatment (the treatment of non-drug products) and under Hatch-Waxman Act treatment (the treatment for new chemical entities). In calculating the length

of protection under Hatch-Waxman, I assume a three-year patent restoration extension – the average such extension calculated by the Congressional Budget Office.¹⁶ Finally, I ignore the potential of brand companies to receive FDA-approval stays and to evergreen their products.¹⁷

In considering table 1's findings, it's important to bear in mind that innovations build on one another. Hence, permanently lengthening monopoly protection from 20 to, say, 25 years represents a 25 percent permanent delay in the advent of the next (the second) innovation. In this case, the second innovation arrives five years late, the third 10 years late, the fourth 15 years late, etc. Over the course of a century, the country experiences not five innovations, but four. And successive generations end up being harmed to an ever-increasing degree.

Compare, to begin, the standard 20-year GATT monopoly protection period with the 29-year period provided under the Eshoo-Barton and Inslee biologics bills, assuming the brand biologic company expends 12 years achieving FDA approval. The difference between 29 years and 20 years is 45 percent. This is a very substantial deviation from GATT and has the potential to substantially reduce the pace of innovation.

Under the Kennedy bill, the duration of monopoly protection for this case is five years shorter, i.e., 24 years. The difference reflects the two-year shorter length of total exclusivity under the

¹⁵ See Shapiro (2008), op. cit.

¹⁶ Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, table 8, p. 40.

¹⁷ These stays appear to have the potential to add another half year of monopoly protection under the Eshoo-Barton and Inslee bills for all cases considered in table 1.

Table 2: Years of Marketing Exclusivity from Date of Patent Application

Years between Patent Application and FDA Approval of Brand Drug	GATT – Non-Drugs	Hatch-Waxman Chemical Drugs	Waxman Biologics Bill	Kennedy Biologics Bill	Eshoo-Barton Bill	Inslee Biologics Bill
6	14	14	14	14	17	17
8	12	14	14	14	17	17
12	8	11	11	12	17	17
16	4	7	7	12	17	17
20	0	5	5	12	17	17

Table assumes no evergreening, incorporates exclusivities, assumes five years for testing and approval of biosimilars commencing at ANDA filing, and assumes a three-year patent restoration period.

Kennedy bill compared to the Eshoo-Barton and Inslee bills and the fact that the Kennedy bill allows filing for ANDA after four years as opposed to after 12 years in the Eshoo-Barton and Inslee bills. Under the Kennedy bill, generic biologic firms would, I assume, spend the eight years after filing, but before being able to receive final FDA approval, in doing the testing under FDA supervision needed to obtain final approval once the eight years of approval exclusivity had run its course.¹⁸

Compared with the Eshoo-Barton and Inslee bills, the Kennedy bill entails shorter monopoly protection. But monopoly protection under the Kennedy bill is still much longer than under Hatch-Waxman in the case the brand company takes more than 12 years to get to market. Remarkably, the Kennedy, Eshoo-Barton, and Inslee bills reward delay in getting to market with longer monopoly protection, with each year of delay beyond 12 leading to roughly one more year of protection. One wonders why legislators would want to encourage delay in the pace at which innovative drugs are brought to market and lower the speed at which today's innovations are incorporated in tomorrow's discoveries.

Table 2 puts this point in higher relief. It shows the duration of marketing exclusivity available to the biologic brand company for different periods of time the brand takes to get to market. Note that Hatch-Waxman and the Waxman biologics bill penalize delays

in reaching the market by reducing monopoly protection by roughly one year for each year of delay.

Can table 2's huge differences in marketing exclusivity periods for a) chemical medications subject to Hatch-Waxman and b) biological medications under either the Kennedy, Eshoo-Barton, or Inslee bills be justified by much longer startup times for new biological entities compared with new chemical entities? The answer is no. As Henry Grabowski has shown, the average development time for new biological entities is only 7.4 months longer than that for new chemical entities.¹⁹ In comparison, relative to Hatch-Waxman, the Eshoo-Barton and Inslee bills call for between 12 months and 120 months of extra monopoly protection depending on when the biologic is brought to market.

What about costs and risk? Do either of these factors justify longer monopoly protection for biologics than chemical entities?

The answer is no. Consider first the issue of cost. There is no question that bringing a new biologic medication to market is exceptionally expensive – an estimated \$1.24 billion.²⁰ But cost per se is not economically relevant. What matters is cost relative to reward. Invention X may cost \$1 million to bring to market and invention Y \$1 billion, but the projected revenues for Y may exceed those for X by far more than a factor of 1,000. In this case, less

¹⁸ Note that patent restoration does not extend the length of monopoly protection in this case, since it adds, by assumption, three years to the GATT's 20, which equals 23, which is less than 24.

¹⁹ Grabowski, Henry. "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition." *Nature Reviews Drug Discovery*, Volume 7, June 2008.

²⁰ See DiMasi, Joseph A. Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *The Journal of Health Economics*, Volume 22, Issue 2, March 2003, pp. 151-185 and Grabowski, Henry, "Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition," *Nature Reviews Drug Discovery*, Volume 7, June 2008. \$802 million is, by the way, the estimated cost of bringing a new chemical medication to market.

monopoly protection is needed to promote invention of Y than of X.

Compared with pharmaceuticals, biologics are more costly to produce. But their reward is also considerably higher. Indeed, compared to chemical medications, biologic medications appear to have a lower ratio of invention cost to invention reward.²¹ Moreover, there is no presumption in the economics literature on optimal monopoly protection that products entailing higher cost relative to reward should be provided longer periods of protection.

Next, consider risk. Only one in five of all drugs tested clinically makes it to market,²² with the success rate possibly lower in biologics. But modern finance teaches us that collections of individual investments, each of which is highly risky, can, thanks to the law of averages (law of large numbers), be quite safe. If only one in 20 experimental drugs makes it to market, but you experiment with 1,000 such drugs, you can be pretty sure that close to 50 will be successful. Stated differently, the risk that most advocates of longer monopoly protection cite as supportive of such a policy is *diversifiable risk* – risk that is diversified away in the financial marketplace and that doesn't raise the cost of capital confronting biotech companies.²³

When it comes to *non-diversifiable risk*, the biotech industry is riskier than most, but not by much. Consequently, the cost of equity capital in biotech is only 18 percent higher than the average across all other industries. Moreover, a quarter of U.S. industries are riskier than biotech, but none of these garner longer monopoly protection. The appendix lists the 25 industries with higher costs of equity capital than biotech. The semiconductor industry is the most risky, with a cost of capital 89 percent above the average. The pharmaceuticals industry, interestingly enough, is much riskier than biotech. Its cost of capital is 35 percent above average.²⁴

Evergreening

Evergreening will multiply the economic costs of expanding monopoly protection via exclusivity arrangements. Brand companies can, and routinely do, make relatively minor changes to their existing products in order to restart their monopoly-protection clocks. These changes include changing the medication strength of pills (e.g., changing the pills from .10 mg to .15 mg), changing the form of medication (e.g., switching from pill to capsule),

modifying the method of delivery (e.g., from injection to inhalation), expanding indications (applying the medicine to additional conditions), pegylation (which has the effect of reducing doses per time period via time-release mechanisms), and glycosolation (adding sugar molecules to the medication).

To understand the risk evergreening poses to true innovation and competition in the industry, suppose either the Eshoo-Barton or Inslee bill is passed and a brand biologic company called BioBrand, Inc., spends 12 years getting its biologic drug produced, tested, and FDA-approved. According to table 1, 17 years later (29 years after the patent is initially filed) generic competitors will finally be able to bring a competing medication to market.

Or will they? Given evergreening, BioBrand can readily come up with a small change along one of the aforementioned product characteristic dimensions, clinically tested, obtained FDA approval of the “new” product, receive another 14 years of data and approval exclusivity, promote it aggressively with doctors and patients (referred to as *converting the market*),²⁵ and effectively extend the monopoly protection on the original product from 29 to 43 years!²⁶ And then BioBrand could tack on another 14 years if it introduced another minor, approved modification in year 43. In the drug world, brand companies have, in such situations, substantially diminished the market for the previous-generation products when they launch a new generation. They do so by converting prescriptions to the new product. Hence, upon approval, the previous-generation generic product has little or no market potential.

Brand companies can, and routinely do, make relatively minor changes to their existing products in order to restart their monopoly-protection clocks.

An effective statutory anti-evergreening provision in biologics would award full monopoly protection only for the discovery and marketing of a new protein. Minor modifications of new proteins should receive either no monopoly protection or very limited protection. Unfortunately, none of the proposed generic biologics bills incorporates any restrictions on evergreening. Instead, they contain vague language about restricting exclusivity provisions to the “previous licensed reference product,” without ensuring that what's defined to be the previous licensed reference product is, in fact, the underlying amino acid sequence of the new protein and nothing more.

21 It's easy for even excellent economists to fail to scale costs by revenues. In his June 2007 Duke University Department of Economics working paper titled “Data Exclusivity for New Biologics Entities,” Henry Grabowski incorrectly states, “From the standpoint of economic theory, industries where the R&D process is costly and risky need longer exclusivity periods to realize innovation benefits, compared to those industries where innovation is easier and less costly.”

22 Henry Grabowski & John Vernon, *Effective Patent Life in Pharmaceuticals*, 19 Int'l J. Tech. Mgmt. 98 (2000).

23 It's also easy even for excellent economists to confuse diversifiable with aggregate risk. See note 11.

24 The publishing industry doesn't appear in the table because its cost of capital, which is only 7 percent above the average, is below that of biotech. Publishing is another example of an industry in which the chances of success of any given book or other product are very low, yet its overall risk is moderate.

25 Using advertising to transform the old purple-colored Prilosec into the “New Purple Pill” Nexium is viewed as the classic example of *converting the market*.

26 Note that patents and exclusivity are different routes to monopoly protection. Minor modifications in medicines need not result in any new patents, yet may still be approved by the FDA as a new product and, therefore, qualify for data as well as approval exclusivity.

The Hatch-Waxman Act – A Balanced Template for Success

The Hatch-Waxman Act provides an excellent guide to establishing a balanced policy with respect to generic biologics. The Act gave the brand and generic companies less than they wanted, but more than they might have expected. The brand companies were forced to confront intense generic competition once their monopoly was finally terminated. In exchange, they received longer monopoly protection. The generics were forced to wait longer to compete, but benefited from an accelerated FDA approval process.

As indicated, the extension of monopoly protection was accomplished via the Act's patent restoration, data exclusivity, approval exclusivity, and ANDA stay provisions. According to the Congressional Budget Office, these and other features of the Act increased the average length of marketing exclusivity by 2.5 years – roughly a 25 percent increase, on average, in the prevailing duration of marketing exclusivity.²⁷ Duke University economists Henry Grabowski and Margaret Kyle report that marketing exclusivity in pharmaceuticals now generally ranges from 12 to 15 years.²⁸

The Hatch-Waxman Act provides an excellent guide to establishing a balanced policy with respect to generic biologics. The Act gave the brand and generic companies less than they wanted, but more than they might have expected.

Gaining access to a market from which they had formerly been excluded (albeit 2.5 years later than they would have preferred) has been a major incentive for generic pharmaceutical companies. Generics, including generics produced by brand companies, now account for two-thirds of the nearly 4 billion U.S. prescriptions being filled each year. This is remarkable given that the generics' prescription share was only 19 percent in 1984 when Hatch-Waxman was passed.²⁹

Generics have achieved this market penetration by offering medically equivalent products at dramatically lower cost. This competition has spurred further innovation. This brings us to Hatch-Waxman's real winner – the American public, which is now able to purchase large numbers of medications at close to their marginal production costs while also benefiting from newly innovated products. In 2007, the sales-weighted discount off

the brand price of the top 100 (ranked by number of prescriptions) generic drugs was 29.0 percent. This is just the average discount. A total of 22 percent of generics are now offering discounts of 40–60 percent, and 20 percent are offering discounts above 60 percent.³⁰

Hatch-Waxman provides four years of data exclusivity, but these four years do not generally preclude generics from reaching market on time. To see this, consider a new chemical medication that receives FDA approval 12 years after initial patent application. Its data exclusivity clock will run out 16 years after initial patent application (i.e., four years after FDA approval). According to table 1, this is still seven years before a generic is able to come to market. Hence, the generic company has seven years to file for and receive FDA ANDA approval.

This example illustrates an important point. Hatch-Waxman's exclusivity provisions, because they are of an appropriate duration, do not lengthen monopoly protection except in extreme cases that FDA approval comes very late – 19 or 20 years – after initial patent application. The real source of Hatch-Waxman's expansion of monopoly protection is patent restoration.³¹

Competition Stimulates Invention

Hatch-Waxman's success did not come at the price of innovation. On the contrary, the legislation appears to have accelerated innovation. Figure 1 shows that research and development in pharmaceuticals, measured relative to sales, increased dramatically in the years after 1984. R&D is now running between 16 percent and 18 percent of sales, on an annual basis, compared with 8–10 percent of sales prior to Hatch-Waxman.

Figures 2 and 3 provide complementary evidence about the acceleration of invention post Hatch-Waxman. Figure 2 shows that the number of new drug patents issued by the U.S. Patent Office rose dramatically after 1984 and, indeed, has exceeded the pre-1984 levels in each year since the Act was promulgated.

Figure 3 reports the average annual number of FDA approvals of new chemical entities (NCEs) for the periods 1973–1983, 1984–1993, and 1994–2007. The figure shows dramatic increases in NCE approvals subsequent to Hatch-Waxman's 1984 passage. NCE approvals increased by one-third in the decade following the bill's passage. Since 1994, NCEs have been coming at twice the rate observed before Hatch-Waxman.

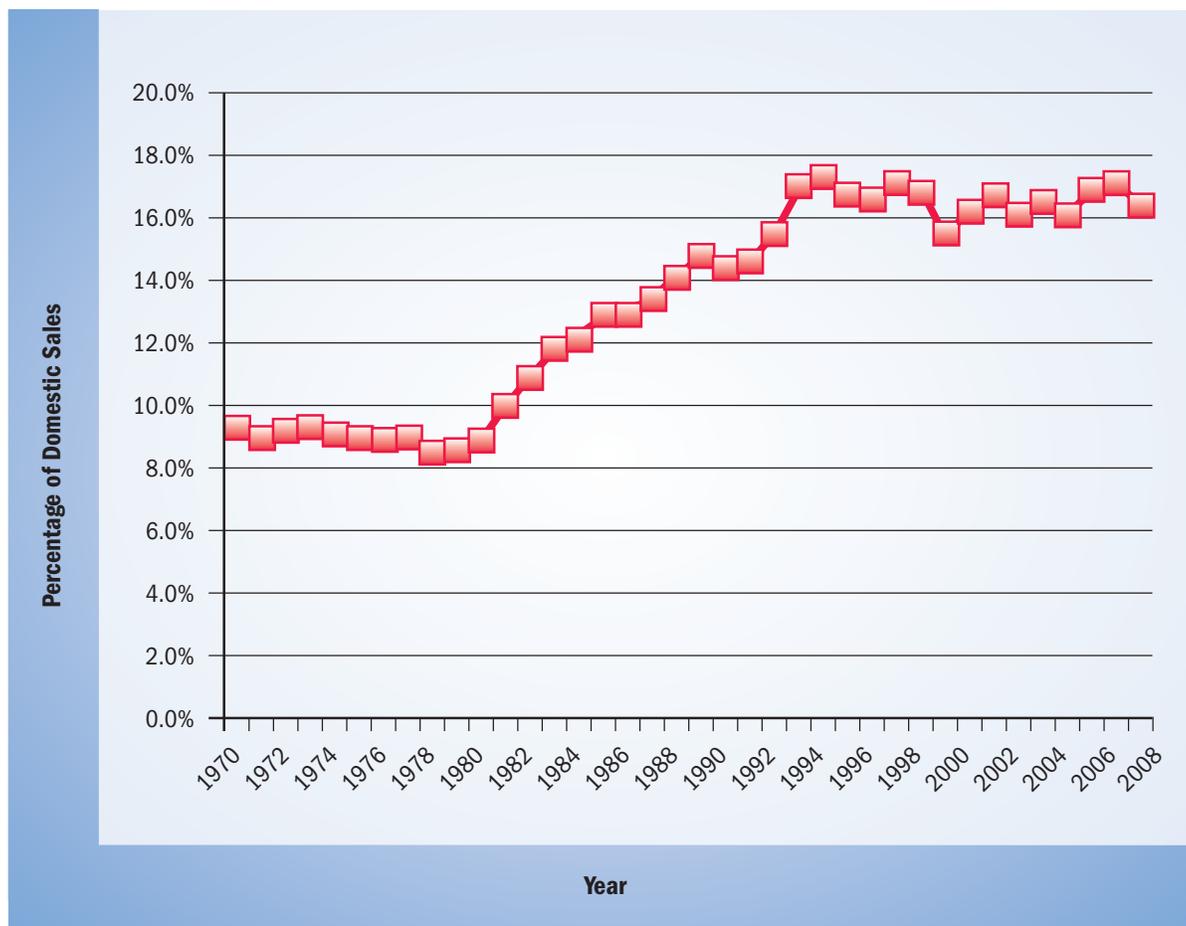
27 Congressional Budget Office, <http://www.cbo.gov/showdoc.cfm?index+656&sequence=1>

28 Grabowski, Henry G. and Margaret Kyle, "Generic Competition and Market Exclusivity Periods in Pharmaceuticals," *Managerial and Decision Economics*, 28, 491-502, 2007, p. 496.

29 The Congressional Budget Office, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998, p. ix.

30 Author's calculations; see note 12.

31 Hatch-Waxman's exclusivity provisions are not, however, without teeth. They prevent competitors from challenging patents for four years after FDA approval and from bringing a competitive product to market for five years from FDA approval in the cases that the patent challenge is successful.

Figure 1: Pharmaceutical R&D as a Share of Sales: 1970–2007

Source: PHRMA 2008 Profile.

The fact that Hatch-Waxman did not deter the brand companies from investigating new drugs and bringing them to market is not surprising. The average extra two-and-a-half years of marketing exclusivity provided the brand companies more time to recoup their investments. In addition, the four years of data exclusivity and one year of approval exclusivity afforded brand companies five years during which they could market their FDA-approved products without having to contend with competing products arising from legitimate patent challenges.

These points notwithstanding, if Hatch-Waxman did, on balance, reduce the profitability of developing new drugs, its effects were surely modest and were offset by other factors. Such factors include a shift toward more reliance on medication in treating illness, increasing demand for medications from an aging society, increasing international demand due to rising incomes abroad, etc.

Evidence supporting this view of at most a minor impact of Hatch-Waxman comes from a highly detailed 1998 Congressional Budget Office study, which states: “For all drugs, on average, the increase in generic sales since 1984 has probably not reduced expected returns below the average capitalized costs of R&D. On the margin, however, it is possible that a few drugs that were barely profitable to develop before may no longer be so now.”³² In reaching this conclusion, the CBO pointed out that the distribution of revenues from new drug discoveries is a highly skewed business, with the successful “blockbuster” drugs generating billions of dollars in sales years before any competition from generic companies comes into play.

Brand companies have also been able to recoup some of the losses arising from generic competition by marketing their brand drugs as generics. In fact, one in every six generic prescriptions is currently being filled with a brand generic.³³

³² Congressional Budget Office, op. cit., p. 28.

³³ Author’s calculation based on IMS Health data.

Figure 2: Utility Patent Grants for Drug, Bio-Affecting, and Body-Treating Compositions, 1969 – 2007



Source: http://www.uspto.gov/web/offices/ac/ido/oeip/taf/tecasga/424_tor.htm
 *The recent decline in new drug patent grants between 2002 and 2007 may reflect an overburdened PTO. For example, according to Annual Performance and Accountability Reports issued by the PTO between 2002 and 2007, filings of patent applications have increased from 353,000 in 2002 to 467,000 in 2007. Total patents pending have increased from 636,000 (2002) to 1.12 million (2007). Lastly, in the Biotechnology and Organic Chemistry Section (Tech Center 1600), pendency has increased from 27.3 months (2002) to 34.3 months (2007).

It's also important to note that although generic drugs now account for the bulk of all prescriptions, they continue to account for only a small minority of all sales. As they did back in 1984, the brand companies garner the lion's share of all pharmaceutical revenue. The brand companies' revenue share is currently 84 percent.³⁴ This revenue, by the way, is now running close to a quarter of a trillion dollars each year.³⁵ Thus, brand drug companies remain hugely profitable, with the average price of a brand drug exceeding that of a generic by a factor of roughly four.³⁶

A final point is that Hatch-Waxman surely lit a fire under the brand companies. It's one thing knowing you have an indefinite monopoly on the development, production, and sale of a medication. It's another thing to know that every year of delay in getting to market means one fewer year during which you are likely to collect monopoly rents on your invention. As table 2's third column documents, Hatch-Waxman sent this message loud and clear to the brand companies.

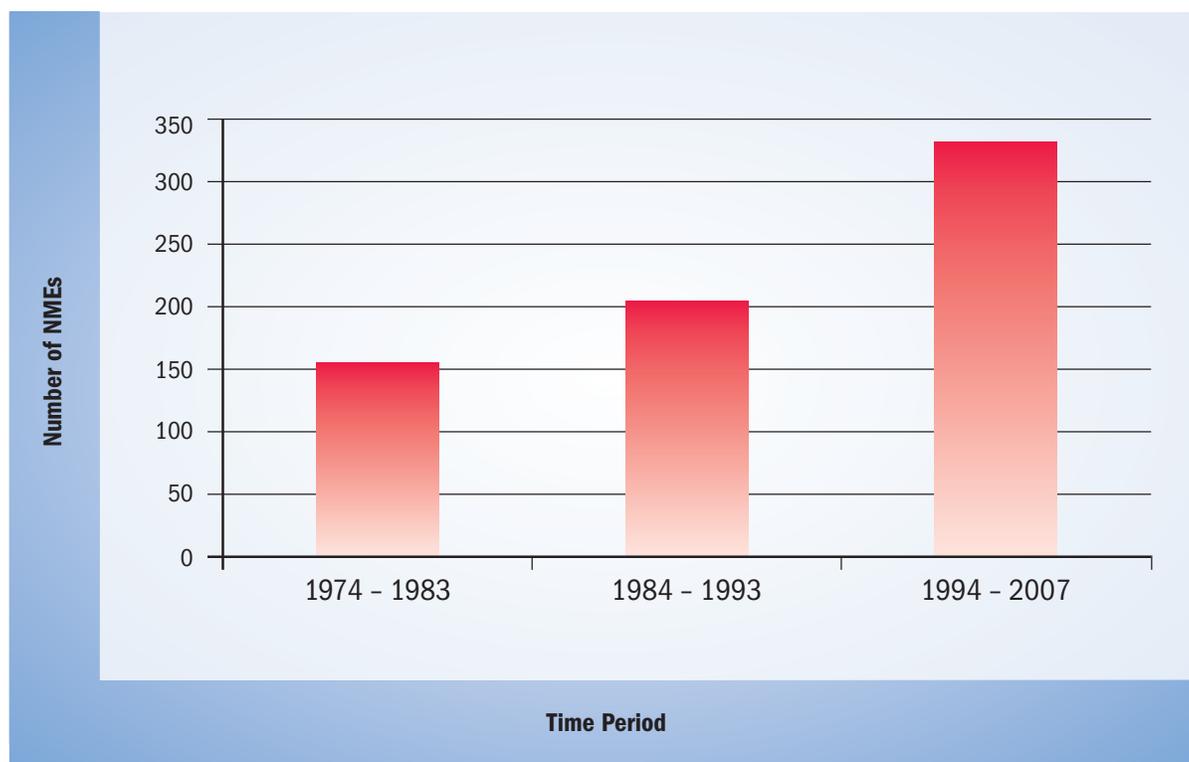
The Economic Case for Biogenics

This final section briefly discusses the potential cost saving and welfare gains from fostering a biogenics industry. I then review some of the relevant economics literature on monopoly protection, making the points that a) innovation is an ongoing process that can be seriously undermined by excessive protection, b) excessive protection can actually reduce incentives to innovate, and c) excessive protection comes at a considerable price in terms of economic efficiency.

Potential Cost Savings from Biogenics

Recent research suggests such an industry would save the American public at least \$25 billion and as much as \$108 billion over the next decade and greater sums thereafter from biogenics leg-

34 IMS Health, "IMS National Prescription Audit Plus, National Sales Perspectives," December 2007.
 35 Generic Pharmaceutical Association, *Statistics: Our Industry*, February 2007
 36 *Ibid.*, *FAQs Generics: Lower Cost*, February 2007

Figure 3: FDA Approvals of New Molecular Entities, 1974–2007

Source (for both) <http://www.fda.gov/cder/da/da.htm>

isolation that properly limits the duration of monopoly protection.³⁷

Numbers of this magnitude are hard to translate into their personal welfare impact. So take Remicade, which is used to treat arthritis and Crohn's disease. For those with severe arthritis, Remicade infusions can mean the difference between walking or not; and for those with advanced Crohn's, the infusions can literally mean the difference between life and death. That's the very good news. The bad news is that taking this miracle drug can cost over \$20,000 per year.³⁸ Costs of this magnitude are obviously prohibitive for the roughly 50 million Americans with no health insurance as well as the tens of millions of other Americans who either have no prescription drug coverage or face very high prescription co-pays.³⁹

Reducing the Costs of Biologics Limits Biologics Expenditure Risk

Another economic argument for limiting monopoly protection to biologics involves risk. Even those with excellent prescription drug insurance need to worry about the risk of having to directly pay the high costs of biologics. Why? Because being insured today doesn't guarantee being insured tomorrow. Moreover, as *The New York Times* recently reported, health insurance plans with prescription drug coverage are beginning to charge very high co-pays for biologics — usually 20–33 percent. These charges can cost *insured* patients tens of thousands of dollars a year.⁴⁰ This includes the roughly 33 million elderly Americans on Medicare. A full 86 percent of Medicare Part D prescription drug insurance

37 <http://www.cbo.gov/ftpdocs/94xx/doc9496/s1695.pdf> and Shapiro, Robert J. "The Potential American Market for Generic Biological Treatments and the Associated Cost Savings." *www.insmed.com*. February 2008. Shapiro's cost savings estimate is much higher than CBO's because he incorporates expanded demand in his analysis. The expansion in demand comes from two sources — more consumption of biologics by those now using biologics and the initiation of use of biologics by those now priced out of the market.

38 Purvis, Leigh and Lee Rucker, AARP Public Policy Institute, May 2007. http://64.233.169.104/search?q=cache:x2DoGbAwrcJ:www.tennicare.org/actions_alerts/alerts/2007_06_09/biologics_top_20_q_and_a.pdf+annual+cost+of+top+biologic+products&hl=en&ct=clink&cd=3&gl=us Remicade is actually inexpensive compared with some biologics. Herceptin, which treats breast cancer, runs \$124,000 per year. Avastin, which treats colorectal cancer, costs \$60,000 annually, and Avonex, which treats multiple sclerosis, is billed at \$84,000 per year. Twelve of the top 20 biologics now on the market have an average cost per year exceeding \$10,000. Sixteen have an annual average cost exceeding \$5,000. See Purvis and Rucker (2007), *op. cit.*

39 Lowering the costs of biologics directly benefits those using the drugs, but there is also a real benefit to the friends and relatives of those helped by these new medicines. Economists refer to a situation in which person X's welfare depends on his own health and consumption of goods and services as well as on person Y's welfare as one subject to *externalities*. There are clear and obvious externalities when it comes to improving public health because the "public," when not ourselves, is often someone to whom we are very close. Remarkably, the economic value of these externalities is entirely ignored when it comes to weighing the costs of ongoing monopoly protection against the gains. The value could be considerable. Suppose, for example, that each person who is directly helped by having access to a low-cost biologic has 10 close friends or relatives who are indirectly helped. Also suppose that the average value of the external benefit is one-tenth the value to the patient herself. In this case, the savings from low-cost biologics would be double those estimated.

40 Golata, Gina, "Co-Payments Go Way Up for Drugs with High Prices," *The New York Times*, April 14, 2008.

plans are now charging 20–30 percent co-pays for expensive biologics.⁴¹ Another example of the risk of paying for biologics involves diabetes. Hundreds of thousands of Americans with diabetes, many of whom have prescription drug coverage, are now spending upwards of \$1,000 per month to cover the costs of insulin.⁴²

Our exposure to the risk of high-cost biologics is not limited to our own medical needs. If our relatives or friends end up facing huge, uninsured bills for biologics, we'll be asked for financial assistance or feel the need to provide such assistance. All of these factors are playing on the minds of Americans on a daily basis. According to Deloitte's *2008 Survey of Health Care Consumers*, 93 percent of American households say they are unprepared for their future healthcare needs. This uncertainty has a cost that economists are well versed in measuring. They do so by determining how much households would be willing to pay to avoid the risk entirely. Although no one has done such a measurement for healthcare expenditure risk in general, let alone biologics per se, the following speculative measurement suggests the potential magnitude of the biologic cost risk.

In fact, each innovation is part of a chain. Today's innovation cannot proceed if yesterday's is not accessible. And tomorrow's innovation must wait until today's innovation is available for use.

Assume there are 100 million Americans who are uninsured either directly or indirectly (via their uninsured relatives' or friends' exposures) for the costs of biologics and that, on average, insurance against these costs is worth \$100 per person. In this case, eliminating this risk would be worth \$10 billion annually.

Now lowering the cost of biologics is not the same as providing insurance against these costs, but it does provide some perspective on the value to American households of less expensive biologics. This value, to repeat, is not simply in reducing expected outlays, including those coming in the form of higher co-pays and prescription drug insurance premiums. It's also in reducing the risk of unaffordable expenditures on biologic medicines.

Limiting Monopoly Protection to Stimulate Innovation

The importance of successive rounds of innovation – of each innovation building on, but also undermining the monopoly position of the prior round⁴³ – was dubbed *creative destruction* by the father of growth theory, Joseph Schumpeter.⁴⁴ According to Schumpeter, innovation is the engine of growth, and it's not pretty. Entrepreneurs must be able to compete and destroy or they will not create.

In Schumpeter's words, "Economic progress, in capitalist society, means turmoil. [What counts is] competition from the new commodity, the new technology, the new source of supply, the new type of organization ... competition which ... strikes not at the margins of the profits and the outputs of the existing firms, but at their foundations and their very lives."

Paul Romer, today's leading theorist of economic growth, emphasizes the self-propelled nature of growth – that growth feeds upon itself. "We consistently fail to grasp how many ideas remain to be discovered. Possibilities do not add up. They multiply."⁴⁵

Sandwiched between Schumpeter and Romer is the past century's third great student of economic growth, Nobel laureate Robert Solow. Solow developed *growth accounting* and showed that innovation (better technology) is a major source of U.S. economic growth.

In fact, each innovation is part of a chain. Today's innovation cannot proceed if yesterday's is not accessible. And tomorrow's innovation must wait until today's innovation is available for use. Moreover, if the current length of monopoly protection suffices to incentivize today's innovation, extending the length of protection will do nothing to increase current innovation. Instead, it will simply delay future innovation with the economy, over time, falling further and further behind with respect to the level of technology it would otherwise have available.

Economists have modeled this process, conceptualizing innovation in a number of different ways. Andrew Horowitz and Edwin Lia wrote a classic paper in 1996, for example, in which they view innovation as moving up a product quality ladder.⁴⁶ Higher rungs on the ladder entail better technology and higher quality products. The innovator in their model, which need not be the same person or company through time,⁴⁷ can be viewed as holding the top

41 <http://www.drugchannels.net/2008/04/tier-4-co-pays-and-pharmacy-prices.html>.

42 Saul, Stephanie, "Bridling at Insulin's Cost, States Push for Generics," *The New York Times*, January 11, 2007. A biologic version of insulin was extracted in the early 1980s; its most effective form has yet to face competition from generic manufacturers.

43 Jorgenson, Dale, "Accounting for Growth in the Information Age," provides a careful empirical analysis available of technology's contribution to U.S. economic growth.

44 Schumpeter, Joseph, *Capitalism, Socialism, and Democracy*, New York, N.Y.: Harper, 1942.

45 <http://www.econlib.org/library/Enc/EconomicGrowth.html>

46 Horowitz, Andrew W. and Edwin L.C. Lai, "Patent Length and the Rate of Innovation," *International Economic Review*, 37 (4), 1996, pp. 785–901. The ladder model for innovation was originally developed by Gene Grossman and Elhanan Helpman in chapter 4 of their book, *Innovation and Growth in the Global Economy*, Cambridge, Mass.: MIT Press, 1992.

47 The current innovator is indifferent between maintaining his company or selling it (his ladder position) to a competitor who would have the same competition-spurred incentive to innovate.

position on the ladder with generics moving up from below. The closer the generics get, the more competition the current innovator faces. This gives the current innovator an incentive to move to yet a higher position on the ladder. Moving up the ladder is innovation, and the more rungs the innovator (or replacement innovator) climbs over a given period of time, the higher the rate of innovation.

Patent length in the model corresponds to the amount of time the government keeps the generics from using the latest technology — moving up the ladder to where the prior innovators have been. Once the current patent expires, the generic can move up. But when he does, he finds that the top-rung innovator has innovated to an even higher rung, the position of which is temporarily protected by a new patent.

This is not a model of evergreening. Each time the top-rung innovator company innovates, it represents a true improvement in technology — one that comes at a real cost to the company. But it's only the threat of competition that keeps the top-rung innovator (the near monopolist) innovating. And setting the patent length correctly is critical. As the authors point out, "Patent length either too short, or too long, will weaken innovative incentives." In particular, patent length that's too long will lead to more innovation when innovation occurs (the top-rung company will move up more rungs when it realizes it has to innovate to stay ahead because its patent is expiring), but to less frequent innovation. In the extreme, making the patent indefinite kills off innovation entirely; in this case, the top-rung company faces no competitive pressure and would compete only against itself by incurring the cost of inventing a better product.

Another classic paper on patent policy is Nancy Gallini's (1992) *Rand Journal* article.⁴⁸ Gallini's model lets competitors invent around incumbents, but at a cost. If patent length is set too long, competitors realize that they'll not be able to use existing knowledge in a timely manner and that the only way they can compete is to come up with their own invention. Under these circumstances, this makes private sense, but it also makes social nonsense for the same reason that it makes no sense to re-invent the wheel. Knowledge that's been acquired at a cost and that can be conveyed at zero cost is knowledge that should be used.

Gallini's paper, in its own way, gets at the cost of patent races alluded to above. Invention that can be monopolized even for a finite period of time represents a prize worth fighting for. But if only one party can win or, in Gallini's case, if multiple parties can win, but not fully, there can be too much effort put into invention. Again, what's privately optimal can be socially undesirable.

The classic example of such *rent seeking* is referred to as *the Tragedy of the Commons*. In this case, there is a common field that shepherds can use to graze their flocks. But since no one owns the commons or cares about the degree to which the grazing of his sheep limits the grazing of other people's sheep, we end

Once the current patent expires, the generic can move up. But when he does, he finds that the top-rung innovator has innovated to an even higher rung, the position of which is temporarily protected by a new patent.

up with overgrazing. In the extreme, there can be so much overgrazing that no one benefits from the commons — a real tragedy. Similarly, if extending patent length too long makes the prize of coming up with the winning invention so great, far too many would-be inventors will abandon their other pursuits and try to strike it rich. The resulting gold rush can lead to collective (social) costs that entirely wipe out the social benefit from the invention.⁴⁹

Gallini's paper provides yet another deep insight into the problem of excessively long monopoly protection. She points out that extending patent life beyond the socially optimal length may actually be counterproductive in terms of incentivizing innovators to invent. The reason is that an innovator, call her X, will realize that if she wins the patent race, her competitors will know that waiting until her patent expires is waiting too long and that the only way to play is to innovate around her patent. In thinking this through, X will realize that having longer life on a patent that others are going to invent around is like having a very short patent that others will not invent around; i.e., it's like having little incentive to invent in the first place. Gallini summarizes this point by stating "Extending patent life ... may not provide the inventor with increased incentive to research or patent the innovation."

Limiting Monopoly Protection to Increase Economic Efficiency

If less monopoly protection can be more when it comes to stimulating invention, the same holds true when it comes to improving economic efficiency. In his fundamental paper on optimal patent life, William Nordhaus argues that "the optimal life for drastic process inventions seems to be very small, in the order of one-tenth of the actual life of patents. The reason for the very

⁴⁸ Gallini, Nancy T., "Patent Policy and Costly Imitation," *Rand Journal of Economics*, 23 (1), Spring 1992.

⁴⁹ Philip Aghion and Peter Howitt in their 1992 *Econometrica* 60, 2, March 1992, pp. 323 - 51 paper titled "A Model of Growth through Creative Destruction" refer to the waste of resources in patent races as "business stealing."

small (optimal) life seems to be that drastic inventions are very important inventions and thus have a great deal of potential deadweight loss if they have long life.⁵⁰

Drastic inventions refer here to inventions that lead to major reductions in the prices facing consumers once patent protection terminates. But the fact that the true economic cost for consumers of consuming a product is quite low means they should be consuming a lot of it. But with extended monopoly protection this doesn't happen, or at least doesn't happen for a very long time. The resulting consumer loss in welfare is called a deadweight loss.

Glenn Loury reaches a similar conclusion to Nordhaus, but in a more realistic setting in which the overall economy's conditions change when patent policy is modified. Loury states, "Social welfare can be maximized by appropriately limiting entry and firm investments with licensing fees and finite patent life."⁵¹

Conclusion

Biologic medications hold enormous promise for improving Americans' health and well-being. Fulfilling that promise requires making sure that all Americans are able to access these medications at affordable prices within a reasonable period of time from their discovery. It also requires ensuring that tomorrow's biological breakthroughs are able to build on today's.

Biologic medications hold enormous promise for improving Americans' health and well being. Fulfilling that promise requires ensuring that all Americans are able to access these medications at affordable prices within a reasonable period of time from their discovery.

Legislation now pending in Congress offers hope to millions of Americans that more affordable versions of biologic medications will soon become available through a competitive marketplace. But exclusivity provisions in three of the four main biogenerics bills significantly undermine the legislation's objectives. These provisions constitute uncontestable grants of monopoly rights by government fiat — something that runs far afield of traditional U.S. patent policy. The provisions would substantially extend the duration of monopoly protection of brand biologic medicines and, thereby, materially delay the arrival of low-cost generic alternatives. These conveyances of exclusive marketing rights not only exclude competing biologic companies from entering the market

with low-cost alternatives for extended periods of time. They also exclude other innovators from building, in a timely manner, on the stock of prior knowledge, much of which was accumulated at public expense. These bills also fail to anticipate and prevent evergreening under which brand companies can obtain repeated periods of exclusivity and monopolize biologic medicines essentially indefinitely.

New medications that alleviate or cure terrible disease are such remarkable gifts to humankind that we must continue to appropriately reward true innovation in this field. But the new drugs of today are not those of tomorrow. And today's inventors are generally not tomorrow's. The reason is clear. Today's inventors have strong incentives to protect their discoveries, not make new ones whose arrival on the market would undermine their existing profits and market share. And, as numerous papers in the economics literature on invention and monopoly protection point out, over-extending monopoly protection can easily boomerang. It may do little or nothing to incentivize new discovery and simply delay when the next discovery comes on board. *In this case, providing greater incentive to innovate leads to less, not more, innovation over time.*

Without question, the American biologics drug industry is a golden goose, which is advancing the healthcare of our citizens. The presumption of many is that feeding this goose more and more will lead it to produce an ever-greater number of eggs at a faster pace. But doing so is very dangerous. After all, why should the goose produce as much when it has less incentive, and why should anyone look for a better goose if the current one cannot be displaced?

Fortunately, we don't need to guess how much to feed the biologics goose. Its chemical cousin — the pharmaceutical goose — is, from all appearances, essentially identical in its diet and response to incentives. What works for the pharmaceutical goose will surely work for the biologics one. And what works for the pharmaceutical goose in promoting and protecting innovation is the Hatch-Waxman legislation — a bill whose exclusivity provisions are sufficiently balanced as to not over-extend the duration of monopoly protection.

Close to a quarter of a century's experience speaks clearly. Hatch-Waxman provides its goose with a balanced diet — one that provides brand companies with appropriate incentives to develop and market their products, one that permits competitors to lower pharmaceutical prices to the public in a timely manner, and one that keeps new pharmaceutical discoveries coming at a rapid pace.

50 Nordhaus, William D., "The Optimal Life of a Patent," Cowles Foundation paper no. 2421, Yale University, November 27, 1967.

51 Loury, Glenn C., "Market Structure and Innovation," *The Quarterly Journal of Economics*, 93, 3, August 1979, 395-410.

Appendix: Industry Beta and Risk-Adjusted Cost of Equity

Industry Name	Firms in Sample	Beta	Beta/ Mean Beta	Cost of Equity	Cost of Equity/ Mean Cost of Equity
Market	7364	1.24	1.00	10.8%	1.00
Semiconductor	138	2.59	2.09	20.4%	1.89
Semiconductor Equipment	16	2.51	2.02	19.8%	1.83
Wireless Networking	74	2.2	1.77	17.6%	1.63
E-Commerce	56	2.08	1.68	16.8%	1.55
Entertainment Tech.	38	2.06	1.66	16.6%	1.54
Telecom. Equipment	124	1.98	1.60	16.1%	1.49
Internet	266	1.97	1.59	16.0%	1.48
Steel (Integrated)	14	1.97	1.59	16.0%	1.48
Manuf. Housing/RV	18	1.92	1.55	15.6%	1.45
Power	58	1.87	1.51	15.3%	1.41
Computers/Peripherals	144	1.86	1.50	15.2%	1.41
Pharmaceuticals	368	1.78	1.44	14.6%	1.35
Coal	18	1.71	1.38	14.1%	1.31
Steel (General)	26	1.71	1.38	14.1%	1.31
Precision Instrument	103	1.66	1.34	13.8%	1.28
Securities Brokerage	31	1.66	1.34	13.8%	1.28
Homebuilding	36	1.64	1.32	13.6%	1.26
Advertising	40	1.6	1.29	13.4%	1.24
Retail Automotive	16	1.58	1.27	13.2%	1.22
Cable TV	23	1.56	1.26	13.1%	1.21
Computer Software/Svcs.	376	1.56	1.26	13.1%	1.21
Auto & Truck	28	1.54	1.24	12.9%	1.20
Recreation	73	1.54	1.24	12.9%	1.20
Entertainment	93	1.53	1.23	12.9%	1.19
Chemical (Basic)	19	1.52	1.23	12.8%	1.18
Biotechnology	103	1.51	1.22	12.7%	1.18

Source: author's calculations based on betas posted 1/08 by Aswath Damodaran, NYU Professor of Finance at http://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/Betas.html. Cost of equity is calculated as $.02 + \text{beta} * (.091 - .02)$, where .02 is the risk-free real rate (based on prevailing TIPS yields) and .091 is the average annual real return on large-cap equity calculated from Ibbotson data from 1926 to the present.

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Laurence J. Kotlikoff is professor of economics at Boston University, research associate of the National Bureau of Economic Research, fellow of the American Academy of Arts and Sciences, fellow of the Econometric Society, and president of Economic Security Planning, Inc., a company specializing in financial planning software. Professor Kotlikoff received his B.A. in economics from the University of Pennsylvania in 1973 and his Ph.D. in economics from Harvard University in 1977. From 1977 through 1983 he served on the faculties of economics of the University of California, Los Angeles and Yale University. In 1981–82 Professor Kotlikoff was a senior economist with the President's Council of Economic Advisers. Professor Kotlikoff has served as a consultant to the International Monetary Fund, the World Bank, the Harvard Institute for International Development, the Organization for Economic Cooperation and Development, the Swedish Ministry of Finance, the Norwegian Ministry of Finance, the Bank of Italy, the Bank of Japan, the Bank of England, the government of Russia, the government of Ukraine, the government of Bolivia, the government of Bulgaria, the Treasury of New Zealand, the Office of Management and Budget, the U.S. Department of Education, the U.S. Department of Labor, the Joint Committee on Taxation, the Commonwealth of Massachusetts, the American Council of Life Insurers, Merrill Lynch, Fidelity Investments, AT&T, AON Corp., and other major U.S. corporations. He has provided expert testimony on numerous occasions to committees of Congress, including the Senate Finance Committee, the House Ways and Means Committee, and the Joint Economic Committee. Professor Kotlikoff is author or co-author of 13 books and hundreds of professional journal articles. His most recent book, co-authored with Scott Burns, is forthcoming with Simon & Schuster and is titled *Spend 'Til the End*. Professor Kotlikoff publishes extensively in newspapers and magazines on issues of deficits, generational accounting, the tax structure, Social Security, Medicare, health reform, pensions, saving, insurance, and personal finance.

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