AUXILIUM

Innovations for Life

2007 Annual Report to Shareholders

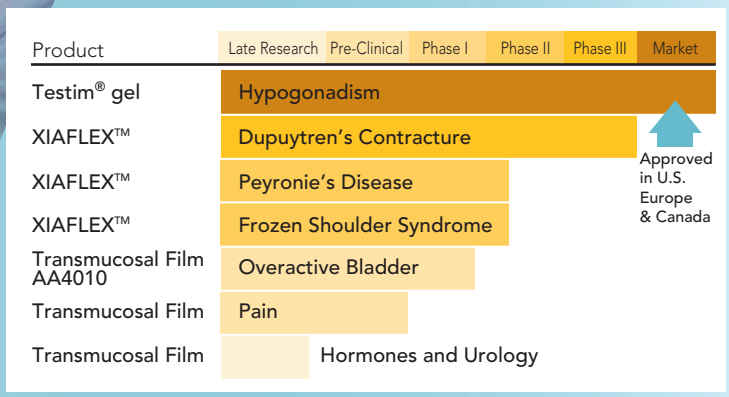
AUXILIUM

Innovations for life

COMPANY PROFILE Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing to urologists, endocrinologists, orthopedists and select primary care physicians. Auxilium markets Testim® 1%, a topical testosterone gel, for the treatment of hypogonadism through its approximately 190-person sales and marketing team. Auxilium has four projects in clinical development. XIAFLEX™ (clostridial collagenase for injection) is in phase III of development for the treatment of Dupuytren's contracture and is in phase II of development for the treatment of Peyronie's disease and Frozen Shoulder syndrome (Adhesive Capsulitis). Auxilium also has options to all indications using XIAFLEX for non-topical formulations. Auxilium's transmucosal film product candidate for the treatment of overactive bladder is in phase I of development. Auxilium has one pain product using its transmucosal film delivery system in pre-clinical development and has rights to seven additional pain products and products for hormone replacement and urologic disease using its transmucosal film delivery system.

Broad Pipeline Maturing in Coming Years

Providing innovative solutions for unique diseases that improve health and quality of life.



Armando Anido
Chief Executive Officer
and President

Letter to Shareholders

DEAR FELLOW SHAREHOLDER:

I am pleased to report that in 2007, we made tremendous progress advancing our mission to provide innovative solutions that improve health and quality of life for patients with unique diseases. In Latin, Auxilium means "assistance" and I believe all of our employees have shown they embody the purest spirit of assistance—striving to assist patients, diligently supporting each other through a busy 2007 and continuing to successfully shepherd our biopharmaceutical development and commercialization efforts. I am proud of our accomplishments in 2007 and believe we have built the foundation to excel and prosper in 2008.

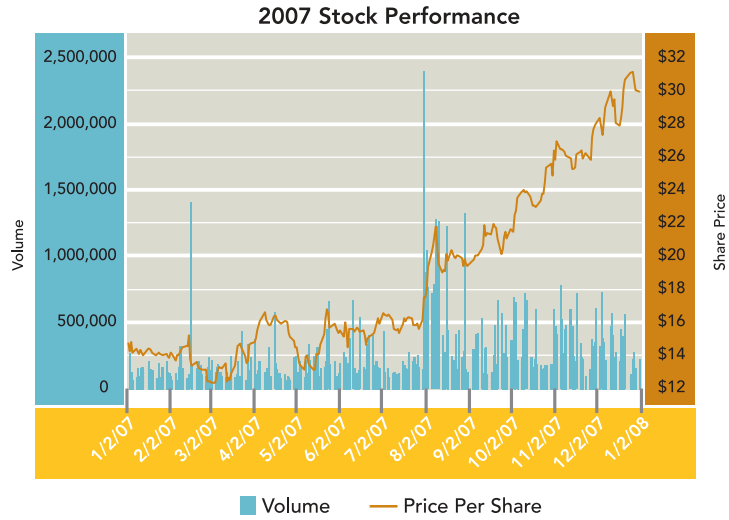
Two products sustain our mission and could offer significant growth opportunities for the Company: XIAFLEX, a potentially Company-transforming product in late-stage clinical development, which could give patients with Dupuytren's contracture and Peyronie's disease an alternative to invasive surgery; and Testim, which improves testosterone levels for hypogonadal men and remains the fastest growing testosterone replacement gel in the United States. During 2007, we focused on advancing our XIAFLEX Dupuytren's contracture Phase III clinical trial program, as well as starting to prepare for its commercialization in the United States and assessing the opportunity in the European Union (EU). At the same time, our sales force continued to drive Testim's growth and market share, and we achieved record sales of Testim in 2007. Both of these achievements reflect the hard work and commitment of our employees, and we thank them for their dedication.

OUR PEOPLE

As a result of our achievements, 2007 was an outstanding year of recognition for the Auxilium team. We were extremely proud to be named "Life Sciences Company of the Year" at the Eastern Technology Council's Enterprise Awards, which recognized outstanding technology and life sciences companies in the Greater Philadelphia region. Auxilium also was named a "Rising Star" in the Deloitte & Touche USA LLP 2007 Technology Fast 50 Program, a ranking of the Greater Philadelphia's 50 fastest growing technology and life sciences companies by percentage revenue growth. In addition, we were recognized as a finalist in the "10 Best Places to Work" competition conducted by the *Philadelphia Business Journal*, an honor which we believe validates our entrepreneurial culture that helps us attract and keep top industry talent. These awards are a testament to the passion and quality of our employees, who are enthusiastically committed to Auxilium's success.

Over the last year, we continued to add significant strength to our management team with seasoned executives in Sales & Marketing and Research & Development. Roger Graham, Jr. assumed the newly created position of Executive Vice President, Sales and Marketing. Dr. Tony DelConte joined the Company in the newly created role of Chief Medical Officer. We also appointed two new industry executives to our Board of Directors: Dr. Renato Fuchs and Dr. Dennis Langer, who bring expertise in biologic manufacturing and research and development, respectively. We believe that these and other new Auxilium team members will bring a breadth of experience that will be invaluable to us as we continue to develop as an organization.

Auxilium's stock price closed 2007 at $29.99, up 104% for the year.



Innovative treatment

XIAFLEX

We believe XIAFLEX will be an important therapeutic advance that could provide patients a new alternative to invasive and potentially unfulfilling surgical procedures and other treatments. Our initial indication for XIAFLEX is Dupuytren's contracture, a condition in which dense collagen accumulates and forms a disfiguring and debilitating cord in one or more fingers. As the disease progresses, the tightening collagen cord causes the fingers to permanently contract and can severely impair a patient's use of his or her hands. Today, the predominant treatment option for patients with Dupuytren's contracture involves anesthesia and surgical removal or slicing of the cord. Dupuytren's contracture prevalence has been estimated at 3-6% of the global Caucasian population and, according to our market research, we believe there are approximately 240,000 Dupuytren's contracture patients receiving surgery or some type of medical intervention in the U.S. and EU annually who could be candidates for XIAFLEX. Additionally, we believe there is a population of "watchful-waiting" Dupuytren's contracture patients who could also be eligible to receive a novel non-surgical treatment for their affected fingers.

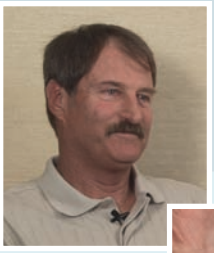
We made tremendous progress in the clinical development of XIAFLEX for Dupuytren's contracture in 2007. Results of our initial Phase III trial in patients with Dupuytren's contracture were published in the July-August 2007 issue of *The Journal of Hand Surgery*. The study was designed to determine whether XIAFLEX could address the need for effective, non-surgical treatment options to help resolve hand deformities that interfere with activities of daily living and quality of life. The results showed that ninety-one percent of patients treated with XIAFLEX achieved the primary endpoint, defined as a reduction in joint contracture to within 0-5° of normal. The study also highlighted that side effects with XIAFLEX were localized to the injection site and were transient as well as mild to moderate in nature.

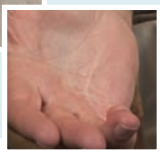
In August 2007, we received clearance from the U.S. Food and Drug Administration (FDA) to initiate our Phase III trials for the treatment of Dupuytren's contracture. By September 2007, we began enrolling patients in the pivotal U.S. CORD I trial and the Australian CORD II trial. I am proud to report that we were able to complete enrollment of these two double-blind, placebo-controlled trials within three months and exceeded our enrollment targets in both studies.

We have enrolled over 1,000 patients in the late-stage clinical trials of XIAFLEX in Dupuytren's contracture, and these patients have received in excess of 2,000 total injections. We anticipate reporting top-line efficacy and safety results from the CORD I and II trials in the second quarter of 2008 and anticipate filing a Biologics License Application (BLA) with the FDA in early 2009. We have also announced that we are exploring partnering opportunities for commercialization of XIAFLEX in the EU and expect to make progress in 2008 on deciding whether we should build our own infrastructure or work with an established pharmaceutical company to deliver the benefits of XIAFLEX in the EU.

XIAFLEX also has potential applications in other indications, and we are currently studying application in Peyronie's disease, which is characterized by build up of a collagen plaque or scarring in tissues of the penis. Like Dupuytren's contracture, this is also a disease that is debilitating for affected men and needs new treatment options as current surgical approaches are invasive and involve compromising outcomes. We have built a base of promising data from previous open-label Phase II studies and anticipate beginning a Phase IIb study by the end of the second quarter of 2008. We plan to continue to develop XIAFLEX in Peyronie's disease and expect to file a Supplemental BLA for a Peyronie's indication after a Dupuytren's contracture BLA approval. We currently estimate there to be

maximizing the value of our products





"As far as Dupuytren's and being a fireman, the disease had an effect on me as far as not being able to open my hand and perform certain day-to-day activities like climbing and in and out of the truck and handling tools. You can't open your hand and let go and almost have to roll your hand off of a handle. The biggest impact it had on me was taking nine months off of work for the surgeries to my right hand. After the first surgery, I was not satisfied with my results. Not at all. Very disappointed that it didn't work and that I had to go back for surgery a second and third time. Very dissatisfied. As far as having another surgical repair done, I would not want to do that. I would be opposed, very opposed."

ROD VAN SICKLE
Firefighter

"I am very excited about the potential of Xiaflex in the treatment of Dupuytren's disease. I think that it should be beneficial for the spectrum of Dupuytren's disease and honestly believe that it will become the first line of treatment for Dupuytren's disease in the future. The results for Xiaflex should be very comparable to what we achieve surgically, with a superior risk profile since it is minimally invasive. I would also expect Xiaflex patients to recover from administration and regain use of their hand much more quickly and with much less pain or dysfunction than we see with surgery."

DR. THOMAS KAPLAN
Clinical Assistant Professor of Orthopaedic Surgery at the Indiana School of Medicine and XIAFLEX clinical investigator

options

approximately 210,000 Peyronie's disease patients in the U.S. and EU on an annual basis that are recommended for surgery or medical treatment and could be candidates for XIAFLEX. Combined with Dupuytren's contracture, these two indications together potentially represent in excess of a $1 billion market opportunity for XIAFLEX. Additionally, we have acquired the world-wide marketing rights to use XIAFLEX in Adhesive Capsulitis (or Frozen Shoulder syndrome), and are currently working to develop a full clinical development program for this very exciting opportunity. We also believe that there may be other uses for XIAFLEX, and we are pleased that we have the exclusive option to secure marketing rights to any such use, other than dermal formulations labeled for topical administration.

While we did face a significant manufacturing challenge with XIAFLEX last year, I am pleased to report that our team responded with experience, urgency and poise to resolve the problem and put it in our rearview mirror. We worked systematically through the issue, making sure that we had the appropriate data to demonstrate that we had corrected the issue before asking the FDA to review our data package. We were rewarded with a very quick review from the FDA and the ability to restart the clinical trials earlier than we had expected. Today, we have not seen any indication that the "meltback" issue will return. We have completed approximately 10 production batches of XIAFLEX in our Horsham, PA manufacturing facility, which includes the commercial scale batches that we plan to submit as the conformance lots within our BLA. We have worked closely with a commercial scale filling and

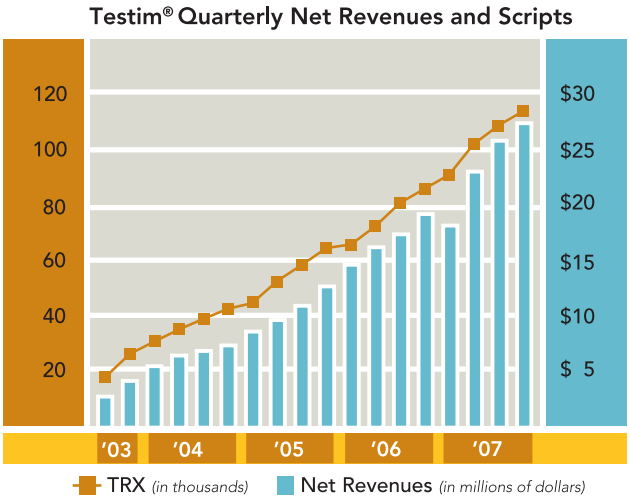
Xiaflex Product Team

Seated from left to right: Dr. Uli Schumann, *Senior Vice President, Clinical Development;* Dr. Ben Del Tito, *Senior Vice President, Regulatory Affairs and Quality;* Nancy Fetrow, *Vice President, Project Management. Standing from left to right:* Mike Cowan, *Vice President, Manufacturing;* Dr. Susan Hart, *Senior Director, Preclinical Development;* Diane Myers, *Vice President, Regulatory Affairs and Quality—U.S.;* Dr. John Rodzvilla, *Vice President, Medical Affairs;* Karen Cashmere, *Senior Vice President, New Product Marketing;* Jim Dahlberg, *Senior Project Director;* Dr. Ted Smith, *Vice President, Technical Operations. Not pictured:* Louise Peacock, *Vice President, Regulatory Affairs—International*

"I explain to patients with Dupuytren's contracture that surgery could possibly make them worse. Therefore surgery is best reserved for those patients whose contracted fingers are causing significant awkwardness on a daily basis. At that point, the benefits of surgery may outweigh the risks. For patients with less severely contracted fingers, it is frustrating for doctor and patient alike to have surgery and then be no better or even worse, and these unsatisfactory outcomes can occur on an entirely unpredictable basis."

DR. ROY MEALS
Clinical Professor of Orthopedic Surgery, UCLA School of Medicine, Los Angeles, California and XIAFLEX clinical investigator

For the full year 2007, net revenues totaled $95.7 million compared to net revenues of $68.5 million for the full year 2006, an increase of 40%.



lyophilization company, and we believe that we have a commercially viable manufacturing process in place that will enable our filing of the XIAFLEX BLA for Dupuytren's contracture in early 2009.

TESTIM

Auxilium's testosterone replacement therapy (TRT) product, Testim, is approved for use in treating men with hypogonadism, or low testosterone. This is a condition marked by lower-than-normal levels of testosterone production in men that can occur as they age. According to a 2006 study of over 2,100 men, it was projected that 39% of men over 45 years of age in the United States have low testosterone, but we estimate that only 10% of affected men are currently receiving treatment. Low testosterone levels have been linked to reduced energy, irritability, a loss in sexual desire, decreased muscle mass, loss of bone mass, and increased body fat. In 2008, we intend to continue to educate all appropriate audiences on a need for screening for low testosterone, as well as educate physicians and affected men on the benefits of Testim.

In 2007, Testim remained the fastest growing TRT on the market and Testim revenues grew to $95.7 million, a 40% increase over 2006. We ended the year with 21.5% share of the testosterone replacement gel market and were able to grow Testim prescriptions 35.2%, which was almost twice the rate of the overall TRT gel market growth. We believe these outstanding results were driven by an increased share of voice from the expansion of our sales force in late 2006 to 150 representatives and believe their efforts will continue to support the growth of Testim in 2008.

Ensuring Testim's long-term success is a focus for all of us at Auxilium. In January 2008, the U.S. Patent and Trademark Office issued a method of use patent covering Testim through January 2025. Since Testim now has extended patent protection, we plan to extend our clinical efforts for Testim and establish a leadership role for Auxilium by expanding the clinical experience with long-term use of TRT. This year, we plan to implement the Testim Registry in the U.S, or TRiUS, which will assess the long and short-term outcomes of TRT. We believe the registry will enhance the available data set for Testim and provide additional insights on its value, as well as that of TRT in the male hypogonadal patient population.

LOOKING AHEAD

We believe Auxilium is poised for continued growth in 2008. We will continue to focus on unlocking the value of our two key assets, XIAFLEX and Testim. We expect to release top-line results of our pivotal U.S. Phase III XIAFLEX Dupuytren's contracture clinical trial in the second quarter of 2008 and submit the BLA for Dupuytren's contracture in early 2009. We anticipate advancing development of a second indication for XIAFLEX with a Phase IIb study in Peyronie's disease in the second quarter of 2008. We also intend to explore partnering opportunities for XIAFLEX in the EU as part of our ongoing evaluation of options to maximize the product's potential outside the U.S. To continue to drive Testim's market share in 2008, we plan to launch a range of branded programs that are aimed at healthcare providers and their patients, as well as initiate clinical studies to support our leadership in the TRT market.

On behalf of Auxilium's management team and board of directors, I would like to thank our shareholders for your continued support. Additionally, I want to thank our employees for their untiring energy, spirited enthusiasm and unyielding commitment to making Auxilium a success. We have never been more excited about Auxilium's prospects, opportunities and potential success.

Sincerely,

Armando Anido
Chief Executive Officer and President

"Stepping off the course as the 2003 PGA Champion, I was certain my future in professional golf was assured. However, symptoms of low testosterone that soon followed my highest career point affected both my game and my family life. Testim therapy over these past few years has clearly helped me get back into the game of life in more ways than one."

SHAUN MICHEEL
Professional Golfer
and Testim Patient

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 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: 000-50855

Auxilium Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**23-3016883** **(I.R.S. Employer Identification No.)**
40 Valley Stream Parkway **Malvern, PA** **(Address of principal executive offices)**	**19355** **(Zip Code)**

(484) 321-5900
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, Par Value $0.01 Per Share	**Common Stock, Par Value $0.01 Per Share**

Securities registered pursuant to Section 12(g) of the Securities Exchange Act of 1934:

None

Indicate by check mark if the 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 Exchange 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.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ 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 voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on The NASDAQ Global Market as of June 30, 2007, was approximately $515.7 million.

As of March 3, 2008, the number of shares outstanding of the issuer's common stock, $0.01 par value per share, was 40,839,617.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for its Annual Meeting of Stockholders to be held on June 12, 2008, to be filed with the Securities and Exchange Commission, are incorporated by reference into Part III of this Form 10-K.

AUXILIUM PHARMACEUTICALS, INC.

FORM 10-K

December 31, 2007

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This Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements of historical information contained herein are forward-looking statements and may contain projections relating to financial results, economic conditions, trends and known uncertainties. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed in this Report. You should review the "Risk Factors" section of this Report for a discussion of the important factors that could cause actual results to differ materially from those described in or implied by the forward-looking statements contained in this Report. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis, judgment, belief or expectation only as of the date hereof. We undertake no obligation to publicly reissue these forward-looking statements to reflect events or circumstances that arise after the date hereof.

As used herein, the terms "Company," "Auxilium," "we," "us," or "our" refer to Auxilium Pharmaceuticals, Inc, and its subsidiaries.

PART I

ITEM 1. *Business*

Company Overview

Company Description

We are a specialty biopharmaceutical company with a focus on developing and marketing products to urologists, endocrinologists, orthopedists and select primary care physicians. We currently have approximately 300 employees, including a sales and marketing organization of approximately 190 people. Our only marketed product, Testim®, is a proprietary, topical 1% testosterone once-a-day gel indicated for the treatment of hypogonadism. Hypogonadism is defined as reduced or absent secretion of testosterone which can lead to symptoms such as low energy, loss of libido, adverse changes in body composition, irritability and poor concentration. We reported revenues in 2007 of $95.7 million, an increase of 40% over the $68.5 million reported in 2006. According to National Prescription Audit data from IMS Health, Inc., or IMS, a pharmaceutical market research firm, Testim's share of total prescriptions for the gel segment of the testosterone replacement therapy, or TRT, market was 21.5% for the month of December 2007, compared with 18.2% for the month of December 2006. For the full year 2007, Testim's share of total prescriptions for the TRT market was 20.0%, versus 17.4% for the full year 2006.

Our current product pipeline includes:

Phase III:

- XIAFLEX™ (clostridial collagenase for injection), formerly referred to as AA4500, for the treatment of Dupuytren's contracture

Phase II:

- XIAFLEX for the treatment of Peyronie's disease
- XIAFLEX for the treatment of Frozen Shoulder syndrome (or Adhesive Capsulitis)

Phase I:

- AA4010, treatment for overactive bladder using our transmucosal film delivery system

Preclinical:

- one pain product using our transmucosal film delivery system.

In addition to the above, we have the rights to develop seven other compounds for the treatment of pain using our transmucosal film delivery system and other products using our transmucosal film technology for treatment of urologic disease and for hormone replacement. We also have the option to license additional indications for XIAFLEX other than dermal products for topical administration.

Company Strategy

Our goal is to build a leading specialty biopharmaceutical company by focusing on disease states that we believe can be addressed through sales to predominantly specialist audiences, such as urologists, endocrinologists, certain targeted primary care physicians and subsets of orthopedic surgeons. We have an experienced development, regulatory and commercial team that has a proven track record. We intend to draw upon our track record and experience to successfully develop our product candidates. Our strategy will focus on developing and commercializing XIAFLEX, optimizing Testim's commercial success and developing and commercializing products utilizing our transmucosal film technology delivery system.

Developing and Commercializing XIAFLEX. We believe that XIAFLEX represents a significant opportunity for us, and we are devoting what we believe to be the appropriate resources to the development and pre-commercialization of this product. For Dupuytren's contracture and Peyronie's disease, we believe there is a large unmet medical need for a non-surgical solution to these debilitating diseases and that the data from our well-controlled phase II studies and from an initial phase III study are encouraging. The product has received orphan drug designation in the U.S. for both indications, and our preliminary market research leads us to believe that urologists and orthopedic surgeons would be very likely to use the product to delay or avoid surgery. We believe that there are approximately 450,000 patients on an annual basis in the U.S. and Europe who could be candidates for XIAFLEX with approximately 240,000 for the treatment of Dupuytren's contracture and approximately 210,000 for the treatment of Peyronie's disease. These patients represent an annual market potential in excess of $1 billion, assuming that we are able to price treatments using XIAFLEX on a basis comparable to the cost of surgery for these indications. We have exclusive worldwide rights to develop, market and sell products containing XIAFLEX, other than dermal formulations labeled for topical administration. Specifically, we currently have rights to XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. We are exploring partnering opportunities for XIAFLEX in Europe as part of our ongoing evaluation of options to maximize the product's potential in Europe. We believe that we have two broad options available to us to commercialize XIAFLEX in Europe, specifically doing it on our own or establishing a partnership. We believe we can only compare the merits of these two options after finding out what a potential out-licensing arrangement could bring. Therefore, the final decision as to how and by whom XIAFLEX will be commercialized in Europe depends on the results of discussions with potential partners.

Optimizing Testim's Commercial Success. Testim has demonstrated an ability to capture market share in the gel segment of the TRT market and the total TRT market. We believe that we can continue to increase sales of Testim by capturing market share, expanding the use of TRT through increased physician and patient awareness and benefiting from the on-going demographic changes that could result in additional patient candidates for TRT treatment.

- Increase Testim market penetration. Through on-going evaluation of physician targeting and greater sales efficiencies, we intend to improve the effectiveness of our sales force. We will continue to work with accredited education groups, thought leaders and professional organizations to further educate physicians about diagnosis and the benefits of TRT, including Testim. We are focusing our 150 sales representatives on urologists, endocrinologists and certain key primary care physicians. This allows us to reach approximately 70% of the physicians that prescribe testosterone replacement therapies. We also have entered into two collaborations with partners for the international commercialization of Testim. Paladin Labs Inc., or Paladin, launched Testim in Canada during 2007, and Ipsen Pharma GmbH, or Ipsen, has been promoting Testim in Europe since 2005.
- Expand market opportunities for Testim and TRT. A 2006 study that was published in *The International Journal of Clinical Practice* showed 39% of men over 45 years of age have low testosterone (total testosterone levels below 300 ng / dL). According to the U.S. Census Bureau, there were 43.6 million men aged 45 to 84 in 2000, and these figures are expected to increase to 54.6 million by 2010. As a result, we expect to see an increase in the number of potential patients over the coming years.

  In addition, it has been demonstrated that low testosterone is associated with conditions such as diabetes, obesity, hyperlipidemia, chronic pain and HIV/AIDS. With improved medical and patient education around the implications of low testosterone and the favorable risk/benefit profile of treating with TRT, we believe physicians will be more proactive in identifying hypogonadism and treating patients. In 2007, the total prescriptions of gel market increased 17.7% over 2006.

  We will continue to incorporate focused educational efforts to both physicians and consumers to create an increased awareness of both the prevalence and medical need for identifying and treating hypogonadism.

Developing and Commercializing Transmucosal Film Technology. We believe delivery of pharmaceuticals across the mucosal membrane of the mouth offers important advantages to patients, including the possibility to achieve therapeutic benefits with significantly lower doses of drug, and the possibility of a convenient, once or twice daily dosing regimen. Our transmucosal film product candidate for the treatment of overactive bladder (AA4010) is in phase I of development. We currently are willing to partner to further develop this product candidate. We have one pain product using our transmucosal film delivery system in pre-clinical development. We also have rights to seven additional pain products and products for hormone replacement and urologic disease using our transmucosal film delivery system.

XIAFLEX Opportunity

XIAFLEX is an injectable collagenase enzyme we in-licensed from BioSpecifics Technologies Corp., or BioSpecifics. Under our agreement with BioSpecifics, we have exclusive worldwide rights to develop, market and sell certain products containing XIAFLEX. Our licensed rights concern the development of products, other than dermal formulations labeled for topical administration. Currently, we are developing XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. We may expand our agreement with BioSpecifics, at our option, to cover other indications as they are developed by us or BioSpecifics.

Dupuytren's Contracture

Disease state and market: Dupuytren's contracture is a condition that affects the connective tissue that lies beneath the skin in the palm. The disease is progressive in nature. Typically, painful nodules develop in the palm as collagen deposits accumulate. As the disease progresses, the collagen deposits form a cord that stretches from the palm of the hand to the base of the finger. Once this cord develops, the patient's fingers contract and the function of the hand is impaired. Currently, surgery is the only effective treatment. According to Dupuytren's Disease by Leclercq published in 2000, the global prevalence of Dupuytren's contracture among today's Caucasian population is estimated to range from 3% to 6%. Common co-morbidities include diabetes, epilepsy, alcoholism or HIV. Dupuytren's contracture is most common in men. It usually starts in adult life, with a peak incidence in people aged 40 to 60. In about 50% of patients, the disease affects both hands, and recurrence after surgical treatment is common (as high as 30% the first two years post-surgery; and 55% within 10 years of surgery). Due to the recurrent nature of the disease, multiple corrective surgeries are often required, which become increasingly complex. XIAFLEX is injected directly into the cord and the procedure could be performed in a physician's office. We believe XIAFLEX as a treatment for Dupuytren's contracture represents an attractive and addressable market for us as a specialty biopharmaceutical company.

Current treatment options: Surgical techniques used to treat patients with Dupuytren's contracture fall into two major groups: fasciotomy which is simply cutting the Dupuytren's cord and fasciectomy which is removing the cords of the diseased tissue. There is risk associated with surgery which includes scarring, infection, hematoma, skin necrosis, finger stiffness and injury to nerves and blood vessels. Several non-operative treatments, including radiotherapy, steroids, interferon and topical vitamin E, have been tried in Dupuytren's disease, but none has been adopted in general use. No medicinal therapy attempted to date other than collagenase has been proven effective. Although preliminary observations suggest that intralesional interferon gamma may reduce the size of Dupuytren's cords (Pittet et al., 1994), further data are needed to assess whether it offers any clinical benefits.

R&D status: An initial phase III study by BioSpecifics was comprised of a randomized, placebo-controlled, double-blind phase, as well as an open-label phase. Data from the double-blind phase showed that injecting XIAFLEX led to a 91% success rate in reducing joint contracture to within five degrees of normal, compared to the placebo group in which no patients achieved success. In the open-label phase, in which patients had additional joints treated with XIAFLEX, results showed that 88% of Metacarpophalangeal (MP) joints and 68% of Proximal Interphalangeal (PIP) joints were fully corrected. This study was published in *The Journal of Hand Surgery* in June 2007 and the data were consistent with phase II data previously published in *The Journal of Hand Surgery* in 2002. In December 2006, we suspended the dosing of patients in our ongoing phase III trials for XIAFLEX for the treatment of Dupuytren's contracture in response to an issue related to the manufacture of clinical supplies. Phase III trials resumed in September 2007. In December, 2007, patient enrollment was completed in Auxilium's second U.S. phase III pivotal trial (CORD I) and its Australian phase III study (CORD II) of XIAFLEX for the treatment of Dupuytren's contracture. In accordance with the study design, all enrolled patients have received their first injection of either XIAFLEX or placebo. We were able to exceed enrollment targets in both studies, with greater than 300 patients enrolled in the CORD I and CORD II studies combined. Auxilium had targeted enrolling 216 patients in CORD I and 60 patients in CORD II. We expect to release top line efficacy results from these two trials in the second quarter of 2008. We have now completed enrollment in the U.S. JOINT I open label study. At this point we continue to actively enroll patients in JOINT II in Europe, and we expect to complete enrollment in the first quarter of 2008. As of March 5, 2008, we have enrolled approximately 890 patients in all of the clinical trials started in the third quarter of 2007 and these patients have received in excess of 1980 total injections.

Peyronie's Disease

Disease state and market: Peyronie's disease is characterized by a plaque or hard lump that occurs on the penis. It begins as a localized inflammation, which progresses to a hardened scar on the shaft of the penis that reduces flexibility and causes the penis to bend during erection. This may cause pain on erection and a deformity that may prevent sexual intercourse altogether. Our market research indicates that, aside from the physical consequences, depression and loss of self-esteem are common in men with Peyronie's disease. According to Peyronie's Disease, A Guide to Clinical Management by Levine, published in 2007, the prevalence of Peyronie's disease has been increasing during the last 30 years and now ranges between 3.7% and 7.1%. However, the actual prevalence may be higher because of patients' reluctance to report this embarrassing condition to their physicians. The pathogenesis of Peyronie's disease appears to be multifactorial, with an interplay of genetic predisposition, trauma, and tissue ischemia. Generally, Peyronie's disease is treated by urologists. To date, no medical therapy has been proven effective for the treatment of Peyronie's disease. Surgical treatment may be an option for some patients, although complications as well as loss of penile length can occur.

Administration of XIAFLEX could be an in-office procedure in which the product is injected directly into the plaque causing the penile curvature. Early phase II clinical work with XIAFLEX in patients with Peyronie's disease indicates that the product improves the curvature of the penis, and in some cases restores the ability to have sexual intercourse. Additional studies will be needed.

Current treatment options: As with Dupuytren's contracture, there are no medicinal products approved for the treatment of Peyronie's disease. There are very few prospective, blinded, randomized and controlled studies with standardized outcomes of sufficient power conducted to date to evaluate the proposed medicinal therapies. The following are therapies that have been used without much success: Vitamin E, Colchicine, Potassium Aminobenzoate (Potaba), Tamoxifen, Interferon a2a, Corticosteroids, and Energy Transfer Treatment including extracorporeal shock wave therapy (ESWT), laser and ultrasound therapy, and orthovoltage radiation. Surgical therapies include application techniques, graft-based techniques and prothetic techniques.

R&D status: Previous phase II studies by BioSpecifics indicate possible effectiveness of XIAFLEX in this disease state. We have conducted an animal study requested by FDA to determine the local effects of XIAFLEX injected in normal penile tissue. We expect to commence a phase IIb study for XIAFLEX as a treatment for Peyronie's disease in the first half of 2008, assuming approval by the FDA of the animal study results and the proposed phase IIb protocol.

Frozen Shoulder Syndrome

Disease state and market: Frozen Shoulder syndrome is a disorder of diminished shoulder motion, characterized by restriction in both active and passive range of motion of the shoulder joint. Frozen Shoulder syndrome usually affects patients aged 40-70 years. According to *Harrison's Principles of Internal Medicine*, it is estimated that 3% of people develop Frozen Shoulder syndrome over their lifetime and that women tend to be affected more frequently than men. The condition may affect both shoulders, either simultaneously or in sequence, in up to 16% of patients. Recurrence of Frozen Shoulder syndrome is common within five years of the onset of the disorder. According to Dahan et. al. in the 2005 eMedicine article "Adhesive Capsulitis," a higher incidence of Frozen Shoulder syndrome exists among patients with diabetes (10-20%) compared to the general population (2-5%) and incidence among patients with insulin-dependent diabetes is even higher (36%), with an increased frequency of bilateral shoulder involvement.

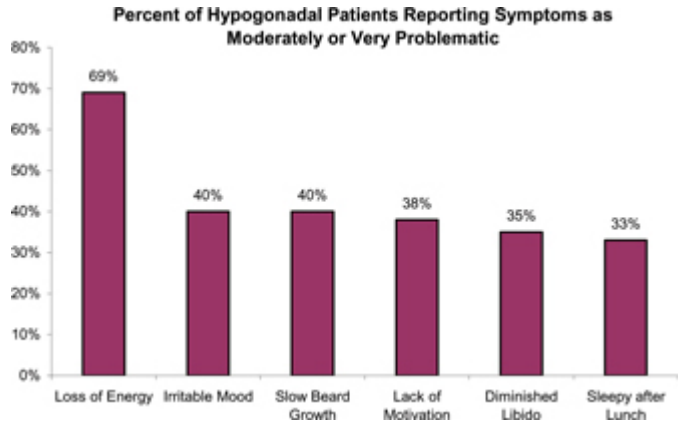
Current treatment options: The most common treatment for Frozen Shoulder syndrome is extensive physical therapy, corticosteroids and/or arthroscopy. Drugs are used to manage pain, but none have been demonstrated to have an impact on Frozen Shoulder syndrome.

R&D status: BioSpecifics has conducted a phase II clinical trial using XIAFLEX for the treatment of Frozen Shoulder syndrome. Three different doses of the enzyme were compared to placebo in this prospective, randomized, 60-subject trial. The results from this trial suggest that local injection of the enzyme is well-tolerated and may be effective in patients suffering from Frozen Shoulder syndrome. Additional studies are needed to assess the optimal dose and dosing regimen of XIAFLEX for this indication. We have started certain non-clinical activities that we believe are necessary for advancing the program to the next stage of clinical trials.

Testim Opportunity

Hypogonadism market

Hypogonadism, or low testosterone, is a disorder that affects millions of men in the U.S. A 2006 study in *The International Journal of Clinical Practice* showed that 39% of men over 45 years of age have low testosterone (total testosterone levels below 300 ng / dL). Hypogonadism also affects a high percentage of men with certain co-morbidities regardless of age. This study documented associations with other co-morbidities such as: Obesity (52%), Diabetes (50%) and Rheumatoid Arthritis (47%)[1]. Other articles have highlighted associations with other conditions: HIV (30%)[2], Erectile Dysfunction (18%)[3] and up to 74% of men being treated with high doses of opioids for chronic pain[4]. The effects of low testosterone lead to symptoms such as low energy, diminished libido, adverse changes in body composition, irritability and poor concentration. According to a recent study, the impact of these symptoms on an afflicted person can be significant.



TRT is the standard treatment for hypogonadism. According to IMS, the total number of prescriptions within the TRT market has grown from 1.0 million to 2.9 million prescriptions between 2000 and 2007. Before 2000, the TRT market consisted of oral, injectable and patch therapies. In 2000, the first topical gel was introduced, and this product segment has been the driver of much of the total growth in the TRT market. According to IMS, the gel segment accounted for approximately 73% of the total prescriptions in the TRT market in the fourth quarter of 2007. Despite this growth, we estimate that approximately 10% of men with hypogonadism currently receive TRT. According to our physician research, this low diagnosis rate stems primarily from low patient and physician awareness of the symptoms, treatment options and monitoring requirements.

Testim has captured a significant portion of the gel prescription growth since its launch in early 2003, and held a 21.5% prescription share of this market in December 2007. In 2007, prescriptions of Testim grew by 35.2% compared to 2006. The gel market continued to drive the growth of the TRT market in 2007. Gel prescriptions grew 17.7% compared to 2006. All other formulations (injectables, patches, orals and buccals) combined increased 6% year over year.

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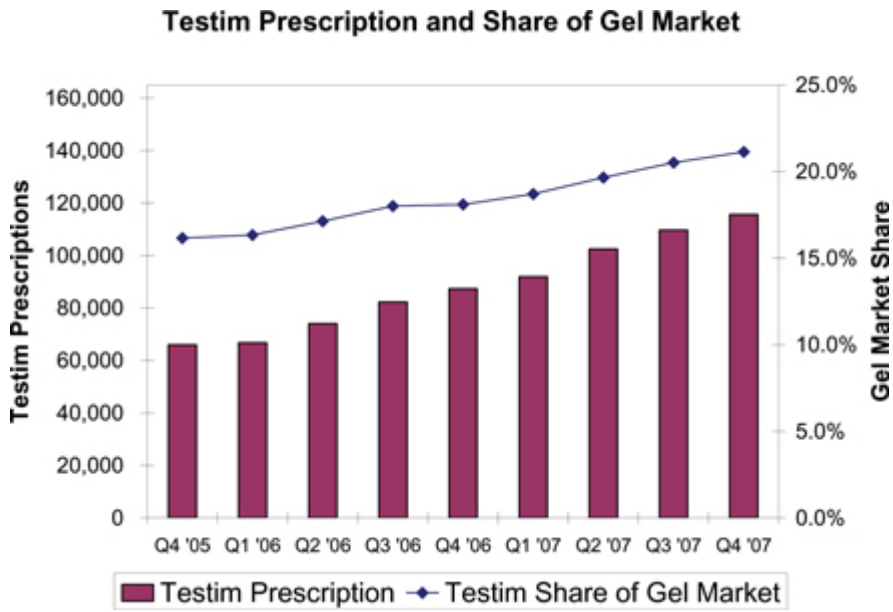
[1] Mulligan T. et al. *Int J. Clin Pract* 2006
[2] Dobs A.S. *Clin Endocrinol Metab.* 1998
[3] Bodie J. et al. *J. Urol.* 2003
[4] Daniell H.W. *J. Pain* 2002



Source: IMS

We believe Testim's growth has been due to Testim's favorable clinical profile and our increased sales and marketing efforts in 2006 and 2007. Our sales organization of approximately 150 representatives promotes Testim to urologists, endocrinologists and key primary care physicians. We believe this focused, consistent messaging will continue to drive the recognition of hypogonadism and increase Testim prescriptions.

Testim is a proprietary, topical 1% testosterone once-a-day gel that treats hypogonadism by restoring testosterone blood levels back to normal for a 24-hour period following application. Testim is packaged in convenient, easy-to-open, single-use tubes. Patients apply Testim once per day to the upper arms and shoulders, enabling Testim's active ingredient, testosterone, to be absorbed through the skin and into the bloodstream.

Clinical data supporting the advantages of Testim. We have designed and conducted our clinical trials to provide prescribing physicians with comprehensive information regarding Testim's benefits. Since 2001, we have completed 16 clinical studies involving approximately 1,800 patients including the largest placebo controlled study (n=400) ever conducted to evaluate the benefits and risks of TRT. We conducted five of these studies using Testim and other TRT products, including a transdermal patch and the other commercial gel. The results from these five studies, taken together, demonstrate that in patients with hypogonadism, testosterone levels directly correlate with patient symptom improvement.

In October, 2007, the manuscript "Efficacy of Testosterone Gel Substitution (Androgel® or Testim) among sub-optimally responsive hypogonadal men" by L. Lipshultz, E. Grober, M. Khera, M. Espinoza was posted in the International Journal of Impotence Research web site. The data from this independent study show improvements in symptoms of decreased libido, energy levels and erectile function in 76 percent of hypogonadal men after switching brands of testosterone replacement gel

therapy. Total testosterone levels increased significantly in patients who switched to Auxilium's Testim® 1% (testosterone gel) following suboptimal response to Solvay S.A.'s Androgel® (testosterone gel) 1% but did not increase significantly in patients who switched from Testim to Androgel.

Cost effectiveness and convenience. We believe that, based on clinical data regarding testosterone levels in patients, market feedback from physicians, and the results of our clinical trials, a higher percentage of patients are treated with only one tube of Testim per day (one dose per day) compared to patients being treated with the other commercial gel who may need more than one dose of that product per day.

Broad prescription coverage. Currently, we have broad third-party payor reimbursement for Testim and Testim is covered by the majority of reimbursement plans.

Broad patent coverage. On January 22, 2008, the U.S. Patent and Trademark Office, or USPTO, issued U.S. Patent No. 7,320,968 covering Testim. The patent expires in January 2025 and has been listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the FDA. Continuations and a divisional application have been filed with the USPTO which if granted should expand patent claims covering Testim.

Transmucosal Film Technology

We are developing product candidates using an oral transmucosal drug delivery system based on patented technology licensed from Formulation Technologies, L.L.C., doing business as PharmaForm. The basis of this technology is a film that adheres to the upper gum. We have the exclusive worldwide right to use this technology platform in therapeutic products that contain hormones or that treat urologic disorders and in certain pain products. We currently have two product candidates using this technology:

- AA4010, our therapy to treat overactive bladder, in phase I of development for which we expect to seek a partner to further develop the product; and
- one pain product candidate in the pre-clinical phase of development for the management of pain.

Licensing

We have entered into agreements for the in-licensing of technology and products. We intend to pursue other licensing agreements and collaborations in the future.

Bentley Pharmaceuticals

We entered into two separate license agreements with Bentley Pharmaceuticals, Inc., or Bentley, that give us access to Bentley's patented transdermal gel technology. In May 2000, Bentley granted us an exclusive, worldwide, royalty-bearing license to make and sell products incorporating Bentley's formulation technology that contains testosterone. We produce Testim under this license. The term of this agreement is determined on a country by country basis and extends until the later of patent right termination in a country or 10 years from the date of first commercial sale. In May 2001, Bentley granted us similar rights for a product containing another hormone, the term of which is perpetual. Under these agreements, we are required to make up-front and milestone payments to Bentley upon contract signing, the decision to develop the underlying product, and the receipt of FDA approval.

BioSpecifics

In June 2004, we entered into a development and license agreement with BioSpecifics and amended the agreement in May 2005 and December 2005 (the BioSpecifics Agreement). Under the BioSpecifics Agreement, we were granted exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme, which we refer to as XIAFLEX. Our licensed rights concern the development of products, other than dermal formulations labeled for topical administration, and currently, our licensed rights cover the indications of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. We may further expand the BioSpecifics Agreement, at our option, to cover other indications as they are developed by us or BioSpecifics.

The BioSpecifics Agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. We may terminate the BioSpecifics Agreement upon 90 days prior written notice.

We are responsible, at our own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products (except for costs paid to third parties to develop the lyophilization of the injection formulation which shall be shared equally by Auxilium and BioSpecifics).

BioSpecifics has the option, exercisable no later than six months after FDA approval of the first New Drug Application or Biologics License Application with respect to a product, to assume the right and obligation to supply, or arrange for the supply from a third party other than a back-up supplier qualified by us, of a specified portion of our commercial product requirements. The BioSpecifics Agreement provides that we may withhold a specified amount of a milestone payment until:

- BioSpecifics executes an agreement, containing certain milestones, with a third party for the commercial manufacture of the product
- BioSpecifics commences construction of a facility, compliant with cGMP, for the commercial supply of the product; or
- 30 days after BioSpecifics notifies us in writing that it will not exercise the supply option.

If BioSpecifics exercises the supply option, commencing on a specified date, BioSpecifics will be responsible for supplying either by itself or through a third party other than a back-up supplier qualified by us, a specified portion of the commercial supply of the product. If BioSpecifics does not exercise the supply option, we will be responsible for arranging for the entire commercial product supply. In the event BioSpecifics exercises the supply option, we and BioSpecifics are required to use commercially reasonable efforts to enter into a commercial supply agreement on customary and reasonable terms and conditions which are not worse than those with back-up suppliers qualified by us.

We must pay BioSpecifics on a country-by-country and product-by-product basis a specified percentage of net sales for products covered by the BioSpecifics Agreement. Such percentage may vary depending on whether BioSpecifics exercises the supply option. In addition, the percentage may be reduced if:

- BioSpecifics fails to supply commercial product supply in accordance with the terms of the BioSpecifics Agreement;
- market share of a competing product exceeds a specified threshold; or
- we are required to obtain a license from a third party in order to practice BioSpecifics' patents without infringing such third party's patent rights.

In addition to the payments set forth above, we must pay BioSpecifics an amount equal to a specified mark-up of the cost of goods sold for products sold by us that are not manufactured by or on behalf of BioSpecifics, provided that, in the event BioSpecifics exercises the supply option, no payment will be due for so long as BioSpecifics fails to supply the commercial supply of the product in accordance with the terms of the BioSpecifics Agreement.

Finally, we will be obligated to make contingent milestone payments upon the filing of regulatory applications and receipt of regulatory approval. Additional milestone obligations will be due if we exercise an option to develop and license XIAFLEX for additional medical indications. Pursuant to the BioSpecifics Agreement, the milestone for each additional indication is $500,000, except for cellulite which is $1,000,000.

PharmaForm

In June 2003, we entered into a license agreement with PharmaForm. Under this agreement, as amended, we were granted an exclusive, worldwide, royalty-bearing license to develop, make and sell products that contain hormones or that are used to treat urologic disorders incorporating PharmaForm's oral transmucosal film technology for which there is an issued patent in the U.S. The term of this license agreement is for the life of the licensed patents.

In February 2005, we entered into an additional license agreement with PharmaForm. Under this agreement, we were granted exclusive, worldwide royalty-bearing rights to develop, manufacture and market eight compounds using PharmaForm's proprietary transmucosal film technology for the management of pain, including acute and chronic pain. The term of this license agreement continues on a product by product and country by country basis until the later of ten years after the first commercial sale or last to expire patent covering the licensed technology. The compounds that may be developed include opioids as well other types of analgesics. In addition, we will have on-going royalty payment obligations to PharmaForm. The timing of the remaining payments, if any, is uncertain.

We also entered into a research and development agreement with PharmaForm on a fee for service basis. We will be the sole owner of any intellectual property rights developed in connection with this agreement.

Manufacturing

We currently use, and expect to continue to depend on, contract manufacturers to manufacture Testim. We may depend on contract manufacturers to manufacture any products for which we receive marketing approval and to produce sufficient quantities of our product candidates for use in preclinical and clinical studies.

We and our contract manufacturers are subject to an extensive governmental regulation process. Regulatory authorities in our markets require that drugs be manufactured, packaged and labeled in conformity with current good manufacturing practices, or cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. We have established an internal quality control and quality assurance program, including a set of standard operating procedures and specifications that we believe is cGMP-compliant.

Testim

DPT. Testim is manufactured for us by DPT Laboratories, Ltd., or DPT, pursuant to a manufacturing and supply agreement that expires on December 31, 2010. During the term of the agreement, subject to our right to qualify and order Testim from a back-up supplier, DPT is required to manufacture all of our worldwide commercial requirements of Testim. The manufacturing fees paid to DPT are based upon the specified annual volume of Testim ordered by us. If we order less than a specified amount of Testim in any calendar year, the parties are required to negotiate to establish new manufacturing fees, with the understanding that DPT will continue to produce Testim for a specified minimum period in order to enable us to identify and utilize another supplier. DPT may terminate the agreement only upon our insolvency or bankruptcy or upon our breach of the agreement. We have qualified a back-up supplier.

Testosterone, a non-animal derived hormone, is currently available to us from only two sources. We purchase testosterone from both sources but do not have an agreement with either of these suppliers. We acquire CPD, a critical ingredient for the manufacture of Testim, from a single source. We endeavor to maintain what we believe is an adequate inventory of the key ingredients of Testim.

XIAFLEX

Horsham. In September 2006, we leased a 50,000 square foot biological manufacturing facility in Horsham, Pennsylvania that we are using to produce the active ingredient of XIAFLEX. The initial term of the lease expires on January 1, 2017. We believe we will be the sole supplier of the active pharmaceutical ingredient for commercial supply of XIAFLEX and will use a contract manufacturer to fill and lyophilize the XIAFLEX bulk substance and produce sterile diluent.

Cobra. We qualified Cobra Biologics Ltd., or Cobra, as the supplier of XIAFLEX for use in our clinical trials. In July 2005, we entered into an agreement with Cobra for the process development, scale up and manufacture of XIAFLEX for phase II/III clinical trials (the Manufacturing Agreement). Through an agreement dated July 14, 2006 (the Amended Manufacturing Agreement), we terminated the Manufacturing Agreement and agreed that Cobra will manufacture the XIAFLEX batches needed for clinical trials and for the Biological License Application (BLA) to be filed under the U.S. Federal Food, Drug and Cosmetic Act and related applicable regulations and will provide related services upon our request. In November 2006, we entered into a letter agreement with Cobra (the Amendment) that further amended the Amended Manufacturing Agreement.

Althea. Pursuant to our agreement with Althea Technologies, Inc., or Althea, Althea filled and lyophilized the XIAFLEX bulk substance, manufactured placebo and produced sterile diluent for XIAFLEX used in our clinical trials.

BioSpecifics. Under the terms of our agreement with BioSpecifics, BioSpecifics has the option, exercisable no later than six months after FDA approval of the first New Drug Application or Biologics License Application with respect to a product, to assume the right and obligation to supply, or arrange for the supply from a third party other than a back-up supplier qualified by us, of a specified portion of commercial product required by us. The terms of our agreement with BioSpecifics are summarized above.

Distribution

We have secured collaboration partners for the sale of Testim in geographic locations where we do not have our own sales force. We may pursue other collaborations for Testim and other products in the future.

Ipsen

We entered into a license and distribution agreement with Ipsen in March 2004. This agreement is exclusive and royalty-bearing for the longer of ten years from the date of first commercial sale by country or the life of the Bentley patent, including any newly issued patents. The European patent that we license from Bentley for Testim expired in November 2006. The European Patent Office granted a new patent, which is included in our license from Bentley, on August 29, 2007. That patent will expire in April 2023. Ipsen is a European pharmaceutical company with a worldwide commercial presence and a strong urology focus. Under this agreement, we granted Ipsen an exclusive license to use and sell Testim on a worldwide basis outside the U.S., Canada, Mexico, and Japan, and in January 2008, we amended that agreement to exclude, in addition, China, Poland, Russia, and South Korea and their territories and possessions. The terms of this agreement require Ipsen to purchase all Testim supply from us or exercise their conditional option for a technology transfer and to make up-front, milestone and royalty payments. Future milestone payments will be due upon regulatory approval, product launch in various countries and supply price reductions. The royalty payments are based on net product revenue and are similar to royalty payments due to Bentley.

Paladin

We entered into a license and distribution agreement with Paladin in December 2006. We granted Paladin an exclusive license to use and sell Testim in Canada. The terms of this agreement require Paladin to purchase all Testim supply from us and to make up-front, milestone and royalty payments.

We do not expect sales of Testim outside of the U.S. pursuant to our current collaboration agreements to have a material impact on our revenues or profitability.

Competition

We face competition in North America, Europe and elsewhere from larger pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies that are developing and commercializing pharmaceutical products. Many of our competitors have substantially greater resources than we have and subsequently may develop products that are more effective, safer or less costly than any that have been or are being developed by us or that are generics. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for Testim or any products for which we receive marketing approval.

AndroGel

The primary competition for Testim in the TRT market is AndroGel, marketed by Solvay Pharmaceuticals, Inc., or Solvay. Solvay has the advantage of having launched AndroGel three years prior to Testim. Watson Pharmaceuticals, Inc., or Watson, began co-promoting AndroGel with Solvay in late 2006, and Par Pharmaceutical Companies, Inc., or Par, began co-promoting AndroGel in early 2007. Solvay and its co-promotion partners collectively have more than 600 sales representatives detailing AndroGel. According to IMS, as of December 31, 2007, AndroGel accounted for 78.5% of the gel prescriptions, down from 81.8% in December, 2006. This resulted from AndroGel's share declining each quarter in 2007, while Testim's share of the gel market increased.

Other Delivery Options

Testim also competes with other TRTs such as injectables, patches, orals and a buccal tablet. The injectables have maintained presence in the market due to the low cost compared to the transdermal options. There are also a significant number of patients who prefer getting a shot every two to three weeks instead of utilizing a daily application of another product. Physicians perceive the disadvantage of the injectables as being the fact that many patients' testosterone levels rise past the normal barrier of 1000 ng/dl which leads to a wide flux of levels in a patient and the potential for side effects such as gynecomastia. Androderm® is a transdermal testosterone patch marketed by Watson. Androderm is the leading patch product and accounted for approximately 7.4% of total TRT prescriptions in December 2007. The number of Androderm prescriptions has decreased in the last year. The buccal therapy accounts less than 1% of total TRT prescriptions in December 2007.

Generic Competition

In July 2003, Watson and Par filed abbreviated new drug applications, or ANDAs, with the FDA to be approved as generics for AndroGel. In response to these ANDAs, Solvay filed patent infringement lawsuits against these two companies to block the approval and marketing of the generic products. In 2006, all the subject companies reached an agreement pursuant to which Watson and Par agreed not to bring a generic to Androgel to the market until 2015. During this time frame, Solvay, Watson and Par will co-promote AndroGel. Any generic for AndroGel will not be a generic for Testim, since Testim is BX rated (or non-substitutable) with AndroGel. Other pharmaceutical companies may develop generic versions of any products that we commercialize that are not subject to patent protection or other proprietary rights. Governmental and other cost containment pressures may result in physicians writing prescriptions for these generic products.

Future Delivery Options

In addition to potential generic competition, several other pharmaceutical companies have TRT products in development that may be approved for marketing in the U.S. and the rest of the world. Based on publicly available information, we believe that these products are in the development phases noted below.

Phase III—Indevus Pharmaceuticals, Inc. has licensed a long acting testosterone injection that is currently marketed in Europe under the trade name, Nebido. With a Prescription Drug User Fee Act, or PDUFA, date of June 27, 2008, we believe that this product would be launched in the U.S. in 2008 if approved by the FDA. This product may enhance compliance with some patients and should be considered as competition to Testim if it were to launch. Ardana Plc, a U.K. company, is developing a testosterone cream for the U.S. market. ProStrakan Group Plc has formed a strategic alliance with NovaQuest, the strategic partnering group of Quintiles Transnational Corporation to commercialize a 2% testosterone gel that began phase III in the third quarter of 2007 under a Special Protocol Assessment. BioSante Pharmaceuticals/Teva Pharmaceutical Industries Ltd. are projected to submit a New Drug Application, or NDA, in the third quarter of 2008 for what they are calling a Bio-T-Gel.

Phase II— Acrux Limited is developing a metered-dose lotion which is targeted to enter phase III in the second quarter of 2008. Clarus Therapeutics, Inc. is developing an oral controlled release testosterone which is in phase II. MacroChem Corporation has developed a testosterone gel that has completed phase I.

Other—Another potential introduction into the marketplace is an oral therapy, called Androxal, from Repros Therapeutics, Inc. or Repros. This molecule is designed to restore normal testosterone production in males rather than externally replacing testosterone like the current alternatives. However, Repros has been informed by the FDA that testosterone levels or Quality of Life measures will not be acceptable for Phase III trials for hypogonadism. Hence, Repros is considering other potential indications. Other new treatments are being sought for TRT, including a new class of drugs called Selective Androgen Receptor Modulators, or SARMs as well as enhanced hydroalcoholic gel formulation of hydrotestosterone. These products are in development and their future impact on the treatment of testosterone deficiency is unknown.

Finally, we face extensive competition in the acquisition or in-licensing of pharmaceutical products to enhance our portfolio of products. A number of more established companies, which have strategies to in-license or acquire products, may have competitive advantages, as may other emerging companies taking similar or different approaches to product acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, resources and experience.

Government Regulation

Government authorities in the U.S., at the federal, state, and local level, and foreign countries extensively regulate, among other things, the following areas relating to our products and product candidates:

- research and development;
- testing, manufacture, labeling and distribution;
- advertising, promotion, sampling and marketing; and
- import and export.

All of our products require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials to demonstrate safety and efficacy and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal, state, local, and foreign statutes and regulations also govern testing, manufacturing, labeling, distribution, storage and record-keeping related to such products and their promotion and marketing. The process of obtaining these approvals and the compliance with federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. In addition, the current regulatory and political environment at FDA could lead to increased testing and data requirements which could impact regulatory timelines and costs.

We have received marketing approval for Testim for the indication of hypogonadism in the U.S., the U.K., Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain and Sweden. Approval in the specified European countries was via the Mutual Recognition Procedure. In May 2006, we received marketing approval for Testim in Canada. In Europe, Testim has been launched in Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the U.K. In December 2007, Ipsen notified Auxilium that a decision was made (for non-safety reasons) to withdraw Testim from the market in Denmark, Finland, and Sweden.

None of our other product candidates has received marketing approval.

U.S. Government Regulation

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing regulations. If we fail to comply with the applicable requirements at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include:

- refusal to approve pending applications;
- withdrawals of approvals;
- clinical holds;
- warning letters;
- product recalls and product seizures; and
- total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution.

Any agency enforcement action could have a material adverse effect on us.

Currently there is a substantial amount of congressional and administration review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S.

The steps required before a drug may be marketed in the U.S. include:

- preclinical laboratory tests, animal studies, formulation, and stability studies;
- submission to the FDA of an investigational new drug exemption, or IND, which must become effective before human clinical trials may begin;
- execution of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication for which approval is sought;
- submission to the FDA of a NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP; and
- FDA review and approval of the NDA or BLA, or any supplements thereto, including, if applicable, a determination of its controlled substance schedule.

Preclinical studies generally are conducted in laboratory animals to evaluate the potential safety and activity of a product. Violation of the FDA's good laboratory practices regulations can, in some cases, lead to invalidation of the studies, requiring these studies to be replicated. In the U.S., drug developers submit the results of preclinical trials, together with manufacturing information and analytical and stability data, to the FDA as part of the IND, which must become effective before clinical trials can begin in the U.S. An IND becomes effective 30 days after receipt by the FDA unless before that time the FDA raises concerns or questions about the proposed clinical trials 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. If these concerns or questions are unresolved, the FDA will not allow the clinical trials to commence.

Clinical trials involve the administration of the investigational product candidate or approved products to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in assessing the safety and the effectiveness of the drug. Typically, clinical evaluation involves a time-consuming and costly three-phase sequential process, but the phases may overlap. Each trial must be reviewed, approved and conducted under the auspices of an independent institutional review board, and each trial must include the patient's informed consent. Phase II and III trials must be registered in a government database of trials. The following sets forth a brief description of the typical phases of clinical trials:

Phase I	Refers typically to closely monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or healthy volunteer subjects. Phase I clinical trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects of the product candidates associated with increasing drug doses and, if possible, to gain early evidence of the product candidate's effectiveness. Phase I trials also include the study of structure-activity relationships and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During phase I clinical trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid phase II studies. The total number of subjects and patients included in phase I clinical trials varies, but is generally in the range of 20 to 80 people.
Phase II	Refers to controlled clinical trials conducted to evaluate appropriate dosage and the effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These clinical trials are typically well-controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase II studies can be sequenced as phase IIa or phase IIb.

Phase III Refers to expanded controlled and uncontrolled clinical trials. These clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Phase III clinical trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III trials usually include from several hundred to several thousand subjects.

Phase IV Refers to trials conducted after approval of a new drug and which explore approved uses and approved doses of the product. These trials must also be approved and conducted under the auspices of an institutional review board. Phase IV studies may be required as a condition of approval.

Clinical testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the first three phases of clinical trials that are conducted in the U.S. and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA can also provide specific guidance on the acceptability of protocol design for clinical trials. The FDA or we may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug candidate.

Assuming successful completion of the required clinical trial, drug developers submit the results of preclinical studies and clinical trials, together with other detailed information including information on the chemistry, manufacture and control of the product, to the FDA, in the form of an NDA or BLA, requesting approval to market the product for one or more indications. In most cases, the NDA/BLA must be accompanied by a substantial user fee. The FDA reviews an NDA/BLA to determine, among other things, whether a product is safe and effective for its intended use. FDA can determine that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of the drug outweigh its risks. The REMS includes periodic assessments of the strategy and can include potential patient and healthcare providers communications plan, training obligations, monitoring, registries and other elements to ensure the drug will be used safely.

Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often 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 and refuse to approve the application by issuing a "not approvable" letter.

The testing and approval process requires substantial time, effort and financial resources, which 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. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications or place other conditions, including restrictive labeling, REMS, or restrictions on distribution as a condition of any approvals, which may impair commercialization of the product. 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.

If the FDA approves the NDA or BLA, the drug can be marketed to physicians to prescribe in the U.S. After approval, the drug developer must comply with a number of post-approval requirements, including delivering periodic reports to the FDA (i.e., annual reports), submitting descriptions of any adverse reactions reported, biological product deviation reporting, and complying with drug sampling and distribution requirements. The holder of an approved NDA/BLA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP which imposes procedural and documentation requirements relating to manufacturing, quality assurance and quality control. 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. The FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional studies to evaluate long-term effects.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved drug for treatment of new indications, which require submission of a supplemental or new NDA and FDA approval of the new labeling claims. The purpose of these trials and studies is to broaden the application and use of the drug and its acceptance in the medical community.

We use, and will continue to use, 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. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills on some kinds of pharmaceutical products. A principal factor in determining the particular requirements of this act, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be listed as a Schedule I, II, III, IV or V substance, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest. Testosterone, the active drug substance in Testim, has been scheduled under the Controlled Substances Act as a Schedule III substance. All regular Schedule III drug prescriptions must be signed by a physician and may not be refilled. Furthermore, the amount of Schedule III substances we can obtain for clinical trials and commercial distribution is limited by the Drug Enforcement Agency, or DEA, and our quota may not be sufficient to complete clinical trials or meet commercial demand, if any. In addition to federal scheduling, Testim is subject to state-controlled substance regulation and may be placed in more restrictive schedules than those determined by the U.S. Drug Enforcement Agency and the FDA. However, to date, testosterone has not been placed in a more restrictive schedule by any state.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a clinical trial or product by the comparable 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 also vary greatly from country to country. Although governed by the applicable country's regulations, clinical trials conducted outside of the U.S. typically are administered with the three-phase sequential process that is discussed above under "U.S. Government Regulation". The foreign equivalent of an IND, a Clinical Trial Application, or CTA, is a prerequisite to performing pilot studies or phase I clinical trials in certain European countries.

Under European Union, or E.U., regulatory systems, we may submit marketing authorization applications either under centralized or decentralized procedures. The centralized procedure which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all E.U. member states. This authorization is a marketing authorization approval. Two decentralized procedures exist as alternatives for approval of products that are not obligated to be submitted by the centralized procedure. The first is the Mutual Recognition procedure, or MRP, which provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization for a product may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. The second procedure, the Decentralized Procedure, was newly established in 2005. This procedure is available to products that have not been approved anywhere in the E.U. The application is submitted simultaneously in the reference member state chosen by the applicant and as desired by applicant. The reference member state carries out the main assessment and consults with the other member states during the process. Like the MRP, approval via this process results in national marketing approvals in the territories where scientific approval was received. All products, irrespective of the route of filing, are afforded 10 years of market exclusivity and eight years of data protection. An additional year of market exclusivity, providing a total of 11 years of market exclusivity, can be obtained for products on approval of an additional indication where that indication represents a significant clinical benefit and significant pre-clinical or clinical studies were carried out in support of the additional indication.

We received approval for Testim in the U.K. in June 2003. A mutual recognition application based on the U.K. approval was initiated in March 2004. The procedure was completed in June 2004 and resulted in scientific approval in the following 14 additional countries: Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain and Sweden. Marketing approvals have been issued in each of these countries. Testim has been launched in Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the U.K. In addition, in May 2006, we received marketing approval for Testim in Canada. In December 2007, Ipsen notified Auxilium that a decision was made by Ipsen (for non-safety reasons) to withdraw Testim from the market in Denmark, Finland, and Sweden.

Furthermore, regulatory approval of prices is required in most countries other than the U.S. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

Fraud and Abuse Laws

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal, civil and/or administrative sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid and veterans' health programs. Because of the far-reaching nature of these laws, there can be no assurance that the occurrence of one or more violations of these laws would not result in a material adverse effect on our business, financial condition and results of operations.

Anti-Kickback Laws. Our operations are subject to federal and state anti-kickback laws. Certain provisions of the Social Security Act prohibit entities such as us from knowingly and willingly offering, paying, soliciting or receiving any form of remuneration (including any kickbacks, bribe or rebate) in return for the referral of items or services for which payment may be made under a federal health care program, or in return for the recommendation, arrangement, purchase, lease or order of items or services for which payment may be made under a federal health care program. Violation of the federal anti-kickback law is a felony, punishable by criminal fines and imprisonment for up to five years or both. In addition, the Department of Health and Human Services may impose civil penalties and exclude violators from participation in federal health care programs such as Medicare and Medicaid. Many states have adopted similar prohibitions against payments intended to induce referrals of products or services paid by Medicaid or other third party payors.

Physician Self-Referral Laws. We also may be subject to federal and/or state physician self-referral laws. Federal physician self-referral legislation (known as the Stark law) prohibits, subject to certain exceptions, a physician from referring Medicare or Medicaid patients to an entity to provide designated health services, including, among other things, certain radiology and radiation therapy services and clinical laboratory services in which the physician or a member of his immediate family has an ownership or investment interest or has entered into a compensation arrangement. The Stark law also prohibits the entity receiving the improper referral from billing any good or service furnished pursuant to the referral. The penalties for violations include a prohibition on payment by these government programs and civil penalties for participation in a circumvention scheme. Various state laws also contain similar provisions and penalties.

False Claims. The federal False Claims Act imposes civil and criminal liability on individuals or entities who submit (or cause the submission of) false or fraudulent claims for payment to the government. Violations of the federal False Claims Act may result in penalties equal to three times the damages which the government sustained, an assessment, civil monetary penalties and exclusion from participation in the Medicare and Medicaid programs.

The federal False Claims Act also allows a private individual to bring a qui tam suit on behalf of the government against an individual or entity for violations of the False Claims Act. In a qui tam suit, the private plaintiff is responsible for initiating a lawsuit that may eventually lead to the government recovering money of which it was defrauded. After the private plaintiff has initiated the lawsuit, the government must decide whether to intervene in the lawsuit and become the primary prosecutor. In the event the government declines to join the lawsuit, the private plaintiff may choose to pursue the case alone, in which case the private plaintiff's counsel will have primary control over the prosecution (although the government must be kept apprised of the progress of the lawsuit). In return for bringing the suit on the government's behalf, the statute provides that the private plaintiff is entitled to receive up to 30% of the recovered amount from the litigation proceeds if the litigation is successful plus reasonable expenses and attorneys fees. Recently, the number of qui tam suits brought against entities in the health care industry has increased dramatically. In addition, a number of states have enacted laws modeled after the False Claims Act that allow those states to recover money which was fraudulently obtained from the state.

Other Fraud and Abuse Laws. The Health Insurance Portability and Accountability Act of 1996 created, in part, two new federal crimes: Health Care Fraud and False Statements Relating to Health Care Matters. The Health Care Fraud statute prohibits the knowing and willful execution of a scheme or artifice to defraud any health care benefit program. A violation of the statute is a felony and may result in fines and/or imprisonment. The False Statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

There are also several new state laws that require the reporting and disclosure of gifts or other value given to health care providers, the disclosure of certain advertising and promotion expenditures and pricing information, and the posting of our compliance plan on our Web site.

Compliance Program

The healthcare laws and fraud and abuse laws applicable to our business are complex and subject to variable interpretations. We maintain certain compliance review, education and training and other programs to further our commitment to high standards of ethical and legal conduct and to minimize the likelihood that we would engage in conduct or enter into

arrangements in violation of applicable authorities. For example, we have (i) established a compliance team consisting of representatives from our Legal, Human Resources and Regulatory Affairs/Quality Assurance departments that meets regularly; (ii) established a compliance hotline that permits our employees to report anonymously any compliance issues that may arise; and (iii) instituted other safeguards intended to help prevent any violations of the applicable fraud and abuse laws and healthcare laws, and to remediate any situations that could give rise to violations. We also review our transactions and agreements, both past and present, to help assure they are compliant.

Through our compliance efforts, we constantly strive to structure our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert non-compliance with respect to our business operations and relationships including these isolated arrangements. While there have been no claims asserted against us for alleged non-compliance with fraud and abuse laws and other healthcare laws, if a claim were asserted and we were not to prevail, possible penalties and sanctions could have a material effect on our financial statements or our ability to conduct our operations.

Third-party Reimbursement and Pricing Controls

In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. To date, we have not experienced any problems with third-party payors; however, third-party payors increasingly are challenging the prices charged for medical products and services. It is, and will be, time consuming and expensive for us to go through the process of seeking reimbursement from Medicaid, Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs through Medicare which may affect the marketing of our products. We elected to participate in the newly enacted Medicare Part D program at the beginning of 2006. The impact that this program will have on Testim may take more time to determine as the competitive environment develops. We feel given the age of the population that suffers from hypogonadism that more men will have access to this therapy than previously.

In many foreign markets, including the countries in the E.U., pricing of pharmaceutical products is subject to governmental control. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Patents and Proprietary Rights

Our success will depend in part on our ability to protect our existing products and the products we acquire or in-license by obtaining and maintaining a strong proprietary position both in the U.S. and in other countries. To develop and maintain such a position, we intend to continue relying upon patent protection, trade secrets, know-how, continuing technological innovations and licensing opportunities. In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we develop or acquire in the future.

Bentley. We have licensed the underlying technology for Testim, our only approved product, from Bentley. The patents that we license from Bentley for Testim cover methods, compositions and formulations for administering drugs, such as testosterone, across the skin and mucus membranes. In the U.S., there is a methods and composition patent that expires in June 2008, and a method of use patent that expires in January 2025. Bentley has filed continuation and divisional applications with the U.S. Patent and Trademark Office, or USPTO, which would provide us with further market protection if a patent or patents issue from any of these applications. In Canada, there are two patents covering Testim, one that expires in January 2010 and another that expires in 2023. The patent recently issued by the European Patent Office covering Testim expires in April 2023. Bentley also has submitted a patent application in Japan that is awaiting examination. All of these patents and any patents that issue from the pending applications are included in our license from Bentley. Testosterone, the active ingredient in Testim, does not have patent protection and is included in competing TRT products.

BioSpecifics. We licensed XIAFLEX, our product candidate for the treatment of Dupuytren's contracture, Peyronie's disease, and Frozen Shoulder syndrome, from BioSpecifics. In addition to the marketing exclusivity which comes with its orphan drug status in the U.S. as a treatment for Dupuytren's contracture and Peyronie's disease, the enzyme underlying this product candidate is covered by two use patents in the U.S., one for the treatment of Dupuytren's contracture and one for the treatment of Peyronie's disease. The Dupuytren's patent, which issued from a reissue proceeding in December 2007, expires in 2014, and the Peyronie's patent expires in 2019. Both patents are limited to the use of the enzyme for the treatment of Dupuytren's contracture and Peyronie's disease within certain dose ranges. While we believe that dose optimization trials in Peyronie's Disease will demonstrate that effective dosing will fall within the patented range, currently, there is not enough data

to establish whether the ultimate approved product will be covered by the patents. While XIAFLEX does not have orphan drug status for any indication in Europe, foreign patents cover these products in certain countries, and on approval of XIAFLEX for a first indication in Europe, the product will benefit from 10 years of market exclusivity and 8 years of data exclusivity. We may obtain an additional year of market exclusivity if the regulatory authorities approve an additional indication that they determine to represent a significant clinical benefit.

In January 2005, a patent application was filed with regard to XIAFLEX for the treatment of Frozen Shoulder syndrome. If this patent is granted, it would expire in 2026. In January 2006, we filed a patent application with regard to the manufacturing process for XIAFLEX; if this patent is granted, it would expire in January 2027.

PharmaForm. We have licensed the transmucosal film technology for our overactive bladder and pain product candidates from PharmaForm. The U.S. patent that we license from PharmaForm expires in 2020. We have filed three patent applications originally in the U.S., now pending as international applications, covering this technology. If patents issue from these applications, they would expire in 2027.

The scope of the intellectual property rights held by pharmaceutical firms involves complex legal, scientific and factual questions and consequently is generally uncertain. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of our current patent applications, or the products or product candidates we develop, acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the U.S. and some other jurisdictions are sometimes maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the USPTO or a foreign patent office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued and challenged, in a court of competent jurisdiction would be found valid or enforceable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

Although we believe these patent applications, if they issue as patents, will provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect our technology. In addition, any patents or patent rights we obtain may be circumvented, challenged or invalidated by our competitors.

While we attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties' patents and proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights. Additionally, because patent prosecution can proceed in secret prior to issuance of a patent, third parties may obtain other patents without our knowledge prior to the issuance of patents relating to our product candidates which they could attempt to assert against us.

Although we believe that our product candidates, production methods and other activities do not currently infringe the intellectual property rights of third parties, we cannot be certain that a third party will not challenge our position in the future. If a third party alleges that we are infringing its intellectual property rights, we may need to obtain a license from that third party, but there can be no assurance that any such license will be available on acceptable terms or at all. Any infringement claim that results in litigation could result in substantial cost to us and the diversion of management's attention away from our core business and could also prevent us from marketing our products. To enforce patents issued to us or to determine the scope and validity of other parties' proprietary rights, we may also become involved in litigation or in interference proceedings declared by the USPTO, which could result in substantial costs to us or an adverse decision as to the priority of our inventions. We may be involved in interference and/or opposition proceedings in the future. We believe there will continue to be litigation in our industry regarding patent and other intellectual property rights.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology or that we can meaningfully protect our trade secrets.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In

the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Orphan Drug Status

The Orphan Drug provisions of the Federal Food, Drug, and Cosmetic Act provide incentives to drug and biologics suppliers to develop and supply drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from its sales in the U.S. Under these provisions, a supplier of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. The marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug for the same indication except under limited circumstances. It would not prevent other drugs from being approved for the same indication.

The FDA granted orphan drug status to XIAFLEX in the U.S. for each of the treatments of Dupuytren's contracture and Peyronie's disease. The designations for the treatment of Dupuytren's contracture and Peyronie's disease have been transferred to us. Orphan drug status means that, if XIAFLEX is the first product to receive FDA approval for the orphan indications, another application to market the same drug for the same indication may not be approved, except in limited circumstances, for a period of up to seven years in the U.S.

The Hatch-Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active ingredient. The Hatch-Waxman Act prohibits an abbreviated new drug application, or ANDA, where the applicant does not own or have a legal right of reference to all the data required for approval, to be submitted by another company for another version of such drug during the five-year exclusive period. Protection under the Hatch-Waxman Act will not prevent the filing or approval of another full NDA, however, the applicant would be required to conduct its own pre-clinical, adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages, or strengths of an existing drug, if new clinical investigations are essential to the approval. This three-year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient or indications.

The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for patent term extension.

Employees

As of December 31, 2007, we had approximately 300 employees. We believe that our relations with our employees are good and we have no history of work stoppages. Generally, our employees are at-will employees. However, we have entered into employment agreements with certain of our executive officers.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy any document we file with the SEC at the SEC's public reference room at 100 F. Street, N.E., Washington, DC 20549, at prescribed rates. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. You may also obtain our SEC filings free of charge from the SEC's Internet Web site at www.sec.gov.

Our Internet Web site address is www.auxilium.com. We make available free of charge through our Web site's "Investor Relations" page most of our filings with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other information. These reports and information are available as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC.

Our Board of Directors has various committees including an audit and compliance committee, compensation committee and nominating and corporate governance committee. Each of these committees has a formal charter. We also have Corporate Governance Guidelines and a Code of Conduct. Copies of these charters, guidelines and codes, and any waivers or amendments to such codes which are applicable to our executive officers, senior financial officers or directors, can be obtained free of charge from our Web site. The references to our Web site and the SEC's Web site are intended to be inactive textual references only, and the contents of those Web sites are not incorporated by reference herein.

In addition, you may request a copy of the foregoing filings, charters, guidelines and codes, and any waivers or amendments to such codes which are applicable to our executive officers, senior financial officers or directors, at no cost by writing us at the following address or telephoning us at the following telephone number:

Auxilium Pharmaceuticals, Inc.
40 Valley Stream Parkway
Malvern, PA 19355
Attention: Investor Relations
Telephone: (484) 321-5900

ITEM 1A. *Risk Factors*

In addition to the other information included in this Report, the following factors should be considered in evaluating our business and future prospects. Any of the following risks, either alone or taken together, could materially and adversely affect our business, financial position or results of operations. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, our actual results may vary materially from what we projected. There may be additional risks that we do not presently know or that we currently believe are immaterial which could also impair our business or financial position.

Risks Related to Our Financial Results and Need for Additional Financing

We have incurred significant losses since our inception and may not achieve profitability in the foreseeable future.

We have incurred significant losses since our inception, including net losses of $40.7 million for the twelve months ended December 31, 2007. As of December 31, 2007, we had an accumulated deficit of $224.2 million. We expect to continue to incur substantial expenses as we:

- market and sell Testim, our only approved product, through our sales force;
- develop XIAFLEX™ (clostridial collagenase for injection), formerly referred to as AA4500, our product candidate for the treatment of Dupuytren's contracture, Peyronie's disease and Adhesive Capsulitis, or Frozen Shoulder syndrome; AA4010, our overactive bladder transmucosal film product candidate; and our pain transmucosal film product candidate and any other product candidates that we license or acquire;
- develop, and subsequently maintain, our manufacturing processes at scale;
- seek regulatory approval for our product candidates;
- prepare for the launch of and commercialize any of our product candidates that receive marketing approval or any approved products that we acquire or in-license; and
- acquire or in-license new technologies or development stage or approved products.

Accordingly, we expect to continue to incur substantial additional losses for the foreseeable future. In order to achieve and maintain profitability, we will need to generate significantly greater revenues from Testim and any other product candidate for which we receive marketing approval. As a result, we are unsure when we will become profitable, if at all. If we fail to achieve profitability within the time frame expected by investors, the value of our common stock may decline substantially.

As a development stage company, our future results are unpredictable, and therefore, our common stock is a highly speculative investment.

We commenced operations in the fourth quarter of 1999 and have a limited operating history for you to evaluate our business. Accordingly, you must consider our prospects in light of the risks and difficulties encountered by companies in their early stages. The risks and difficulties that we may encounter include:

- increasing the sales of Testim, our only product with marketing approval;
- successfully developing, obtaining marketing approval for and manufacturing or having manufactured our current product candidates, including XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease, and Frozen Shoulder syndrome, AA4010 for the treatment of overactive bladder and our pain transmucosal film product candidate;
- successfully identifying and developing new product candidates;
- effectively commercializing any approved product candidates that we develop or any approved products that we acquire;
- responding to competitive pressures from other businesses, including the launch of any products, including generics, that compete with Testim in the treatment of hypogonadism;
- identifying and negotiating favorable agreements with third parties for the manufacture, distribution and marketing and sales of our approved products; and
- effectively managing our relationships with vendors and third parties.

All of our revenues to date have been generated from the sale or out-licensing of Testim, and, if these revenues do not grow, and we cannot commercialize new products, we will not become profitable.

Our only product with marketing approval is Testim and our product revenues to date have been generated solely from the sale and out-licensing of Testim. Until such time as we develop, acquire or in-license additional products that are approved for marketing, we will continue to rely on Testim for all of our revenues. Accordingly, our success depends significantly on our ability to increase sales of Testim. Our sales and marketing efforts may not be successful in increasing prescriptions for Testim. Sales of Testim are subject to the following risks, among others:

- growth of the overall androgen market which may be influenced by the sales and marketing efforts of our competitors;
- acceptance by the medical community or the general public of Testim or testosterone as a safe or effective therapy for hypogonadism;
- increasing awareness and continued acceptance of hypogonadism by the medical community, regulators or the general public as a medical disorder requiring treatment;
- illegal substitution by pharmacists of AndroGel for Testim;
- pressures from existing or new competing products, including generic products, that may provide therapeutic, convenience or pricing advantages over Testim or may garner a greater share of voice;
- failure of third-party payors to provide coverage and sufficient reimbursement for Testim; and
- impact of coverage and reimbursement changes, including Medicare Part D coverage and reimbursement.

For the foreseeable future, if we are unable to grow Testim sales and out-licensing revenues, we will be unable to increase our revenues or achieve profitability and we may be forced to delay or change our current plans to develop other product candidates.

If we are unable to meet our needs for additional funding in the future, we may be required to limit, scale back or cease our operations.

Our operations to date have generated substantial and increasing needs for cash. Our negative cash flows from operations are expected to continue for at least the foreseeable future. Our strategy contains elements that we will not be able to execute without outside funding. Specifically, we may need to raise additional capital to:

- enhance or expand our sales and marketing efforts for Testim or other products we may co-promote, acquire, in-license or develop;
- fund our product development, including clinical trials;
- commercialize and supply any product candidates that receive regulatory approval;
- acquire or in-license approved products or product candidates or technologies for development; and
- acquire another company.

We believe that our existing cash resources and interest on these funds will be sufficient to meet our anticipated operating requirements through the second quarter of 2009. Our future funding requirements will depend on many factors, including:

- Testim market acceptance and sales growth;
- our ability to realize sales efficiency and effectiveness of our sales force;
- growth of the overall androgen market which may be influenced by the sales and marketing efforts of our competitors;
- entry into the marketplace of competitive products;
- third-party payor coverage and reimbursement for Testim;
- the cost of manufacturing, distributing, marketing and selling Testim;
- the scope, rate of progress and cost of our product development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing, co-promotion and other arrangements that we may establish;
- the cost and timing of regulatory approvals;

- the accuracy of market research regarding the commercial potential of XIAFLEX for a particular indication and any of our product candidates;
- the market acceptance and sales growth of XIAFLEX for a particular indication and any of our product candidates upon regulatory approval;
- the costs of supplying and commercializing XIAFLEX and any of our product candidates;
- increased administrative costs to support a growing infrastructure;
- acquisition or in-licensing costs;
- the effect of competing technological and market developments;
- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products and technologies.

These factors could result in variations from our currently projected operating and liquidity requirements. If our existing resources are insufficient to satisfy our liquidity requirements, we may need to borrow money or sell additional equity or debt securities. We may not be able to borrow money on commercially reasonable terms. Moreover, the terms of the sale of any equity or debt securities may not be acceptable to us and could result in substantial dilution of your investment. If we are unable to obtain this additional financing, we may be required to:

- reduce the size or scope, or both, of our sales and marketing efforts for Testim or any of our future products;
- delay or reduce the scope of, or eliminate one or more of our planned development, commercialization or expansion activities;
- seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; and/or
- relinquish, license or otherwise dispose of rights to technologies, product candidates or products that we currently market or would otherwise seek to develop or commercialize ourselves on terms that are less favorable than might otherwise be available.

Our revenues, operating results and cash flows may fluctuate in future periods and we may fail to meet investor expectations, which may cause the price of our common stock to decline.

Variations in our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. We are a relatively new company and our sales prospects are uncertain. We have been selling Testim, our only approved product, since the first quarter of 2003 and cannot predict with certainty the timing or level of sales of Testim in the future. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. In addition to the other factors discussed under these “Risk Factors,” specific factors that may cause fluctuations in our operating results include:

- demand and pricing for Testim, including any change in wholesaler purchasing patterns or cost structures for our products or their services;
- growth of the overall androgen market which may be influenced by the sales and marketing efforts of our competitors;
- prescription levels relating to physician and patient acceptance of, and prescription costs for, Testim or any of our future products;
- government or private healthcare reimbursement policies;
- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;
- introduction of competing products, including generics;
- any interruption in the manufacturing or distribution of Testim or any of our future products;
- the timing and results of clinical trials for our product candidates;
- the costs incurred in the manufacture of Testim and our product candidates;
- our operating expenses, many of which are relatively fixed;
- timing and costs associated with any new product or technology acquisitions we may complete;

- variations in our rates of product returns, allowances and rebates and discounts; and
- milestone payments.

Forecasting our revenues is further complicated by difficulties in estimating inventory levels at our wholesaler and chain drug store customers, prescription levels, the timing of purchases by wholesalers and retailers to replenish inventory and the occurrence and amount of product returns.

As a result of these factors, we believe that period-to-period comparisons of our operating results are not a good indication of our future performance.

Our investments in auction rate securities are subject to risks which may cause losses and affect the liquidity of these investments.

As of March 7, 2008, we held $5.8 million of taxable auction rate securities, or ARS, which are classified as short-term investments. These investments are private placement securities with long-term stated maturities for which interest rates are reset through a "Dutch" auction every 28 or 35 days. They carry AAA/Aaa ratings and are backed by student loans which carry guarantees as provided under the Federal Family Education Loan Program of the U.S. Department of Education. The Dutch auctions have in the past provided a liquid market for these types of securities. With the liquidity issues experienced in global credit and capital markets, auctions of all the ARS we hold experienced failed auctions, beginning on February 11, 2008, as the amount of securities submitted for sale exceeded the amount of purchase orders. If the uncertainties in the credit and capital market continue, these markets deteriorate further or there are ratings downgrades on any of the ARS we hold, we may be required to adjust the value of these investments through an impairment charge to earnings, if the fair value of these securities has declined to below their cost and such decline is assessed to be "other than temporary" under SFAS No. 115. Further, we may not be able to liquidate these investments until successful auctions occur, a buyer outside the auction process is found, the issuer calls these debt securities, or the securities mature.

Risks Related to Compliance

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable regulations.

We are a relatively small company and we rely heavily on third parties to conduct many important functions. As a biopharmaceutical company, we are subject to a large body of legal and regulatory requirements. In addition, as a publicly traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002, or SOA, some of which have either only recently been adopted or are currently proposals subject to change. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, impede our ability to raise capital or lead to the de-listing of our stock.

Our controls over external financial reporting may fail or be circumvented.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the SOA to report annually on our internal control over financial reporting. If we, or our independent registered public accounting firm, determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. This reporting requirement could also make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. Any failure or circumvention of the controls and procedures or failure to comply with regulation concerning control and procedures could have a material effect on our business, results of operation and financial condition. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers.

Risks Related to Development of Our Product Candidates

We may not be able to develop product candidates into viable commercial products, which would impair our ability to grow and could cause a decline in the price of our stock.

The process of developing product candidates involves a high degree of risk and may take several years. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trials may show our product candidates to be ineffective or not as effective as anticipated or to have harmful side effects or any unforeseen result;
- our inability to enroll patients in clinical trials within the expected timeframes;
- our inability to obtain authorization from FDA or other regulatory authority to initiate clinical trials within the expected timeframes;
- product candidates may fail to receive regulatory approvals required to bring the products to market;
- manufacturing costs and delays and manufacturing problems in general, the inability to scale up to produce supplies for clinical trials or commercial supplies, or other factors may make our product candidates uneconomical;
- the proprietary rights of others and their competing products and technologies may prevent our product candidates from being effectively commercialized or to obtain exclusivity; and
- failure to meet one or more of management's target product profile criteria.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. Currently, there is substantial congressional and administration review of the regulatory approval process for drug candidates in the U.S. Any changes to the U.S. regulatory approval process could significantly increase the timing or cost of regulatory approval for our product candidates making further development uneconomical or impossible.

In addition, developing product candidates is very expensive and will have a significant impact on our ability to generate profits. Factors affecting our product development expenses include:

- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;
- the cost and timing of manufacturing clinical or commercial supplies of product candidates, including the cost and timing of the implementation of any necessary corrective actions;
- regulatory approval of tradenames for our product candidates and the timing thereof;
- our ability to raise any additional funds that we need to complete our trials;
- the number and outcome of clinical trials conducted by us and/or our collaborators;
- the number of products we may have in clinical development;
- in-licensing or other partnership activities, including the timing and amount of related development funding, license fees or milestone payments; and
- future levels of our revenue.

Our product development efforts also could result in large and immediate write-offs, significant milestone payments, incurrence of debt and contingent liabilities or amortization of expenses related to intangible assets, any of which could negatively impact our financial results. Additionally, if we are unable to develop our product candidates into viable commercial products, we may remain reliant solely on Testim sales for our revenues, potentially limiting our growth opportunities.

If clinical trials for our product candidates are delayed, we would be unable to commercialize our product candidates on a timely basis, which could materially harm our business.

Clinical trials that we may conduct may not begin on time or may need to be restructured or temporarily suspended after they have begun. Clinical trials can be delayed or may need to be restructured for a variety of reasons, including delays or restructuring related to:

- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;

- obtaining an investigational new drug exemption, or IND, or other regulatory approval to commence a clinical trial;
- timing of responses required from regulatory authorities;
- negotiating acceptable clinical trial agreement terms with prospective investigators or trial sites;
- obtaining institutional review board, or equivalent, approval to conduct a clinical trial at a prospective site;
- recruiting subjects to participate in a clinical trial;
- competition in recruiting clinical investigators;
- shortage or lack of availability of clinical trial supplies from external and internal sources;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion;
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial; and
- manufacturing issues associated with clinical supplies.

Prior to commencing clinical trials in the U.S., we must have an effective IND for each of our product candidates. An IND has been filed and is effective for XIAFLEX for the treatment of Dupuytren's contracture, XIAFLEX for the treatment of Peyronie's disease, and XIAFLEX for the treatment of Frozen Shoulder syndrome; however, INDs have not been filed for AA4010 or our pain transmucosal film product candidate. We will not be able to commence clinical trials in the U.S. for these product candidates until we file, and the FDA fails to object to, an IND for each candidate. The foreign equivalent of an IND, a Clinical Trial Application (CTA) is a prerequisite to performing pilot studies or phase I clinical trials in many European countries. A CTA has been filed in select European countries and is effective for XIAFLEX for the treatment of Dupuytren's contracture.

We have four projects in clinical development, specifically XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome, and AA4010. Completion of clinical trials for each product candidate will be required before commercialization. In December 2006, we suspended the dosing of patients in our ongoing phase III trials for XIAFLEX for the treatment of Dupuytren's contracture because of an issue related to the manufacture of clinical supplies of XIAFLEX and, as a result, the FDA placed a clinical hold on our XIAFLEX trials for the treatment of Dupuytren's contracture and Peyronie's disease. The FDA lifted the clinical hold in August 2007 and cleared us to resume our XIAFLEX trials. With regard to the development of XIAFLEX for the treatment of Peyronie's disease, the FDA is requiring that certain additional pre-clinical studies be completed prior to the initiation of the phase IIb study or any other human study for Peyronie's disease. If we experience delays in, or termination of, clinical trials, or fail to enroll patients in clinical trials in a timely manner, or if the cost or timing of the regulatory approval process increases, our financial results and the commercial prospects for our product candidates will be adversely impacted. In addition, our product development costs would increase and our ability to generate additional revenue from new products could be impaired.

Adverse events or lack of efficacy in our clinical trials may force us to stop development of our product candidates, prevent regulatory approval of our product candidates, or impact our existing products which could materially harm our business.

Patients participating in the clinical trials of our product candidates may experience serious adverse health events. A serious adverse health event includes death, a life-threatening condition, hospitalization, disability, congenital anomaly, or a condition requiring intervention to prevent permanent impairment or damage. The occurrence of any of these events could interrupt, delay, suspend or halt clinical trials of our product candidates and could result in the FDA, or other regulatory authorities, denying approval of our product candidates for any or all targeted indications. Also, the occurrence of any of these events could impact our existing products. An institutional review board or independent data safety monitoring board, the FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Our product candidates may prove not to be safe for human use. Any delay in the regulatory approval of our product candidates could increase our product development costs and allow our competitors additional time to develop or market competing products. If our product candidates do not receive the necessary regulatory approval, we may remain reliant on sales of Testim as our sole source of revenue.

Our failure to successfully in-license or acquire additional technologies, product candidates or approved products could impair our ability to grow.

We intend to in-license, acquire, develop and market additional products and product candidates so that we are not solely reliant on Testim sales for our revenues. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers to sell or license products or technologies to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates, products and technologies. To date, we have in-licensed the formulation technology underlying Testim from Bentley, the transmucosal film technology underlying AA4010 and our pain transmucosal film product candidate from PharmaForm, and the enzyme underlying XIAFLEX from BioSpecifics Technologies Corp., or BioSpecifics.

We may not be able to successfully identify any other commercial products or product candidates to in-license, acquire or internally develop. Moreover, negotiating and implementing an economically viable in-licensing arrangement or acquisition is a lengthy and complex process. Other companies, including those with substantially greater resources, may compete with us for the in-licensing or acquisition of product candidates and approved products. We may not be able to acquire or in-license the rights to additional product candidates and approved products on terms that we find acceptable, or at all. If we are unable to in-license or acquire additional commercial products or product candidates, we may be reliant solely on Testim sales for revenues. As a result, our ability to grow our business or increase our profits could be severely limited.

If we engage in any acquisition, we will incur a variety of costs, and we may never realize the anticipated benefits of the acquisition.

Since our inception, we have acquired the underlying technology for Testim and all of our product candidates through in-licensing arrangements. The underlying technology for Testim was licensed from Bentley. The transmucosal film technology underlying AA4010 and the pain product candidates was licensed from PharmaForm. XIAFLEX, our product candidate for Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome, was licensed from BioSpecifics. One of our strategies for business expansion is the acquisition of additional products and product candidates. We may attempt to acquire these product candidates, or other potentially beneficial technologies, through in-licensing or the acquisition of businesses, services or products that we believe are a strategic fit with our business. If we undertake an acquisition, the process of integrating any newly acquired business, technology, service or product into our existing operations could be expensive and time consuming and may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. Moreover, we may fail to realize the anticipated benefits of any acquisition for a variety of reasons, such as an acquired product candidate proving to not be safe or effective in later clinical trials or not reaching its forecasted commercial potential. We may fund any future acquisition by issuing equity or debt securities, which could dilute your ownership percentage or limit our financial or operating flexibility as a result of restrictive covenants related to new debt. Acquisition efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote resources to potential acquisitions that are never completed. If we are unable to acquire and successfully integrate product candidates through in-licensing or the acquisition of businesses, services or products, we may remain reliant solely on Testim sales for revenue. In pursuing our acquisition strategy, we may expend significant management time, consulting costs and legal expenses without consummating a transaction.

Risks Related to Regulatory Approval of Our Product Candidates

We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The testing, development, manufacture and distribution of our products are subject to regulation by numerous governmental authorities in the U.S., Europe and the rest of the world. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of Testim and our product candidates, as well as safe working conditions and the experimental use of animals. Noncompliance with any applicable regulatory requirements can result in refusal of the government to approve facilities for testing or manufacture of products as well as refusal to approve products for commercialization. Noncompliance with any applicable regulatory requirements also can result in criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S. In addition, the regulatory requirements relating to the manufacturing, testing, labeling, promotion, marketing and distribution of our products may change in the U.S. or the other jurisdictions in which we may have obtained or be seeking regulatory approval for our products or product candidates. Such changes may increase our costs and adversely affect our operations.

Testosterone is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Our pain transmucosal film product candidates may also involve the use of scheduled substances. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. For example, all regular Schedule III drug prescriptions must be signed by a physician and may not be refilled. Furthermore, the amount of Schedule III substances we can obtain for clinical trials and commercial distribution is limited by the DEA and our quota may not be sufficient to complete clinical trials or meet commercial demand, if any.

Entities must be registered annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. State controlled substance laws also require registration for similar activities. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration.

Products containing controlled substances may generate public controversy. As a result, these products may have their marketing rights or regulatory approvals withdrawn. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of our product candidates. For some scheduled substances or any product, the FDA may require us to develop a comprehensive risk management program to reduce the inappropriate use of our products and product candidates, including the manner in which they are marketed and sold, so as to reduce the risk of improper patient selection and diversion or abuse of the product. Developing such a program in consultation with the FDA may be a time-consuming process and could delay approval of any of our product candidates. Such a program or delays of any approval from the FDA could increase our product development costs and may allow our competitors additional time to develop or market competing products.

Additionally, failure to comply with or changes to the regulatory requirements that are applicable to Testim or our other product candidates may result in a variety of consequences, including the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of Testim or a product candidate from the market;
- voluntary or mandatory recall of Testim or a product candidate;
- fines against us;
- suspension or withdrawal of regulatory approvals for Testim or a product candidate;
- suspension or termination of any of our ongoing clinical trials of a product candidate;
- refusal to permit to import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- product seizure; and
- injunctions, consent decrees, or the imposition of civil or criminal penalties against us.

If our product candidates are not demonstrated to be sufficiently safe and effective, they will not receive regulatory approval and we will be unable to commercialize them.

Other than Testim, all of our other product candidates are in preclinical or clinical development and have not received regulatory approval from the FDA or any foreign regulatory authority. An IND has been filed and is effective for XIAFLEX for the treatment of Dupuytren's contracture, XIAFLEX for the treatment of Peyronie's disease, and XIAFLEX for the treatment of Frozen Shoulder syndrome; however, INDs have not been filed for AA4010 or our pain transmucosal film product candidate. The regulatory approval process typically is extremely expensive, takes many years and the timing or likelihood of any approval cannot be accurately predicted. The foreign equivalent of an IND, a CTA, is a prerequisite to performing pilot studies or phase I clinical trials in many European countries. A CTA has been filed in select European countries and is effective for XIAFLEX for the treatment of Dupuytren's contracture.

As part of the regulatory approval process, we must conduct preclinical studies and clinical trials for each product candidate to demonstrate safety and efficacy. The number of preclinical studies and clinical trials that will be required varies depending on the product candidate, the indication being evaluated, the trial results and regulations applicable to any particular product candidate.

The results of preclinical studies and initial clinical trials of our product candidates do not necessarily predict the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through initial clinical trials. We cannot assure you that the data collected from the preclinical studies and clinical trials of our product candidates will be sufficient to support FDA or other regulatory approval. In addition, the continuation of a particular study after review by an institutional review board or independent data safety monitoring board does not necessarily indicate that our product candidate will achieve the clinical endpoint.

The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;
- a product candidate may not be deemed to be safe or effective;
- the ability of the regulatory agency to provide timely responses as a result of its resource constraints;
- the manufacturing processes or facilities may not meet the applicable requirements; and
- changes in their approval policies or adoption of new regulations may require additional clinical trials or other data.

Any delay in, or failure to receive, approval for any of our product candidates or the failure to maintain regulatory approval for Testim could prevent us from growing our revenues or achieving profitability.

Risks Related to Commercialization

If medical doctors do not prescribe our products or the medical profession or patients do not accept our products, our ability to grow or maintain our revenues will be limited.

Our business is dependent on market acceptance of our products by physicians, healthcare payors, patients and the medical community. Medical doctors' willingness to prescribe, and patients' willingness to accept, our products depend on many factors, including:

- perceived safety and efficacy of our products;
- convenience and ease of administration;
- prevalence and severity of adverse side effects in both clinical trials and commercial use;
- availability of alternative treatments;
- cost effectiveness;
- effectiveness of our marketing strategy and the pricing of our products;
- publicity concerning our products or competing products; and
- our ability to obtain third-party coverage or reimbursement.

Even though we have received regulatory approval for Testim, and even if we receive regulatory approval and satisfy the above criteria for any of our other product candidates, physicians may not prescribe, and patients may not accept, our products if we do not promote our products effectively. Factors that could affect our success in marketing our products include:

- the adequacy and effectiveness of our sales force and that of any co-promotion partners or international partner's sales force;
- the adequacy and effectiveness of our production, distribution and marketing capabilities and those of our international partners;
- the success of competing products, including generics; and
- the availability and extent of reimbursement from third-party payors.

If any of our products or product candidates fails to achieve market acceptance, we may not be able to market and sell the products successfully, which would limit our ability to generate revenue and could harm our business.

If testosterone replacement therapies are perceived to create or create health risks, our sales of Testim may decrease and our operations may be harmed.

Publications have, from time to time, suggested potential health risks associated with testosterone replacement therapy, or TRT. Potential health risks are described in various articles, including a 2002 article published in *Endocrine Practice* and a 1999 article published in the *International Journal of Andrology*. The potential health risks detailed are fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, including prostate

cancer, increased cardiovascular disease risk and the suppression of sperm production. It is possible that studies on the effects of TRT could demonstrate these or other health risks. This, as well as negative publicity about the risks of hormone replacement therapy, including TRT, could adversely affect patient or prescriber attitudes and impact Testim sales. In addition, investors may become concerned about these issues and decide to sell our common stock. These factors could adversely affect our business and the price of our common stock.

Testim competes in a very competitive market, and if we are unable to compete effectively with the other companies that produce products for the treatment of urologic or sexual health disorders, our ability to generate revenues will be limited.

The pharmaceutical industry is highly competitive. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for Testim or any products for which we receive marketing approval. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies. The primary competition for Testim is AndroGel®, marketed by Solvay and its co-promotion partners. AndroGel was launched approximately three years before Testim. Testim also competes with other forms of testosterone replacement therapies such as oral treatments, patches, injectables and a buccal tablet. Androderm® is a transdermal testosterone patch marketed by Watson Pharmaceuticals, Inc., or Watson. Many of our competitors have more substantial resources, than we do. Accordingly, our competitors may:

- develop or license products or other novel technologies that are more effective, safer or less costly than Testim or product candidates that are being developed by us;
- obtain regulatory approval for products before we do; or
- commit more resources than we can to developing, marketing and selling competing products.

In addition to potential generic competition, several other pharmaceutical companies have TRT products in development that may be approved for marketing in the U.S. Based on publicly available information, we approximate that these products are in the development phases noted below.

Phase III—Indevus Pharmaceuticals, Inc. has licensed a long acting testosterone injection that is currently marketed in Europe under the trade name, Nebido. With a PDUFA date of June 27, 2008 we believe that this product could be launched in the U.S. in 2008 if approved by the FDA. This product may enhance compliance with some patients and would be considered as competition to Testim if it were to launch. Ardana plc, a U.K. company, is developing a testosterone cream for the U.S. market. Prostrakan Group Plc has formed a strategic alliance with NovaQuest to commercialize a 2% testosterone gel that began phase III in the third quarter of 2007 under a Special Protocol Assessment. BioSante/Teva is projected to submit a New Drug Application, or NDA, in the third quarter of 2008 for what they calling a Bio-T-Gel.

Phase II— Acrux Limited is developing a metered-dose lotion which is targeted to enter phase III in the second quarter of 2008. Clarus Therapuetics is developing an oral controlled release testosterone which is in phase II. MacroChem Corp. has developed a testosterone gel that has completed phase I.

Other—Another potential introduction into the marketplace is an oral therapy, called Androxal, from Repros Therapeutics, or Repros. This molecule is designed to restore normal testosterone production in males rather than externally replacing testosterone like the current alternatives. However, Repros has been informed by the FDA that testosterone levels or Quality of Life measures will not be acceptable for Phase III trials for hypogonadism. Hence, Repros is considering other potential indications. Other new treatments are being sought for TRT, including a new class of drugs called Selective Androgen Receptor Modulators, or SARMs as well as enhanced hydroalcoholic gel formulation of hydrotestosterone. These products are in development and their future impact on the treatment of testosterone deficiency is unknown.

Finally, we face extensive competition in the acquisition or in-licensing of pharmaceutical products to enhance our portfolio of products. A number of more established companies, which have strategies to in-license or acquire products, may have competitive advantages, as may other emerging companies taking similar or different approaches to product acquisitions. In addition, a number of established research-based pharmaceutical and biotechnology companies may acquire products in late stages of development to augment their internal product lines. These established companies may have a competitive advantage over us due to their size, resources and experience.

If other pharmaceutical companies develop generic versions of any products that compete with our commercialized products or any of our products, our business may be adversely affected.

Other pharmaceutical companies may develop generic versions of any products that compete with our commercialized products or any of our products that are not subject to patent protection or other proprietary rights. For example, because the ingredients of Testim are commercially available to third parties, it is possible that competitors may design formulations,

propose dosages or develop methods of administration that would be outside the scope of the claims of one or more, or of all, of the patent rights that we in-license. This would enable their products to effectively compete with Testim. Governmental and other pressures to reduce pharmaceutical costs may result in physicians writing prescriptions for these generic products. Increased competition from the sale of competing generic pharmaceutical products could cause a material decrease in revenue from our products.

The primary competition for Testim is AndroGel, marketed by Solvay, and its co-promotion partners. According to public announcements by Solvay, Watson and Par Pharmaceutical Companies, Inc., pursuant to separate settlements of patent litigation in September 2006, no generic to AndroGel will be sold until 2015. Any generic for AndroGel will not be a generic for Testim, since Testim is BX rated (or non-substitutable) with AndroGel. Other pharmaceutical companies may develop generic versions of any products that we commercialize that are not subject to patent protection or other proprietary rights. Governmental and other cost containment pressures may result in physicians writing prescriptions for these generic products.

If third-party payors do not reimburse customers for Testim or any of our product candidates that are approved for marketing, they might not be used or purchased, and our revenues and profits will not grow.

Our revenues and profits depend heavily upon the availability of coverage and reimbursement for the use of Testim, and any of our product candidates that are approved for marketing, from third-party healthcare and state and federal government payors, both in the U.S. and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination the product is:

- competitively priced;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Since reimbursement approval for a product is required from third-party and government payors, seeking this approval, particularly when seeking approval for a preferred form of reimbursement over other competitive products, is a time-consuming and costly process. Third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of any product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products or at all. Once reimbursement at an agreed level is approved by a third-party payor, we may lose that reimbursement entirely or we may lose the similar or better reimbursement we receive compared to competitive products. As reimbursement is often approved for a period of time, this risk is greater at the end of the time period, if any, for which the reimbursement was approved. To date, we have not experienced any problems with third-party payors. This does not mean that we will not experience any problems with third-party payors in the future. We do not know what the impact of changes to reimbursement programs, including Medicare Part D, might be.

International commercialization of Testim and our product candidates faces significant obstacles.

As with Testim, we may commercialize some of our product candidates internationally on our own or through collaborative relationships with foreign partners. We have limited foreign regulatory, clinical and commercial resources. We may not be able to enter into collaboration agreements with appropriate partners for important foreign markets on acceptable terms, or at all. Future collaborations with foreign partners may not be effective or profitable for us.

Healthcare reform measures could adversely affect our business.

The business and financial condition of pharmaceutical companies is affected by the efforts of governmental and third-party payors to contain or reduce the costs of healthcare. In the U.S. and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the healthcare system. For example, in some countries other than the U.S., pricing of prescription drugs is subject to government control, and we expect proposals to implement similar controls in the U.S. to continue. In particular, in January 2006, new Medicare prescription drug coverage legislation (Medicare Part D) was implemented. The prescription drug program established by this legislation and future amendments or regulatory interpretations of the legislation could have the effect of reducing the prices that we are able to charge for any products we develop and sell through these plans. This prescription drug legislation and related amendments or regulations could also cause third-party payors other than the federal government, including the states under the Medicaid program, to discontinue coverage for Testim or any products we develop or to lower reimbursement amounts that they pay. The impact that this program will have on Testim will take more time to determine as the competitive environment develops.

Further federal, state and foreign healthcare proposals and reforms are likely. While we cannot predict the legislative or regulatory proposals that will be adopted or what effect those proposals may have on our business, including the future reimbursement status of any of our product candidates, the pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

We could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws, false claims laws and federal and state anti-referral laws.

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws, false claims laws and physician self-referral laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state health care programs, including Medicare, Medicaid, Department of Defense and Veterans' health programs. We have not been challenged by a governmental authority under any of these laws and believe that our operations are in compliance with such laws.

However, because of the far-reaching nature of these laws, we may be required to alter one or more of our practices to be in compliance with these laws. Health care fraud and abuse regulations are complex, and even minor, inadvertent irregularities can potentially give rise to claims that the law has been violated. Any violations of these laws could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

We could become subject to false claims litigation under federal or state statutes, which can lead to civil money penalties, criminal fines and imprisonment, and/or exclusion from participation in federal health care programs. These false claims statutes include the federal False Claims Act, which allows any person to bring suit alleging the false or fraudulent submission of claims for payment under federal programs or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in recent years and have increased the risk that companies like us may have to defend a false claim action. We could also become subject to similar false claims litigation under state statutes. If we are unsuccessful in defending any such action, such action may have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

The commercialization of Testim and the clinical testing, manufacture and commercialization of our product candidates, if approved, involves significant exposure to product liability claims. We have clinical trial and product liability insurance that covers Testim and the clinical trials of our other product candidates that we believe is adequate in both scope and amount and has been placed with what we believe to be reputable insurers. We are self-insured for the first $1.0 million of liability under these policies. Our product liability policies have been written on a claims-made basis. If any of our product candidates are approved for marketing, we may seek additional coverage. We cannot predict all of the adverse health events that Testim or our product candidates may cause. As a result, our current and future coverages may not be adequate to protect us from all the liabilities that we may incur. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. Whether or not we are ultimately successful in product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which would impair our business. We may not be able to maintain our clinical trial insurance or product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses. If we are required to pay a product liability claim, we may not have sufficient financial resources and our business and results of operations may be harmed.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities and our commercial product, Testim, involve the use of testosterone and large amounts of alcohol which are classified as hazardous materials and chemicals. XIAFLEX, our product candidate for the treatment of Dupuytren's contracture, Peyronie's disease and Adhesive Capsulitis, or Frozen Shoulder syndrome, is a biologic product. Biologic products may present a manufacturing health hazard due to risk of infection with the bacterial cell line used to produce the product or with potential bacteriophage contamination with the fermentation. Although we believe that our safety procedures for using, storing, handling, manufacturing and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business and financial condition. To our knowledge, we have not been the subject of any investigation by any agency or authority for failure to comply with any rules or regulations applicable to hazardous materials or chemicals. We do not maintain specific insurance for the handling of biological, hazardous and radioactive materials. We have contracts with third-party providers for the storage and disposal of hazardous waste and believe that any claims against us in these areas would be the responsibility of these third parties. However, we may be held responsible for these claims despite the fact that we have contracted with third parties for the storage and disposal of hazardous waste. If we are exposed to these types of claims, we could be held responsible for liabilities that exceed our financial resources, which could severely affect our operations.

Risks Related to the Manufacture of XIAFLEX

We have limited experience in manufacturing pharmaceutical products and may encounter difficulties in the manufacture of the active ingredient of XIAFLEX at our facility in Horsham, Pennsylvania which could materially adversely affect our results of operations or delay or disrupt our development timelines for XIAFLEX.

The manufacture of pharmaceutical products requires significant expertise and capital investment. Although we leased our facility in Horsham in order to have direct control over the manufacturing of the active ingredient of XIAFLEX, for which we expect to be the sole supplier for commercial supply, we have limited experience in manufacturing XIAFLEX or any other pharmaceutical product. We may encounter difficulties with the manufacture of the active ingredient of XIAFLEX which could materially adversely affect our results of operations or delay or disrupt our development timelines for XIAFLEX. These problems may include:

- our ability to develop and implement an internal manufacturing capability;
- our ability to make necessary modifications and validate the facility;
- difficulties with production and yields, including scale-up and achieving adequate capacity for such supply;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations; and
- lack of capital funding.

Furthermore, our manufacturing operations expose us to a variety of significant risks, including:

- product defects;
- contamination of product or product loss;
- environmental liabilities or claims resulting from our production process or contamination at our Horsham facility;
- sudden loss of inventory; and
- inability to manufacture products at a cost that is competitive with third party manufacturing operations.

If we are unable to gain regulatory approval for XIAFLEX, we may not have an alternate use for our Horsham facility but will be required to make payments under our lease.

We have entered into a lease for our facility in Horsham, which expires on January 1, 2017. If we are unable to gain regulatory approval for XIAFLEX, we may not have an alternate use for the manufacturing facility but will be required to make payments under our lease. As of December 31, 2007, the total future minimum lease payments of this lease during its initial noncancellable term are approximately $21.7 million.

Our Horsham facility is subject to regulatory oversight, which may delay or disrupt our development and commercialization efforts for XIAFLEX.

We must ensure that all of the processes, methods, equipment and facilities employed in the manufacture of XIAFLEX at our Horsham facility are compliant with the current Good Manufacturing Practices, or cGMP. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. Compliance with cGMP requires record keeping and quality control to assure that the clinical and commercial product meets applicable specifications and other requirements. Our Horsham facility will be subject to inspection by regulatory agencies after the filing for approval of XIAFLEX with regulatory authorities. If an inspection by regulatory authorities indicates that there are deficiencies including non-compliance with regulatory requirements, we could be required to take remedial actions, stop production or close our Horsham facility, which would disrupt the manufacturing processes, limit the supplies of XIAFLEX and delay clinical trials and subsequent licensure. If we fail to comply with these requirements, we may not be permitted to sell our products or may be limited in the jurisdictions in which we are permitted to sell them.

Following licensure of our Horsham facility, noncompliance with any applicable regulatory requirements may result in refusal by regulatory authorities to allow use of XIAFLEX made at our Horsham facility in clinical trials, refusal of the government to allow distribution of XIAFLEX for commercialization, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts.

Risks Related to Our Dependence on Third-Party Manufacturers and Service Providers

Since we currently rely on third-party manufacturers and suppliers, we may be unable to control the availability or cost of manufacturing our products, which could adversely affect our results of operations.

We currently do not manufacture Testim or any of our product candidates, except for the active ingredient for XIAFLEX for which we expect to be the sole source of supply for the commercial supply. Testim is manufactured for us by DPT, under a contract that expires on December 31, 2010. We have qualified a back-up supplier to manufacture Testim. Our transmucosal film product candidates are manufactured by PharmaForm.

The manufacture of pharmaceutical products requires significant expertise and capital investment. DPT, our back-up supplier for Testim, or any other third-party manufacturer may encounter difficulties in production. These problems may include:

- difficulties with production costs and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations; and
- lack of capital funding.

DPT, PharmaForm, or any of our other third-party manufacturers may not perform as agreed or may terminate its agreement with us, which would adversely impact our ability to produce and sell Testim or our ability to produce XIAFLEX or other product candidates for clinical trials. The number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture bulk drug substance on a commercial scale is limited, and it would take a significant amount of time to arrange and receive regulatory approval for alternative arrangements. We may not be able to contract for the manufacturing of Testim or any of our product candidates on acceptable terms, if at all, which would materially impair our business.

In December 2006, we suspended the dosing of our ongoing phase III trials for XIAFLEX for the treatment of Dupuytren's contracture in response to an issue related to the manufacture of clinical supplies and, as a result, the FDA placed these trials on clinical hold. The FDA lifted the clinical hold in August 2007 and cleared us to resume our XIAFLEX trials. While we believe that we have taken all appropriate remedial measures to address this issue, we cannot assure you that we will not encounter similar or other issues related to the manufacture of our products and product candidates.

Any of these factors could increase our costs and result in us being unable to effectively commercialize or develop our products. Furthermore, if DPT, our back-up supplier for Testim or any other third-party manufacturer fails to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, we may be unable to meet the demand for our products and we may lose potential revenues.

We rely on a single source supplier and a limited number of suppliers for two of the primary ingredients for Testim and the loss of any of these suppliers could prevent us from selling Testim, which would materially harm our business.

We rely on third-party suppliers for our supply of testosterone and CPD, two key ingredients of Testim. Testosterone is available to us from only two sources. We rely exclusively on one outside source for our supply of CPD. We do not have any agreements with these suppliers regarding these key ingredients. If either of the two sources that produce testosterone stops manufacturing it, or if we are unable to procure testosterone on commercially favorable terms, or if we are not able to obtain it in a timely manner, we may be unable to continue to produce or sell Testim on commercially viable terms, if at all. In addition, if our third-party source of CPD stops manufacturing pharmaceutical grade CPD, or does not make CPD available to us on commercially favorable terms, we may be unable to continue to produce or sell Testim on commercially viable terms, if at all. Furthermore, the limited number of suppliers of testosterone and CPD may provide such companies with greater opportunity to raise their prices. Any increase in price for testosterone or CPD may reduce our gross margins.

Due to our reliance on contract research organizations or other third parties to assist us in conducting clinical trials, we are unable to directly control all aspects of our clinical trials.

Currently, we rely in part on third parties to conduct our clinical trials for the expansion of Testim and the development of our product candidates. As a result, we have had and will continue to have less control over the conduct of the clinical trials, the timing and completion of the trials and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- experience regulatory compliance issues; or
- undergo changes in priorities or may become financially distressed.

These factors may adversely affect their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Our contracts with the contract research organizations on which we currently rely are each terminable upon 30-days prior written notice. If we must replace any of these contract research organizations or any other contract research organization we may use in the future to conduct our clinical trials, our trials may have to be suspended until we find another contract research organization that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of our product candidates or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that the contract research organizations on which we rely offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of the relevant product candidate and preclude our ability to commercialize the product, thereby limiting our ability to generate revenue from the sales of products other than Testim, which may result in a decrease in our stock price.

Our third-party manufacturers are subject to regulatory oversight, which may delay or disrupt our development and commercialization efforts.

Third-party manufacturers of our products or product candidates must ensure that all of the processes, methods and equipment are compliant with the current Good Manufacturing Practices, or cGMP, and conduct extensive audits of vendors, contract laboratories and suppliers. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. Compliance by third-party manufacturers with cGMP requires record keeping and quality control to assure that the product meets applicable specifications and other requirements. Manufacturing facilities are subject to inspection by regulatory agencies at any time. If an inspection by regulatory authorities indicates that there are deficiencies, third-party manufacturers could be required to take remedial actions, stop production or close the facility, which would disrupt the manufacturing processes and limit the supplies of Testim or our product candidates. If they fail to comply with these requirements, we also may be required to curtail the clinical trials of our product candidates, which are also supplied by these manufacturers, and may not be permitted to sell our products or may be limited in the jurisdictions in which we are permitted to sell them.

Over 90% of our product shipments are to only three customers; if any of these customers refuse to distribute Testim on commercially favorable terms, or at all, our business will be adversely affected.

We sell Testim to wholesale drug distributors and chain drug stores who generally sell products to retail pharmacies, hospitals and other institutional customers. We do not promote Testim to these customers, and they do not determine Testim prescription demand. However, over 90% of our product shipments during the period covered by this Report were to only three customers: Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation. Our business would be harmed if any of these customers refused to distribute Testim or refuse to purchase Testim on commercially favorable terms to us.

It is possible that wholesalers could decide to change their policies or fees, or both, in the future. This could result in their refusal to distribute smaller volume products, or cause higher product distribution costs, lower margins or the need to find alternative methods of distributing products. Such alternative methods may not exist or may not be economically viable.

If we are unable to grow our sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to grow our business.

As an organization, we have a limited history in sales, marketing and distribution. To directly market and distribute Testim or any of our product candidates which receive regulatory approval, we must continue to enhance our sales and marketing efforts. For our direct sales efforts, we will need to hire additional salespeople in order to grow and manage any turnover that occurs in our sales force. For some market opportunities, we may need to enter into co-promotion agreements or other licensing arrangements with pharmaceutical or biotechnology firms in order to increase the commercial success of our products.

We may not be able to grow our direct sales, marketing and distribution capabilities or enter into future co-promotion or similar licensing arrangements with third parties in a timely manner, or on acceptable terms. To the extent that we enter into future co-promotion or other licensing arrangements, our product revenues may be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful or our future partners may not devote sufficient resources to our products. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

Risks Related to Intellectual Property

If we breach any of the agreements under which we license commercialization rights to products or technology from others, we could lose license rights that are critical to our business.

We are a party to a number of license agreements by which we have rights to use the intellectual property of third parties that are necessary for us to operate our business. In particular, we have obtained the exclusive right to develop and commercialize Testim pursuant to a license agreement with Bentley. Bentley may unilaterally terminate the agreement if we fail to make payments under this agreement and this failure continues for a period of 30 days following written notice to us by Bentley. If the agreement is properly terminated by Bentley, we may not be able to manufacture or sell Testim.

Additionally, we have obtained exclusive rights to make and sell products that are used for hormone replacement, to treat any type of urologic disorder or as a pain therapy incorporating PharmaForm's transmucosal film technology. This agreement continues for the life of the licensed patent rights. Either party may terminate this agreement under certain events of bankruptcy or insolvency by the other party. PharmaForm may unilaterally terminate this agreement if:

- we fail to make payments under this agreement and this failure continues for a period of 30 days following written notice to us by PharmaForm; or
- we fail to initiate clinical trials within two years of availability of final formulation in quantities adequate for clinical testing and associated documentation for clinical trials.

If our agreement with PharmaForm is properly terminated by PharmaForm, we may not be able to execute our strategy to develop, manufacture or sell transmucosal film products. To the extent that unpatented PharmaForm trade secrets are necessary for the manufacture of the transmucosal product candidates, our license to such trade secrets would expire with the expiration of the licensed patents in 2020 or later and potentially impair our continued commercialization of our transmucosal product candidates thereafter.

We have also obtained exclusive worldwide rights from BioSpecifics to develop, market and sell products, other than dermal formulations labeled for topical administration, that contain BioSpecifics' enzyme, which we refer to as XIAFLEX, for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. We may expand the agreement, at our option, to license products which contain BioSpecifics' enzyme for other indications, excluding dermal formulations labeled for topical administration, as they are developed by BioSpecifics or by us. This agreement continues on a product by product and country by country basis until the later of:

- the last to expire valid claim of a patent covering such product;
- the expiration of the regulatory period conveyed by orphan drug designation with respect to such product; and
- 12 years.

Upon expiration of the agreement pursuant to the preceding sentence, we will have a fully paid-up license to the products developed under the agreement. Either party may terminate this agreement in the event of bankruptcy or insolvency by the other party. Additionally, either party may terminate this agreement if the other party is in material breach of its obligations under the agreement which continues for a period of 90 days following receipt of written notice of such material breach. We may terminate this agreement in its entirety, or on a country by country basis, on an indication by indication basis, or on a product by

product basis, at any time upon 90 days prior written notice to BioSpecifics. If this agreement is properly terminated by BioSpecifics, we may not be able to execute our strategy to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome or to develop and commercialize future product candidates utilizing BioSpecifics' enzyme.

We expect to enter into additional licenses in the future. These licenses may impose various development, commercialization, funding, royalty, diligence or other obligations on us. If we breach any of these obligations, the licensor may have the right to terminate the license or render the license non-exclusive, which could make it impossible for us to develop, manufacture or sell the products covered by the license.

Disputes may arise with respect to our licensing agreements regarding manufacturing, development and commercialization of any products relating to our in-licensed intellectual property, including Testim. These disputes could lead to delays in or termination of the development, manufacture and commercialization of Testim or our product candidates or to litigation.

We have only limited patent protection for Testim and our product candidates, and we may not be able to obtain, maintain and protect proprietary rights necessary for the development and commercialization of Testim or our product candidates.

Our business and competitive positions are dependent upon our ability to obtain and protect our proprietary position for Testim and our product candidates in the U.S., Europe and elsewhere. Because of the substantial length of time and expense associated with development of new products, we, along with the rest of the biopharmaceutical industry, place considerable importance on obtaining and maintaining patent protection for new technologies, products and processes. The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our and our licensors' patents and patent applications may not protect our technologies and products because, among other things:

- there is no guarantee that any of our or our licensors' pending patent applications will result in issued patents;
- we may develop additional proprietary technologies that are not patentable;
- there is no guarantee that any patents issued to us, our collaborators or our licensors will provide us with any competitive advantage or cover our product candidates;
- there is no guarantee that any patents issued to us or our collaborators or our licensors will not be challenged, circumvented or invalidated by third parties; and
- there is no guarantee that any patents previously issued to others or issued in the future will not have an adverse effect on our ability to do business.

We attempt to protect our intellectual property position by filing or obtaining licenses to patent applications and, where appropriate, patent applications in other countries related to our proprietary technology, inventions and improvements that are important to the development of our business. Our PharmaForm transmucosal film product candidates are covered by a formulation patent in the U.S. only. This patent expires in 2020. Testosterone, the active ingredient in Testim, is off-patent and is included in competing TRT products. In the U.S., there is a methods and composition patent that expires in June 2008, and a method of use patent that expires in January 2025. Even though a patent has issued that will not expire until 2025, if a generic version of Testim is launched in the U.S., we may not be able to halt sales of such generic during the pendency of a patent infringement suit against generics, if ever. Bentley has filed continuation and divisional applications with the U.S. Patent and Trademark Office, or USPTO, which would provide us with further market protection if a patent or patents issue from any of these applications. In Canada, there are two patents, one that expires in January 2010 and another that expires in 2023. The patent recently issued by the European Patent Office covering Testim expires in April 2023. Bentley also has submitted a patent application in Japan that is awaiting examination. All of these patents and any patents that issue from the pending applications are included in our license from Bentley.

XIAFLEX, licensed from BioSpecifics is covered by two method of use patents in the U.S., one for the treatment of Dupuytren's contracture and one for the treatment of Peyronie's disease. The Dupuytren's patent, which was issued in December 2007 after a reissue proceeding, expires in 2014, and the Peyronie's patent expires in 2019. The patents are limited to the use of XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease, respectively, with certain dose ranges and/or concentration ranges. Currently there is not enough data to establish whether any approved product for Dupuytren's contracture or Peyronie's disease or Frozen Shoulder syndrome will be covered by these patents. In January 2005, a patent application was filed with regard to XIAFLEX for the treatment of Frozen Shoulder syndrome. If this patent is granted, it would expire in 2026. In January 2006, we filed a patent application with regard to the manufacturing process for XIAFLEX; if this patent is granted, it would expire in January 2027.

Foreign patents and pending applications may also cover these products in certain countries depending upon the concentration and dosage ranges of such products. Some countries will not grant patents on patent applications that are filed after the public sale or disclosure of the material claimed in the patent application. The U.S., by contrast, allows a one year grace period after public disclosure in which to file a patent application.

The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Limitations on patent protection in some countries outside the U.S., and the differences in what constitutes patentable subject matter in these countries, may limit the protection we seek outside of the U.S. For example, methods of treating humans are not patentable subject matter in many countries outside of the U.S. In addition, laws of foreign countries may not protect our intellectual property to the same extent as would laws of the U.S. In determining whether or not to seek a patent or to license any patent in a particular foreign country, we weigh the relevant costs and benefits, and consider, among other things, the market potential of our product candidates in the jurisdiction, and the scope and enforceability of patent protection afforded by the law of the jurisdiction. Failure to obtain adequate patent protection for our proprietary product candidates and technology would impair our ability to be commercially competitive in these markets. 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 others.

We intend to seek patent protection whenever it is available for any products or product candidates we acquire in the future. However, any patent applications for future products may not issue as patents, and any patent issued on such products may be challenged, invalidated, held unenforceable or circumvented. Furthermore, the claims in patents which have been issued on products we may acquire in the future may not be sufficiently broad to prevent third parties from commercializing competing products. If we fail to obtain adequate patent protection for our products, our ability to compete could be impaired.

Technology in-licensed by us is important to our business. We may not control the patent prosecution, maintenance or enforcement of our in-licensed technology. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our internally developed intellectual property. For example, in-licensed patents for which our rights are limited to a particular field of use could be or become licensed in other fields to other licensees and, therefore, become subject to enforcement by such other licensees without our participation. Consequently, such licensed patents could be held invalid or unenforceable or could have claims construed in a manner adverse to our interests in litigation, which we would not control or to which we would not be a party. If any of the intellectual property rights of our licensors is found to be invalid, this could have a material adverse impact on our operations.

If we are not able to protect and control unpatented trade secrets, know-how and other technological innovation, we may suffer competitive harm. We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. However, trade secrets are difficult to protect. To maintain the confidentiality of trade secrets and proprietary information, we generally seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of a relationship with us. However, we may not obtain these agreements in all circumstances. Nor can we guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, or that we will have an adequate remedy for any such breach. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. Others may have developed, or may develop in the future, substantially similar or superior know-how and technology. The loss or exposure of our trade secrets, know-how and other proprietary information, as well as independent development of similar or superior know-how, could harm our operating results, financial condition and future growth prospects. Many of our employees and consultants were, and many of our consultants may currently be, parties to confidentiality agreements with other companies. Although our confidentiality agreements with these employees and consultants require that they do not bring to us, or use without proper authorization, any third party's proprietary technology, if they violate their agreements, we could suffer claims or liabilities.

We may have to engage in costly litigation to enforce or protect our proprietary technology or to defend challenges to our proprietary technology by our competitors, which may harm our business, results of operations, financial condition and cash flow.

The pharmaceutical field is characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our licensed patents will be enforceable. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Litigation may be necessary to protect our proprietary rights, and we cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights.

Competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement lawsuits, which are expensive and time-consuming. In any such proceeding, a court may decide that a patent of ours is not valid or is unenforceable, may narrow our patent claims or may refuse to stop the

other party from using the technology at issue on the grounds that our patents do not cover its technology. In particular, if a competitor were to file a paragraph IV certification under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, in connection with that competitor's submission to the FDA of an abbreviated new drug application, or ANDA, for approval of a generic version of any of our products for which we believed we held a valid patent, then we could initiate a lawsuit against such competitor claiming patent infringement and defending the relevant patent's validity and enforceability. Depending on the facts and circumstances, the FDA may stay the approval of the ANDA for a generic version of any of our products for 30 months so long as we initiate litigation against the filer of the ANDA within 45 days of receiving the paragraph IV certification. If a court found that one of our patents was invalid or not infringed, then the FDA would be permitted to approve the competitor's ANDA resulting in a competitive generic product. In the event that the FDA did not grant the 30 month stay, FDA would be permitted to approve the competitor's ANDA; however, we could engage in legal proceedings, such as an injunction, to attempt to preclude the generic competitor from entering the market during the pendency of the patent litigation, but we may not prevail in which event the competitor could enter the market, despite the ongoing patent litigation.

Our ability to market our products may be impaired by the intellectual property rights of third parties.

Our commercial success will depend in part on not infringing the patents or proprietary rights of third parties. We are aware of competing intellectual property relating to the TRT gel market. While we currently believe we have freedom to operate in the TRT gel market, others may challenge our position in the future. We are also aware of at least one third-party patent relating to BioSpecifics' enzyme that may impair BioSpecifics' freedom to operate in the manufacture of XIAFLEX. We are also aware of third-party patents relating to PharmaForm's transmucosal film delivery system that may impair PharmaForm's freedom to operate in the manufacture of product candidates using a transmucosal film delivery system. There has been, and we believe that there will continue to be, significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

Third parties could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or products. A third party might request a court to rule that the patents we in-license are invalid or unenforceable. In such a case, even if the validity or enforceability of those patents were upheld, a court might hold that the third party's actions do not infringe the patent we in-license thereby, in effect, limiting the scope of our patent rights. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. However, there can be no assurance that any such license will be available on acceptable terms or at all. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

We may not be able to obtain or maintain orphan drug exclusivity for our product candidates, and our competitors may obtain orphan drug exclusivity prior to us, which could significantly harm our business.

Some jurisdictions, including Europe and the U.S., may designate drugs for relatively small patient populations as orphan drugs. The FDA granted orphan drug status to XIAFLEX in the U.S. for the treatment of Dupuytren's contracture and Peyronie's disease. Orphan drug designation must be requested before submitting an application for marketing authorization. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity and specific tax credits in the U.S. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity means that another application to market the same drug for the same indication may not be approved, except in limited circumstances, for a period of up to 10 years in Europe and for a period of seven years in the U.S. Obtaining orphan drug designations and orphan drug exclusivity for our product candidates, including XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease, may be critical to the success of these product candidates. Our competitors may obtain orphan drug exclusivity for products competitive with our product candidates before we do, in which case we would be excluded from that market. Even if we obtain orphan drug exclusivity for any of our product candidates, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. In addition, even if we obtain orphan drug exclusivity for any of our product candidates, a viable commercial market may never develop and we may never derive any meaningful revenues from the sales of these products.

If Testim or our future products or product candidates infringe the intellectual property of our competitors or other third parties, we may be required to pay license fees or cease these activities and pay damages, which could significantly harm our business.

Even though Testim and our product candidates may be covered by patents, they may nonetheless infringe the patents or violate the proprietary rights of third parties. In these cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to sell and use Testim and develop and commercialize our product candidates. We may not, however, be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property.

Third parties may assert patent or other intellectual property infringement claims against us, or our licensors or collaborators, with respect to technologies used in potential product candidates. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. We may not have sufficient resources to effectively litigate these claims. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from business operations. In addition, any patent claims brought against our licensors or collaborators could affect their ability to carry out their obligations to us.

Furthermore, if a patent infringement suit were brought against us, or our licensors or collaborators, the development, manufacture or potential sale of product candidates claimed to infringe a third party's intellectual property may have to cease or be delayed. Ultimately, we may be unable to commercialize one or more of our product candidates, our patent claims may be substantially limited or may have to cease some portion of our operations as a result of patent infringement claims, which could severely harm our business.

Risks Related to Employees and Growth

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. In addition, an important element of our strategy is to leverage the development, regulatory and commercialization expertise of our current management in our development activities. Our employment agreements with our executive officers are terminable on short notice or no notice. The loss of key employees may 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 further commercialization of Testim or the development and commercialization of our product candidates. If we are unable to attract and retain qualified and talented senior management personnel, our business may suffer.

To grow we will need to hire a significant number of qualified personnel. However, there is intense competition 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 commercialization of Testim and the development and commercialization of our product candidates. As we grow, the inability to attract new employees when needed or to retain existing employees could severely limit our growth and harm our business.

Changes in the expensing of stock-based compensation have resulted in unfavorable accounting charges and may require us to change our compensation practices. Any change in our compensation practices may adversely affect our ability to attract and retain qualified scientific, technical and business personnel.

We rely heavily on stock options to compensate existing employees and attract new employees. We also have an employee stock purchase plan under which employees can purchase our common stock at a discount. The Financial Accounting Standards Board has announced new rules for recording expense for the fair value of stock options and purchase rights under employee stock purchase plans. As a result of these new rules, commencing on January 1, 2006, we began expensing the fair value of stock options and purchase rights under our employee stock purchase plan, thereby increasing our operating expenses and reported losses. Although we intend to continue to include various forms of equity in our compensation plans, if the extent to which we use forms of equity in our plans is reduced due to the negative effects on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

Our operations may be impaired unless we can successfully manage our growth.

As of December 31, 2007, we had approximately 300 employees. In order to continue to achieve our business goals, we currently anticipate that we will need to add employees to our existing departments over each of the next two years. Expansion may place a significant strain on our management, operational and financial resources. Moreover, higher than expected market growth of Testim, the acquisition or in-licensing of additional products, as well as the development and commercialization of our other product candidates or marketing arrangements with third parties, could accelerate our hiring needs beyond our current expectations. To manage further growth, we will be required to continue to improve existing, and implement additional, operational and financial systems, procedures and controls, and hire, train and manage additional employees. Our current and planned personnel, systems, procedures and controls may not be adequate to support our anticipated growth and we may not be able to hire, train, retain, motivate and manage required personnel. Our failure to manage growth effectively could limit our ability to achieve our business goals. In addition, our direct sales force consists of relatively newly hired employees. Turnover in our direct sales force or marketing team could adversely affect Testim and future product sales growth.

Risks Related to Stock Market Price

The market price of our common stock is likely to be volatile.

Prior to our initial public offering in July 2004, there was no public market for our common stock. Since our initial public offering, our stock price has, at times, been volatile. We cannot assure you that an active trading market for our common stock will exist at any time. Holders of our common stock may not be able to sell shares quickly or at the market price if trading in our common stock is not active. Substantially all of our outstanding shares of our common stock are eligible for sale in the public market. For the 30 days prior to the end of the period covered by this Report, our average daily trading volume was approximately 359,000 shares. Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that holders of a large number of shares intend to sell shares, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities, even if our business is doing well. In addition, the market price of our common stock could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;
- Testim market acceptance and sales growth;
- growth of the overall androgen market, which may be influenced by the sales and marketing efforts of our competitors;
- entry into the marketplace of competitive products;
- developments concerning therapies that compete with Testim in the treatment of hypogonadism;
- our ability to manufacture any products to commercial standards;
- results of our clinical trials;
- the regulatory status of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- regulatory developments in the U.S. and foreign countries;
- developments or disputes concerning our patents or other proprietary rights;
- public concern over our drugs;
- litigation involving us, our general industry or both;
- future sales of our common stock;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- departure of key personnel;
- the degree to which any co-promotion, licensing or distribution arrangements generate revenue;
- period-to-period fluctuations in our financial results or those of companies that are perceived to be similar to us;
- announcements of material events by those companies that are our third-party manufacturers and services providers, our partners, our competitors or perceived to be similar to us;
- changes in estimates of our financial results or recommendations by securities analysts;
- investors' general perception of us; and
- general economic, industry and market conditions.

Furthermore, market prices for securities of pharmaceutical, biotechnology and specialty biopharmaceutical companies have been particularly volatile in recent years. The broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. If any of these risks occurs, it could cause our stock price to fall and may expose us to class action lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Possible dilutive effect of outstanding options and warrants.

At the end of the period covered by this Report, stock options to purchase 3,776,105 shares of common stock and warrants to purchase 2,281,939 shares of common stock were outstanding. In addition, as of December 31, 2007, a total of 2,567,396 stock options are available for grant under our 2004 Equity Compensation Plan amended and restated as of June 13, 2007. A total of 3,434,991 of the outstanding options and warrants are "in the money" and exercisable as of December 31, 2007. "In the money" means that the current market price of the common stock is above the exercise price of the shares subject to the warrant or option. The issuance of common stock upon the exercise of these options and warrants could adversely affect the market price of the common stock or result in substantial dilution to our existing stockholders.

Provisions in our certificate of incorporation and bylaws and under Delaware law may prevent or frustrate a change in control in management that stockholders believe is desirable.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a 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.

The affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote is necessary to amend or repeal the above provisions of our certificate of incorporation. In addition, absent approval of our board of directors, our bylaws may only be amended or repealed by the affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote.

In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

ITEM 1B. *Unresolved Staff Comments*

None.

ITEM 2. *Properties*

Malvern. We currently lease approximately 62,092 square feet of space for our headquarters in Malvern, Pennsylvania, of which approximately 57,130 square feet is dedicated to office space and approximately 4,962 square feet is dedicated to warehousing and packaging operations. The initial term of this lease ends on December 31, 2013.

Horsham. We lease a 50,000 square foot biological manufacturing facility in Horsham, Pennsylvania that we are using to produce the active ingredient of XIAFLEX. The initial term of this lease ends on January 1, 2017. The Horsham facility is subject to, and we are in the process of preparing for, regulatory inspection.

ITEM 3. *Legal Proceedings*

We are not engaged in any material legal proceedings.

ITEM 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to the vote of stockholders through the solicitation of proxies or otherwise during the quarter ended December 31, 2007.

PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market on July 23, 2004 under the symbol "AUXL." Prior to that time, there had been no market for our common stock. In November 2006, we were included in the NASDAQ Biotechnology Index. The following table sets forth the high and low closing sales prices per share for our common stock for the periods indicated, as reported by The NASDAQ Global Market:

Year Ended December 31, 2007:	High	Low
First Quarter	$ 15.17	$ 12.31
Second Quarter	$ 16.77	$ 13.11
Third Quarter	$ 21.94	$ 15.32
Fourth Quarter	$ 31.11	$ 21.45

Year Ended December 31, 2006:	High	Low
First Quarter	$ 7.93	$ 5.58
Second Quarter	$ 9.39	$ 7.09
Third Quarter	$ 11.29	$ 7.34
Fourth Quarter	$ 17.43	$ 10.12

Holders of Record

As of March 3, 2008, there were approximately 104 holders of record of our common stock. Because many of such shares are held by brokers and other institutions on behalf of stockholders, the Company is unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never paid or declared any cash dividends on our common stock. We currently intend to retain any earnings for future growth and, therefore, do not expect to pay cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information under the heading "Equity Compensation Plan Information" in our definitive Proxy Statement for our Annual Meeting of Stockholders to be held on June 12, 2008, to be filed with the SEC, is incorporated herein by reference.

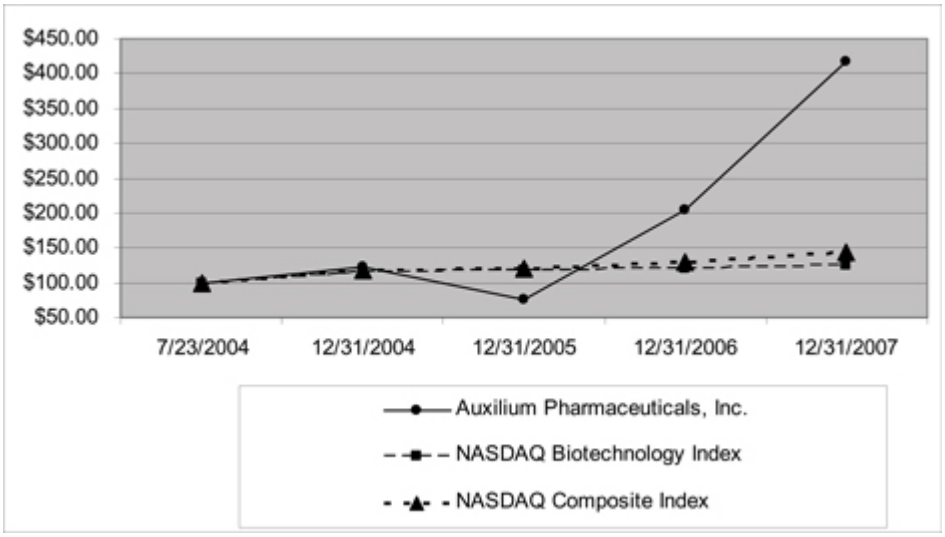
Recent Sales of Unregistered Securities

During the quarter ended December 31, 2007, we did not issue any unregistered shares of our common stock.

Comparative Stock Performance Graph

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total stockholder return of (i) the NASDAQ Composite Index, and (ii) the NASDAQ Biotechnology Index, assuming an investment of $100 on July 23, 2004, the date our shares began public trading on NASDAQ, in each of our common stock; the stocks comprising the NASDAQ Composite Index; and the stocks comprising the NASDAQ Biotechnology Index.

Comparison of Cumulative Total Return* Among Auxilium Pharmaceuticals, Inc, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



- Total return assumes $100 invested on July 23, 2004 in our common stock, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index and reinvestment of dividends through fiscal year ended December 31, 2007.

	7/23/2004	12/31/2004	12/31/2005	12/31/2006	12/31/2007
Auxilium Pharmaceuticals, Inc	$ 100.00	$ 122.92	$ 76.39	$ 204.03	$ 416.53
NASDAQ Biotechnology Index	$ 100.00	$ 115.56	$ 118.84	$ 120.05	$ 125.55
NASDAQ Composite Index	$ 100.00	$ 117.65	$ 119.27	$ 130.62	$ 143.44

ITEM 6. ***Selected Financial Data***

SELECTED CONSOLIDATED FINANCIAL DATA
(In thousands, except share and per share data)

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this Report. The consolidated statements of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 have been derived from our audited consolidated financial statements and related notes, which are included elsewhere in this Report. The consolidated statement of operations data for the years ended December 31, 2004 and 2003 and the consolidated balance sheet data as of December 31, 2005, 2004 and 2003 have been derived from audited financial statements which do not appear in this Report. The historical results presented are not necessarily indicative of results to be expected in any future period.

	Years Ended December 31,				
	2007	2006	2005	2004	2003
Consolidated Statement of Operations Data:					
Net revenues	$ 95,734	$ 68,490	$ 42,804	$ 27,025	$ 8,822
Operating expenses:					
Cost of goods sold	24,609	17,692	13,119	8,148	3,762
Research and development	42,802	37,900	24,301	15,993	7,175
Selling, general, and administrative	72,768	61,277	43,935	31,210	27,475
Total operating expenses	140,179	116,869	81,355	55,351	38,412
Loss from operations	(44,445)	(48,379)	(38,551)	(28,326)	(29,590)
Interest income (expense), net	3,740	2,429	1,496	(192)	(1,007)
Other income (expense), net	—	2	(1,203)	—	1,722
Net loss	(40,705)	(45,948)	(38,258)	(28,518)	(28,875)
Accretion of redeemable convertible preferred stock	—	—	—	(395)	(490)
Deemed dividend to warrant holders	—	—	—	(173)	—
Dividends accrued on redeemable convertible preferred stock	—	—	—	—	(3,909)
Net loss applicable to common stockholders	$ (40,705)	$ (45,948)	$ (38,258)	$ (29,086)	$ (33,274)
Basic and diluted net loss per common share (1)	$ (1.07)	$ (1.48)	$ (1.54)	$ (3.11)	$ (59.08)
Weighted average common shares outstanding (1)	38,187,662	30,956,889	24,913,087	9,361,153	563,194

(1) The increase in weighted average common shares outstanding and the corresponding decrease in basic and diluted net loss per common share in 2004 is primarily the result of the conversion of all the Company's redeemable convertible preferred stock and the issuance of common shares both related to the Company's initial public offering in July of 2004. The increase in weighted average common shares outstanding and the corresponding decrease in basic and diluted net loss per common share in 2007, 2006 and 2005 is primarily the result of the issuance of common shares in the June 2007 public offering, September 2006 public offering and the June 2005 private placement, respectively.

	As of December 31,				
	2007	2006	2005	2004	2003
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 70,290	$ 44,835	$ 31,380	$ 32,707	$ 28,446
Restricted cash	—	—	—	—	9,500
Short-term investments	5,800	9,909	25,350	14,100	—
Working capital	64,861	46,819	47,052	42,028	25,364
Total assets	106,979	76,759	72,695	61,040	49,759
Long-term liabilities	11,166	11,737	11,578	8,823	577
Redeemable convertible preferred stock	—	—	—	—	93,287
Total stockholders' equity (deficit)	64,016	42,329	39,873	36,244	(65,804)

ITEM 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

As used herein, the terms "Company," "Auxilium," "we," "us," or "our" refer to Auxilium Pharmaceuticals, Inc. and its subsidiaries.

Overview

We are a specialty biopharmaceutical company with a focus on developing and marketing products to urologists, endocrinologists, orthopedists and select primary care physicians. We currently have approximately 300 employees. Our only marketed product, Testim®, is a proprietary, topical 1% testosterone once-a-day gel indicated for the treatment of hypogonadism. Hypogonadism is defined as reduced or absent secretion of testosterone which can lead to symptoms such as low energy, loss of libido, adverse changes in body composition, irritability and poor concentration.

Our current product pipeline includes:

Phase III:

- XIAFLEX™ (clostridial collagenase for injection), formerly referred to as AA4500, for the treatment of Dupuytren's contracture

Phase II:

- XIAFLEX for the treatment of Peyronie's disease

- XIAFLEX for the treatment of Frozen Shoulder syndrome, or Adhesive Capsulitis

Phase I:

- AA4010, treatment for overactive bladder using our transmucosal film delivery system

Preclinical:

- one pain products using our transmucosal film delivery system.

In addition to the above, we have the rights to develop seven other compounds for the treatment of pain using our transmucosal film technology and other products using our transmucosal film technology for treatment of urological disease and for hormone replacement therapy. We also have the option to license other indications for XIAFLEX other than dermal products for topical administration.

In December 2006, we suspended our phase III trials for XIAFLEX for the treatment of Dupuytren's contracture because of a manufacturing issue. After implementing corrective actions and following batches of product manufactured earlier this year for stability, we determined that the product exhibited an appropriate, consistent stability profile over a reasonable time period and submitted the data to the FDA. As a result, the FDA lifted the clinical hold in August 2007. In September 2007, we began dosing patients in the phase III trials in the U.S. and in Australia. In December 2007, we completed patient enrollment in the phase III trials in the U.S. and in Australia.

With regard to the development of XIAFLEX for the treatment of Peyronie's disease, which also had been placed on clinical hold by FDA and then released from clinical hold in August 2007, the FDA is requiring that we conduct an animal study in order to evaluate the potential impact of XIAFLEX on normal penile tissue, in case the injection misses the targeted Peyronie's plaque, prior to commencing phase IIb studies. In late 2006, we conducted several pilot studies in dogs, the results of which were used to design the protocol for the definitive study. The definitive dog study protocol was approved by the FDA in June 2007, at which time it was initiated. Based on current project plans, including communications with the FDA on their expectations for the animal studies, we expect to submit the results of these studies to the FDA during the first half of 2008 and, pending FDA approval, commence a phase IIb study in the second quarter of 2008. We anticipate that this phase IIb study will test different regimens and further validate a patient-reported outcomes questionnaire that we have developed for Peyronie's disease.

We have never been profitable and have incurred an accumulated deficit of $224.2 million as of December 31, 2007. We expect to incur significant operating losses for the foreseeable future. We anticipate that commercialization expenses, development costs, and in-licensing milestone payments related to existing and new product candidates and to enhance our core technologies will continue to increase in the near term. In particular, we expect to incur increased costs for selling and marketing as we continue to market Testim, additional development and pre-commercialization costs for:

- existing and new product opportunities;
- acquisition costs for new product opportunities; and
- increased general and administration expense to support the infrastructure required to grow and operate as a public company.

We will need to generate significant revenues to achieve profitability.

We expect that quarterly and annual results of operations will fluctuate for the foreseeable future due to several factors including:

- the overall growth of the androgen market;
- the timing and extent of research and development efforts; and
- the outcome and extent of clinical trial activities.

Our limited operating history makes accurate prediction of future operating results difficult.

Net revenues. To date, all of our net revenues have been generated by the sales and out-licensing of Testim. For the near term, we expect Testim to continue to be the primary source of our net revenues. We sell Testim to pharmaceutical wholesalers, who have the right to return Testim prior to the units being dispensed through patient prescriptions. Prior to 2006, we recognized revenue based on prescription units dispensed to patients, since they are not subject to return and we did not have sufficient historical experience to reasonably estimate product returns. Based on the product return history gathered through the end of the first quarter of 2006, we determined we had the information to reasonably estimate customer returns. Therefore, in the first quarter of 2006, we began recognizing revenue for Testim sales at the time of shipment of the product to customers, net of appropriate allowances for cash discounts, rebates, patient coupons and product returns. We do not anticipate that sales of Testim outside of the U.S., pursuant to our current agreements for international distribution rights of Testim, will have a material impact on our revenues or profitability. In addition to the up-front and milestone payments these international agreements afford us, we believe they also benefit us by providing opportunities for manufacturing efficiencies through increased sales of Testim, as well as, making us an attractive partner to future licensors by providing us with global development and commercialization capabilities. We are a relatively new company and our sales prospects are uncertain. We expect our revenues to fluctuate due to:

- market acceptance and pricing for Testim, including any change in wholesaler purchasing patterns;
- commercialization of and market acceptance of our future products, if any;
- regulatory approvals and market acceptance of new and competing products, including generics;
- government or private healthcare reimbursement policies, particularly with respect to Testim and our other product candidates; and
- promotional efforts of our competitors and the impact on sales.

We use a third-party distributor, ICS, a division of AmerisourceBergen Corporation, or ABC, for commercial distribution activities. The majority of our sales in the U.S. are to pharmaceutical wholesalers that, in turn, distribute product to chain and other retail pharmacies, hospitals, mail-order providers and other institutional customers. Over 90% of Testim purchases are from three customers: ABC, Cardinal Health, Inc. and McKesson Corporation. Outside of the U.S., we currently rely on third parties to market, sell and distribute Testim and any of our product candidates for which we receive marketing approval from any foreign jurisdictions. For Canada, we have an agreement with Paladin Labs, Inc. to market and distribute Testim. We have entered into an agreement, as amended, with Ipsen Pharma GmbH for the rest of the world, excluding Canada, China, Japan, Mexico, Poland, Russia, South Korea, and the U.S.

Under contractual agreements with our three largest wholesalers, we provide a fee for service to the wholesalers based on shipment activity. The agreements also provide for targeted levels of required distributor inventory. Otherwise, distributors independently manage their inventories with no intervention by us. Aside from the service fees required under these agreements, we do not offer incentives for wholesalers to take shipment of product.

We record sales of Testim net of allowances for prompt payment discounts, fees to wholesalers based on shipment activity under the terms of wholesaler service agreements, managed care contract rebates and government health plan charge backs, product coupons and, commencing in the first quarter of 2006 with the change to the wholesaler method of revenue recognition, product returns. In connection with the change in revenue recognition policy, we established a reserve totaling $1,019,000 for estimated product returns and allowances. Excluding the impact of the change in revenue recognition, total product sales allowances have amounted to 18.3%, 17.4% and 16.0% of total gross revenue for the years ended December 31, 2007, 2006 and 2005, respectively. The year-over-year growth of this percentage results primarily from our entry into additional pricing contracts with managed care providers, additional distributor service agreements and new product coupon programs designed to increase revenue growth.

Cost of goods sold. All of our cost of goods sold currently relate to the sale of Testim and consists of:

- raw materials;
- fees paid to our contract manufacturers and related costs;
- royalty payments, which currently consist solely of payments due to Bentley;
- personnel costs associated with quality assurance and manufacturing oversight; and
- distribution costs, including warehousing, freight and product liability insurance.

We do not anticipate any material changes in our gross margin rate in the U.S. We anticipate our gross margins for sales outside the U.S. will continue to be significantly lower than those seen in the U.S. This is due to a combination of factors which include the terms of our distribution agreements and the royalty payments due to our licensor.

Research and development. Our research and development expenses consist of:

- salaries and expenses for our development personnel;
- payments to consultants, investigators, contract research organizations and manufacturers in connection with our preclinical and clinical trials;
- costs of developing and obtaining regulatory approvals; and
- product license and milestone fees paid prior to regulatory approval.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the cost to complete projects in development cannot be reasonably estimated. Currently, Testim is our only marketed product. XIAFLEX is in phase III of development for the treatment of Dupuytren's contracture. XIAFLEX is in phase II of development for the treatment of Peyronie's disease and Frozen Shoulder syndrome. AA4010 is in phase I of development. Results from clinical trials may not be favorable. Further, data from clinical trials is subject to varying interpretation, and may be deemed insufficient by the regulatory bodies reviewing applications for marketing approvals. As such, clinical development and regulatory programs are subject to risks and changes that may significantly impact cost projections and timelines. We expect our research and development expenses for our current products to increase as a result of further development of XIAFLEX for Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. In addition, the current regulatory and political environment at the FDA, could lead to increased data requirements which could impact regulatory timelines and costs. We expect further significant increases in our expenditures to develop any other potential new product candidates that we would in-license or acquire. Expenditures will increase to develop any other product candidates that we in-license or acquire.

Selling, general and administrative. Selling, general and administrative expenses consist primarily of salaries and other related costs for personnel, marketing and promotion costs, professional fees and facilities costs. We anticipate increases in selling, general and administrative expenses due to sales and marketing costs associated with Testim, hiring of additional personnel, XIAFLEX pre-launch investment, stock compensation expense, investment in information technology, investor relations and other activities associated with operating as a publicly traded company.

Results of Operation

Accounting changes

As discussed in Note 2(e) to the Company's consolidated financial statements contained herein and under the heading "Critical Accounting Policies and Significant Judgments and Estimates" set forth below, in the first quarter of 2006 the Company began recognizing revenue for Testim sales at the time of shipment of the product to customers. Prior to 2006, the recognition of revenue on shipments of Testim units to customers was deferred until the units were dispensed through patient prescriptions. As a result of this change in revenue recognition, net revenues for year ended December 31, 2006 include a one-time benefit of $1.2 million and the net loss for the year ended December 31, 2006 includes a one-time benefit of $0.7 million, or $0.02 per share.

In addition, as discussed in Note 2(o) to the Company's consolidated financial statements contained herein, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R effective January 1, 2006 using the modified prospective transition method, which requires the application of SFAS No. 123R as of January 1, 2006, the first day of the Company's calendar year. The Company's consolidated financial statements as of and for the year ended December 31, 2006 reflect the application of SFAS No.123R. This accounting standard requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. In accordance with the modified prospective method, the Company's consolidated financial statements for periods prior to 2006 have not been restated and do not include the effect of SFAS 123R. Prior to 2006, the Company recognized the compensation expense related to stock-based awards measured by the intrinsic value of the award at grant date in accordance with APB No. 25. As a result of this change, the Company's net loss for the year ended December 31, 2006 was $2.6 million (or $0.08 per share) higher than if the Company had continued to account for share-based compensation under APB No. 25.

Years Ended December 31, 2007 and 2006

Net revenues. For fiscal year 2007, net revenues totaled $95.7 million compared to net revenues of $68.5 million for the year 2006, an increase of 40%. This increase in net revenues resulted primarily from substantial growth in Testim demand resulting from increased prescriptions and increases in pricing, net of discounts, rebates and coupons. According to National Prescription Audit (NPA) data from IMS Health (IMS), a pharmaceutical market research firm, Testim total prescriptions for 2007 grew 35.2% compared to 2006. We believe that Testim prescription growth in the 2007 period over the 2006 period was driven by physician and patient acceptance that Testim provides better patient outcomes, the shift in prescriptions away from the testosterone patch product and the other gel product to Testim, and the continued focus of our sales force on the promotion of Testim to urologists, endocrinologists and select primary care physicians. Net revenues for 2007 benefited from price increases having a cumulative impact of 11% over the comparable 2006 period, which was partially offset by increases in wholesaler discounts due to increased distribution costs, product rebates as Testim became more widely prescribed by managed care providers and increased coupon usage. Net revenues in 2007 and 2006 include $2.3 million and $0.6 million, respectively, of international product shipments and $0.7 million, in each year, of revenues related to up-front and milestone payments. Net revenues for 2006 include one-time benefits of $1.2 million recorded upon adoption of the wholesaler method of revenue recognition and of $0.6 million representing previously received non-refundable payments that were forfeited upon the mutual termination of an international distribution agreement.

Cost of goods sold. Cost of goods sold were $24.6 million and $17.7 million for the years ended December 31, 2007 and 2006, respectively. The increase in cost of goods sold in 2007 over 2006 was directly attributable to the increase in Testim revenue. Gross margin on net revenues was 74.3% in 2007 compared to 74.2% for 2006. The improvement in gross margin in 2007 over 2006 reflects the impact on year-over-year price increases which was substantially offset by a lower margin rate on international shipments, increased coupon usage and costs related to Testim manufacturing and quality improvement programs. The cost of goods sold for international product shipments in 2007 and 2006 amounted to $1.9 million and $0.6 million, respectively. Gross margin for U.S. revenues was 75.5% in 2007 compared to 74.6%, excluding the impact of the change in revenue recognition discussed above, for 2006.

Research and development expenses. Research and development expenses were $42.8 million and $37.9 million for the years ended December 31, 2007 and 2006, respectively. The increase in 2007 over 2006 was primarily due to the increased spending for development and manufacturing scale-up associated with XIAFLEX and additional stock-based compensation expense attributable to research and development. These increases were offset by a $5.3 million decrease in costs associated with the discontinuance of TestoFilm development.

Selling, general and administrative expenses. Selling, general and administrative expenses were $72.8 million and $61.3 million for the years ended December 31, 2007 and 2006, respectively. The increase in 2007 over 2006 was due primarily to selling and marketing expenses increasing by $8.4 million resulting from the increases in our Testim sales force made in late 2006 and pre-launch marketing for XIAFLEX, offset by the decrease in costs resulting from the termination in 2006 of a co-promotion agreement with Oscient. General and administrative expenses increased by $3.1 million as a result of the additional stock-based compensation expense and increases in administrative headcount.

Interest income (expense), net. Interest income (expense), net was $3.7 million and $2.4 million for the years ended 2007 and 2006, respectively. Net interest income in 2007 and 2006 relates primarily to interest earned on the invested proceeds from our registered direct offerings in June 2007 and September 2006.

Income Taxes. At December 31, 2007, we had federal net operating loss carryforwards of approximately $194.6 million, which will expire in 2019 through 2027, if not utilized. In addition, we had state net operating loss carryforwards of approximately $165.8 million, of which $77.7 million relate to Pennsylvania, which will expire 2010 through 2027 if not utilized. Future utilization of Pennsylvania net operating losses is limited to the greater of 12.5% of Pennsylvania taxable income or $3.0 million per year. At December 31, 2007, we had federal research and development credits of approximately $4.3 million that will expire in 2020 through 2027, if not utilized.

The Internal Revenue Code provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes that could limit our ability to utilize these carryforwards. We may have experienced various ownership changes, as a result of past financings. Accordingly, our ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, we may not be able to take full advantage of these carryforwards for federal income tax purposes.

On 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*", which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation did not have any material impact on the Company's results of operation or financial position.

Years Ended December 31, 2006 and 2005

Net revenues. For fiscal year 2006, net revenues totaled $68.5 million compared to net revenues of $42.8 million for the year 2005, an increase of 60%. This increase in net revenues resulted primarily from substantial growth in Testim demand resulting from increased prescriptions and increases in pricing, net of discounts, rebates and coupons. According to NPA data from IMS, a pharmaceutical market research firm, Testim total prescriptions for 2006 grew 37.7% compared to 2005. We believe that Testim prescription growth in the 2006 period over the 2005 period was driven by physician and patient acceptance that Testim provides better patient outcomes, the shift in prescriptions away from the testosterone patch product and the other gel product to Testim, the continued focus of our sales force on the promotion of Testim to urologists, endocrinologists and select primary care physicians, and our co-promotion agreement with Oscient Pharmaceuticals, Inc., or Oscient. Net revenues for 2006 benefited from price increases having a cumulative impact of 10% over the comparable 2005 period, which was partially offset by increases in wholesaler discounts due to increased distribution costs and product rebates as Testim became more widely prescribed by managed care providers. Net revenues for 2006 include one-time benefits of $1.2 million recorded in the first quarter upon adoption of the wholesaler method of revenue recognition and of $0.6 million recorded in the fourth quarter representing previously received non-refundable payments that were forfeited upon the mutual termination of the distribution agreement with Bayer, Inc., or Bayer. Net revenues in 2006 and 2005 also include $0.6 million and $1.0 million, respectively, of product shipped to Ipsen and $0.7 million and $0.6 million, respectively, of revenues related to up-front and milestone payments.

Cost of goods sold. Cost of goods sold were $17.7 million and $13.1 million for the years ended December 31, 2006 and 2005, respectively. The increase in cost of goods sold in 2006 over 2005 was directly attributable to the increase in Testim revenue. Gross margin on net revenues was 74.2% in 2006 compared to 69.4% for 2005. The improvement in gross margin in 2006 over 2005 principally reflects the year-over-year price increases, a reduction in the royalty rate paid to the Company's licensor, and manufacturing cost reductions, as well as the one-time revenue benefits discussed above. The cost of goods sold for product shipped to Ipsen in 2006 and 2005 amounted to $0.6 million and $0.9 million, respectively. Excluding the impact of the change in revenue recognition discussed above, gross margin for U.S. revenues was 74.6% in 2006 compared to 70.4% for 2005.

Research and development expenses. Research and development expenses were $37.9 million and $24.3 million for the years ended December 31, 2006 and 2005, respectively. The increase in 2006 over 2005 was primarily due to $9.0 million increase in cost associated with XIAFLEX due to the increased spending for development and manufacturing scale and the $1.1 million payment to Cobra Biologics Ltd., or Cobra, upon amendment of the manufacturing agreement with Cobra, a $2.4 million increase in development spending for TestoFilm prior to discontinuance of its development in October 2006 and a $1.7 million increase in administrative costs due primarily to an increase in headcount. These increases were offset by a $1.1 million decrease in costs associated with phase IV clinical trials for Testim.

Selling, general and administrative expenses. Selling, general and administrative expenses were $61.3 million and $43.9 million for the years ended December 31, 2006 and 2005, respectively. The increase in 2006 over 2005 was due primarily to selling and marketing expenses increasing by $13.7 million resulting from higher marketing costs and co-promotion and termination fees associated with the terminated co-promotion agreement with Oscient, the increases in our Testim sales force made in late 2006, and pre-launch marketing for XIAFLEX. General and administrative expenses increased by $3.6 million as a result of the additional stock-based compensation expense resulting from the adoption of SFAS 123R and the costs associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Interest income (expense), net. Interest income (expense), net was $2.4 million and $1.5 million for the years ended 2006 and 2005, respectively. Net interest income in 2006 and 2005 relates primarily to interest earned on the invested proceeds from our registered direct offering in September of 2006 and our private placement in June of 2005.

Other Income (expense), net. Other income (expense), net was $0 and $(1.2) million for the years ended December 31, 2006 and 2005, respectively. Other income (expense), net in 2005 relates to $0.2 million of placement agent fees and transaction costs associated with our private placement in June of 2005 which were allocated to the financing-related liability and the non-cash change in the fair value of the financing-related liability of $1.0 million during 2005. On December 30, 2005, the financing related liability of $7.2 million was reclassified to permanent equity as a result of amendments to the Securities Purchase Agreements. There were no such costs incurred in 2006.

Sources and Uses of Cash

Cash used in operations was $30.5 million, $43.6 million and $28.8 million for 2007, 2006 and 2005, respectively. Negative operating cash flows during 2007, 2006 and 2005 were caused primarily by operating losses.

Cash provided by (used in) investing activities was $(0.4) million, $11.8 million and $(12.5) million for 2007, 2006 and 2005, respectively. Cash provided by (used in) investing activities relates primarily to the net effect of purchases of short-term investments with part of the proceeds from our equity offerings in each of these years and redemptions of short-term investments for operational cash needs, together with our investments in property and equipment and, in 2006, the investment of $1.9 million to secure the lease of a manufacturing facility.

Cash provided by financing activities was $56.3 million, $45.2 million and $40.0 million in 2007, 2006 and 2005, respectively. Cash provided by financing activities in 2007 results primarily from the $49.9 million in net proceeds we received in the June 2007 registered direct offering and $6.4 million in cash receipts from stock option exercises and employee stock purchases. Cash provided by financing activity in 2006 results primarily from the $43.3 million in net proceeds we received in the September 2006 registered direct offering, $1.0 million cash received from warrant exercises and $1.2 million in cash receipts from stock option exercises and employee stock purchases. Cash provided by financing activity in 2005 results primarily from the $39.0 million received from the June 30, 2005 private placement and the $0.7 million in cash receipts from stock option exercises.

Liquidity and Capital Resources

Since inception through December 31, 2007, we have financed our product development, operations and capital expenditures primarily from private and public sales of equity securities. Since inception through December 31, 2007, we received net proceeds of approximately $276.1 million from our initial public offering, registered direct offering, private sales of securities and the exercise of stock options and warrants. We had approximately $76.1 million and $54.7 million in cash, cash equivalents and short-term investments as of December 31, 2007 and December 31, 2006, respectively.

We believe that our current financial resources and sources of liquidity will be adequate to fund our anticipated operations through the second quarter of 2009. We may, however, need to raise additional funds prior to this time in order to enhance our sales and marketing efforts for additional products we may acquire, commercialize any product candidates that receive regulatory approval, acquire or in-license approved products or product candidates or technologies for development and to maintain adequate cash reserves to minimize financial market fundraising risks. Insufficient funds may cause us to delay, reduce the scope of, or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including:

- Testim market acceptance and sales growth;
- our ability to realize sales efficiency and effectiveness of our sales force;
- third-party payor coverage and reimbursement for Testim;
- the cost of manufacturing, distributing, marketing and selling Testim;
- the scope, rate of progress and cost of our product development activities;
- future clinical trial results;
- the terms and timing of any future collaborative, licensing, co-promotion and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the costs of supplying and commercializing XIAFLEX and any of our product candidates;
- acquisition or in-licensing costs;
- the effect of competing technological and market developments;
- changes to the regulatory approval process for product candidates in those jurisdictions, including the U.S., in which we may be seeking approval for our product candidates;

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities or from bank or other loans. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

In 2006 and 2005, we received $0.9 million and $3.8 million, respectively, in payments from our agreements for Testim in other territories. These receipts are the result of up-front and milestone payments primarily related to contract signings and regulatory approvals. We might also enter into additional arrangements with corporate partners that could provide us with additional funding in the form of equity, debt, licensing, milestone or royalty payments. We might not be able to enter into such arrangements or raise any additional funds on terms favorable to us or at all.

As of March 7, 2008, we held $5.8 million of taxable auction rate securities (ARS). These investments are private placement securities with long-term stated maturities for which interest rates are reset through a "Dutch" auction every 28 or 35 days. They carry AAA/Aaa ratings and are backed by student loans which carry guarantees as provided under the Federal Family Education Loan Program of the U.S. Department of Education. The Dutch auction mechanism, which allows investors to sell or hold the securities at par, has in the past provided a liquid market for these types of securities. Given this liquidity, we have classified ARS as "available for sale" securities under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and, accordingly, reported such investments as short-term investments. With the liquidity issues experienced in global credit and capital markets, all of the ARS we hold experienced failed auctions, beginning February 11, 2008, as the amount of securities submitted for sale exceeded the amount of purchase orders. As a result, the interest rates on our securities have been reset at the contractual interest rate, ranging from 4.1% to 10.9%. Our ability to access in the near term the funds we invested in ARS is dependent on the success of future scheduled auctions, finding a buyer outside the auction process or a decision by the issuer of the securities to call the securities. If the uncertainties in the credit and capital market continue, these markets deteriorate further or there are ratings downgrades on any of the ARS we hold, we may be required to reclassify these investments to long-term investments and/ or adjust their carrying value through an impairment charge to earnings, if the fair value of these securities has declined to below their cost and such decline is assessed to be "other than temporary" under SFAS No. 115.

In August 2007, we filed a registration statement with the SEC to allow for the potential future sale by us, from time to time, in one or more offerings, of up to $150 million of certain debt and equity instruments specified therein. The shelf registration statement became effective on September 19, 2007. We believe it is good corporate policy to maintain an effective shelf registration statement at this time.

Contractual Commitments

We are involved with in-licensing of products which are generally associated with payments to the partner from whom we have licensed the product. Such payments frequently take the form of:

- an up-front payment, the size of which varies depending on the phase of the product and how many other companies would like to obtain the product, which is paid very soon after signing a license agreement;
- milestone payments which are paid when certain parts of the overall development program are accomplished, or in some cases, when a patent issues;
- payments upon certain regulatory events, such as the filing of an IND, and NDA, approval of an NDA, or the equivalents in other countries; and
- payments for achievement of certain sales thresholds, such as a payment due the first year a product achieves $100 million in sales.

We may also out-license products, for which we hold the rights, to other companies for commercialization in other territories, or at times, for other uses. When this happens, typically there is:

- an up-front payment made at or shortly after signing a partnering agreement;
- milestone payments that may be made on completion of a phase of a clinical program, or regulatory approval in a given territory; and
- a payment or payments made upon achievement of a certain level of sales in a given year.

Bentley

In May 2000 and May 2001, we entered into license agreements with Bentley for its patented transdermal gel technology. For details regarding the Bentley agreements, please refer to the discussion in Item 1.

Through December 31, 2007, we have made aggregate upfront and milestone payments under the three license agreements with Bentley of approximately $0.6 million. If all events under the Bentley license agreements occur, we would be obligated to pay a maximum of approximately $1.0 million in milestone payments. The timing of the above payments, if any, is uncertain.

BioSpecifics

In June 2004, we entered into a development and license agreement with BioSpecifics and amended such agreement in May 2005 and in December 2005 (the BioSpecifics Agreement). For details regarding the BioSpecifics agreement, please refer to the discussion in Item 1.

Through December 31, 2007, we paid up-front and milestone payments under the BioSpecifics Agreement of $8.0 million and an option exercise fee of $0.5 million for the Frozen Shoulder syndrome indication. We could make up to an additional $5.5 million of contingent milestone payments under the BioSpecifics Agreement if all existing conditions are met. Additional milestone obligations may be due if we exercise an option to develop and license XIAFLEX for additional medical indications.

PharmaForm

In June 2003, we entered into a license agreement with Formulation Technologies, L.L.C., d/b/a/ PharmaForm, or PharmaForm. In February 2005, we entered into an additional license agreement with PharmaForm. We also entered into a research and development agreement with PharmaForm on a fee for service basis. For details regarding the PharmaForm agreements, please refer to the discussion in Item 1.

In 2005, we paid an up-front payment of $0.5 million and could make up to an additional $21.2 million in contingent milestone payments if all underlying events for these eight products occur. In addition, we will have on-going royalty payment obligations to PharmaForm. The timing of the remaining payments, if any, is uncertain.
The following summarizes our contractual commitments as of December 31, 2007, as adjusted for the February 2008 amendment to the Malvern lease agreement discussed in Note 8 of the Notes to Consolidated Financial Statements (in thousands):

	Total	Less than 1 year	2-3 years	4-5 years	5+ years
Notes payable	$ 5	$ 5	$ —	$ —	$ —
Operating leases	27,713	3,730	6,550	6,703	10,730
Purchase commitment (1)	570	190	380	—	—
	$ 28,288	$ 3,925	$ 6,930	$ 6,703	$ 10,730

(1) Amount represents a minimum annual manufacturing fee of $0.2 million.

The contractual commitments reflected in this table exclude $27.7 million of contingent milestone payments that we may be obligated to pay in the future. We do not expect to pay any of these contingent milestone payments through December 31, 2008. These remaining milestones relate primarily to manufacturing process development, filing of regulatory applications and receipt of regulatory approval. The above table also excludes future royalty payments and wholesaler distribution fees because they are contingent on product sales.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a) (4) of Regulation S-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations, which are based on our consolidated financial statements, have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We are subject to uncertainties

that may cause actual results to differ from these estimates, such as changes in the healthcare environment, competition, legislation and regulation. We believe the following accounting policies, which have been discussed with our audit committee, are the most critical because they involve the most significant judgments and estimates used in the preparation of our consolidated financial statements:

- revenue recognition and
- estimating the value of our equity instruments for use in stock-based compensation calculations.

Revenue Recognition. We sell Testim to pharmaceutical wholesalers. Prior to the units being dispensed through patient prescriptions, these companies have the right to return Testim for any reason for up to one-year after product expiration. Revenue for this product is recognized in accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists*, and Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104 (together SAB No. 101). Among its criteria for revenue recognition from sale transactions where a buyer has a right of return, SFAS No. 48 requires the amount of future returns to be reasonably estimated. In order to develop a methodology, and provide a basis, for estimating future product returns on sales to our customers at the time of shipment, we have been tracking the Testim product return history, taking into consideration product expiration dating at time of shipment and levels of inventory in the wholesale channel. Based on the product return history gathered through the end of the first quarter of 2006, we believed we had the information to reasonably estimate customer returns and, therefore, in the first quarter of 2006, began recognizing revenue for Testim sales at the time of shipment of the product to our customers. Prior to 2006, we were unable to reasonably estimate customer returns and, therefore, deferred the recognition of revenue on product shipments of Testim units until the units were dispensed through patient prescriptions because units dispensed through prescriptions are not subject to return. We estimated prescription units dispensed based on distribution channel data provided by external, independent sources.

In addition, we must make estimates for discounts and rebates provided to third-party payers and coupons provided to patients. Testim is covered by Medicare, Medicaid and numerous independent insurance and pharmacy benefit managers (PBMs). Some of these programs have negotiated rebates. We obtain estimates of prescription units dispensed under the various rebate programs from the same external sources discussed above. We make estimates of the future rebates based on the external-source reports of volumes and actual contract terms. In addition, we provide coupons to physicians for use with prescriptions as promotional incentives. We utilize a contract service provider to process and pay claims to patients for actual coupon usage. As Testim becomes more widely used and as we continue to add managed care and PBMs, actual results may differ from our previous estimates. To date, our estimates have not resulted in any material adjustments to our operating results.

For revenues associated with licensing agreements, we use revenue recognition criteria outlined in Staff Accounting Bulletin (SAB) No. 101 and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the underlying agreement. We currently have license and distribution agreements with Paladin to distribute Testim in Canada and with Ipsen, as amended, to market and distribute Testim worldwide, except for the U.S., Canada, Mexico, Japan, Poland, Russia, South Korea and China, their territories and possessions. Under these agreements, the distributor and the licensee are each required to purchase Testim from us and make up-front, milestone and royalty payments. Under these agreements, the distributor and the licensee may each cancel the agreements if there is a breach of contract or if any party files for bankruptcy. Only milestone payments for product supply price reductions are refundable if we subsequently increase the supply price; otherwise, no up-front or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications or if any of the agreements are terminated due to our nonperformance. We are obligated under the agreements to provide multiple deliverables, including the license/product distribution rights, regulatory filing services and commercial product supply. Under EITF No. 00-21, all deliverables under each of these agreements are treated as single units of accounting as the Company does not have evidence to support that the consideration for the undelivered item, Testim units to be shipped, is at fair value. We have deferred revenue recognition for non-refundable up-front and milestone payments until at least the first product shipment under each agreement.

Upon product shipment, non-refundable up-front and milestone revenue is recognized as revenue on a straight line basis over the remaining contract term. The amortization period is based upon contractual terms of the respective agreement and is currently estimated to be 17 years for the Ipsen agreement and 10 years for the Paladin agreement. The Company has started to amortize milestones received over these periods since the first product shipment under the respective agreement. When earned by us in future periods, additional milestone payments achieved will be amortized over the remaining period. Refundable milestone payments will be deferred and only included in the revenue recognition equation with non-refundable milestone consideration when the refund right effectively lapses.

We record sales of Testim net of the following allowances: (*a*) prompt payment discounts, (*b*) fees to wholesalers based on shipment activity under the terms of wholesaler service agreements, (*c*) product returns, (*d*) managed care contract rebates and government health plan charge backs, and (*e*) product coupons. The table below provides the balances of accruals relating to each of these allowances as of December 31, 2007 and 2006.

	December 31,	
	2007	2006
	(in thousands)	
Accounts receivable reserves:		
Prompt pay discounts	$ 240	$ 139
Accrued liabilities:		
Wholesaler service agreements	1,577	1,118
Product returns	1,674	1,132
Managed care contract rebates	3,950	3,240
Product coupons	229	253
Subtotal	7,430	5,743
Total	$ 7,670	$ 5,882

The nature of each of these allowances and the methodology we use to determine the reserve accrual with respect to each allowance are described below:

(a) **Prompt pay discounts** - Prompt payment discounts are offered to all wholesalers in return for payment within 30 days following the invoice date. Based on historical experience, which indicates that virtually all wholesaler payments reflect a deduction for prompt payment discounts, we record sales net of the discount amount. We adjust the reserve at the end of each reporting period to approximate the percentage discount applicable to the outstanding gross accounts receivable balances.

(b) **Wholesaler service agreements** - Under contractual agreements with our three largest wholesalers (sales to which collectively represented over 90% of 2007 shipments to all of our customers), we provide a fee for service based on shipment activity. The fee rates are set forth in the individual contracts. We track shipments to each wholesaler every period and accrue a liability relating to the unpaid portion of these fees by applying the contractual rates to such shipments.

(c) **Product returns** - Our return policy permits product returns from wholesalers during a period from six months prior to the product's expiration date until 12 months subsequent to the expiration date. However, once dispensed by a pharmacy, product may not be returned. In order to estimate product returns, we monitor the remaining shelf life of the product when shipped to customers, actual product returns by individual production batches, NPA data (representing retail prescription information) obtained from IMS, and estimated inventory levels in the distribution channel. By analyzing these factors, we developed an estimated return rate for product sales that remain subject to return and began recording a return reserve based on this estimated return rate upon our change to the wholesaler method of revenue recognition in the first quarter of 2006. Under the change to the wholesaler method of revenue recognition, we began recognizing revenue at the point of title transfer of product to our wholesale customers (which requires us to estimate and accrue for potential future returns), in contrast to our earlier practice of recognizing revenue only when the product was prescribed to patients, at which time it was not returnable.

(d) **Managed care contract rebates and government health plan charge-backs** - Managed care contract rebates and government health plan charge backs are rebates and payments provided by us under agreements with private and government heath plans. We accrue the contractual rebates per unit of product for each individual plan using the most recent historically invoiced plan prescription volumes, adjusted for each individual plan's prescription growth or contraction, based on data acquired from IMS. The accrual is continually validated through the payment process, typically within a three month cycle.

(e) **Product coupons** - Product coupons offer patients the ability to receive free or discounted product through their prescribing physician, to whom we provide an inventory of coupons. We use a third party administrator who invoices us on a monthly basis for the cost of coupons redeemed in the period. Prior to the completion of the financial statements, we generally receive invoices for which the reserve was established. At the end of a reporting period, the accrual for product coupons represents these unpaid invoice amounts and an estimate for unexpired coupons (if any) outstanding. We base our estimates on the historical coupon redemption rate. We maintain the accrual for unexpired coupons based on inventory in the distribution channel and the historical coupon usage, and adjust the accrual whenever changes in coupon usage rate occur.

The following table provides a roll-forward of the revenue allowances discussed above, in the aggregate, for the years ended December 31, 2007, 2006 and 2005.

	Year ended December 31,		
	2007	2006	2005
		(in thousands)	
Beginning balance	$ 5,882	$ 2,345	$ 1,089
Current estimate related to sales in current period	21,370	14,382	8,282
Current estimate related to sales in prior periods	40	36	(129)
Current estimate related to change in revenue recognition method (Establish initial reserves for returns) (a)	—	1,019	—
Actual returns / credits in current period related to sales in current period	(14,155)	(9,760)	(6,039)
Actual returns / credits in current period related to sales in prior period	(5,467)	(2,140)	(858)
Ending balance	$ 7,670	$ 5,882	$ 2,345

(a) As described in note 2(e) to the Company's financial statements for the year ended December 31, 2007, as a result of the Company's change in revenue recognition policy, net revenues for the year ended December 31, 2006 include a one-time benefit of $1,198.

Valuation of Equity Instruments used in Stock-Based Compensation. Effective January 1, 2006, we account for stock-based compensation costs in accordance with SFAS No. 123R, which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors including stock options and employee stock purchases related to the 2004 Employee Stock Purchase Plan amended and restated June 13, 2007. Under SFAS No. 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period. The determination of fair value of share-based payment awards on the grant date requires significant judgment. Assumptions concerning our stock price volatility and projected employee exercise behavior over the contractual life of the award can significantly impact the estimated fair value of an award. Given the limited history of our Company, such assumptions are principally based on the observed history of other companies, which may not be reflective of the patterns we will experience. If our actual experience differs significantly from the assumptions used to compute stock-based compensation cost, or if different assumptions had been used, we may have recorded too much or too little expense for our share-based payment awards.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*", which becomes effective, in part, for financial statements issued for fiscal years beginning after November 15, 2007. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This statement is applicable to other accounting literature that requires fair value measurement and does not require any new fair value measurements. The Company is currently evaluating the effect, if any, the adoption of SFAS No. 157 will have on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities"*, which becomes effective for fiscal years beginning after November 15, 2007. SFAS No. 159 will provide companies the option to measure at fair value many financial instruments and certain other assets and liabilities on an instrument-by-instrument basis. The Company is currently evaluating the effects, if any, SFAS No. 159 could have on the Company's consolidated financial statements.

ITEM 7A. *Quantitative and Qualitative Disclosures About Market Risk*

We do not use derivative financial instruments or derivative commodity instruments for trading purposes. Our financial instruments consist of cash, cash equivalents, short-term investments, trade accounts receivable, accounts payable and long-term obligations. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Our investment policy specifies credit quality standards for our investments. The maximum allowable duration of a single issue is three months. Our investment policy permits us to invest in ARS with maturities of greater than three months, provided that the interest reset date, the date in which the ARS may be readily liquidated to a market maker, for the ARS is less than three months. As the underlying maturity date of our ARS investments is greater than three months, and as we classify these investments as available

for sale, we classify our ARS investments as short-term investments on our consolidated balance sheet. As discussed in Note 3 of the Notes to Consolidated Financial Statements, with liquidity issues experienced in global credit and capital markets, all of the ARS we held as of March 7, 2008 experienced failed auctions, beginning on February 11, 2008, as the amount of securities submitted for sale exceeded the amount of purchase orders. Our ability to access in the near term the funds invested in ARS is dependent on the success of future scheduled auctions, finding a buyer outside the auction process or a decision of the issuer of the securities to call the securities. If the uncertainties in the credit and capital market continue, these markets deteriorate further or there are ratings downgrades on any of the ARS we hold, we may be required to reclassify these investments to long-term investments and/ or adjust their carrying value through an impairment charge to earnings, if the fair value of these securities has declined to below their cost and such decline is assessed to be "other than temporary" under SFAS No. 115.

Our investment portfolio is subject to interest rate risk, although limited given the nature of the investments, and will fall in value in the event market interest rates increase. All our cash, cash equivalents and short-term investments at December 31, 2007, amounting to approximately $76.1 million, were maintained in bank demand accounts, money market accounts, U.S. government backed securities, commercial paper, corporate rate notes and ARS. We do not hedge our interest rate risks, as we believe reasonably possible near-term changes in interest rates would not materially affect our results of operations, financial position or cash flows.

Transactions relating to Auxilium UK, Limited are recorded in pounds sterling. Upon consolidation of this subsidiary into our consolidated financial statements, we translate the balance sheet asset and liability accounts to the U.S. dollar based on exchange rates as of the balance sheet date; balance sheet equity accounts are translated into the U.S. dollar at historical exchange rates; and all statements of operations and cash flows amounts are translated into the U.S. dollar at the average exchange rates for the period. Exchange gains or losses resulting from the translation are included as a separate component of stockholders' equity. In addition, we conduct clinical trials in Australia and certain European countries, exposing us to cost increases if the U.S. dollar declines in value compared to the Australian Dollar and the Euro. We do not hedge our foreign exchange risks, as we believe reasonably possible near-term fluctuations of exchange rates would not materially affect our results of operations, financial position or cash flows.

ITEM 8. ***Financial Statements and Supplementary Data***

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets, December 31, 2007 and 2006

Consolidated Statements of Operations, Years ended December 31, 2007, 2006, and 2005

Consolidated Statements of Stockholders' Equity and Comprehensive Loss, Year ended December 31, 2007

Consolidated Statements of Stockholders' Equity and Comprehensive Loss, Year ended December 31, 2006

Consolidated Statements of Stockholders' Equity and Comprehensive Loss, Year ended December 31, 2005

Consolidated Statements of Cash Flows, Years ended December 31, 2007, 2006, and 2005

Notes to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To Board of Directors and Stockholders
of Auxilium Pharmaceuticals, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of Auxilium Pharmaceuticals, Inc. and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective 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 (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements, and on the Company's internal control over financial reporting based on our audits (which were integrated audits in 2007 and 2006). 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As disclosed in Note 1 to the Consolidate Financial Statement, the company changed the manner in which it accounts for stock-based compensation in 2006.

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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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.

/s/ PricewaterhouseCoopers LLP

Philadelphia, PA
March 10, 2008

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2007	December 31, 2006
Assets		
Current assets:		
Cash and cash equivalents	$ 70,290	$ 44,835
Short-term investments	5,800	9,909
Accounts receivable, trade	11,678	9,267
Accounts receivable, other	619	507
Inventories	5,142	2,807
Prepaid expenses and other current assets	3,129	2,187
Total current assets	96,658	69,512
Property and equipment, net	7,903	4,732
Other assets	2,418	2,515
Total assets	$ 106,979	$ 76,759
Liabilities and Stockholders' Equity		
Current liabilities:		
Notes payable, current portion	$ 5	$ 61
Accounts payable	3,944	2,073
Accrued expenses	26,742	19,522
Deferred revenue, current portion	748	686
Deferred rent, current portion	358	351
Total current liabilities	31,797	22,693
Notes payable, long-term portion	—	5
Deferred revenue, long-term portion	9,500	10,294
Deferred rent, long-term portion	1,666	1,438
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value per share, 5,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock, $0.01 par value per share; authorized 120,000,000 shares; issued 40,768,809 and 35,677,008 shares at December 31, 2007 and 2006, respectively	408	357
Additional paid-in capital	288,122	225,577
Accumulated deficit	(224,168)	(183,463)
Deferred compensation	—	—
Treasury stock at cost: 26,276 and 13,377 shares at December 31, 2007 and 2006, respectively	(322)	(113)
Accumulated other comprehensive income (loss)	(24)	(29)
Total stockholders' equity	64,016	42,329
Total liabilities and stockholders' equity	$ 106,979	$ 76,759

See accompanying notes to consolidated financial statements.

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Years Ended December 31,		
	2007	2006	2005
Net revenues	$ 95,734	$ 68,490	$ 42,804
Operating expenses:			
Cost of goods sold	24,609	17,692	13,119
Research and development*	42,802	37,900	24,301
Selling, general and administrative*	72,768	61,277	43,935
Total operating expenses	140,179	116,869	81,355
Loss from operations	(44,445)	(48,379)	(38,551)
Interest income	3,744	2,445	1,553
Interest expense	(4)	(16)	(57)
Other income (expense), net	—	2	(1,203)
Net loss	(40,705)	(45,948)	(38,258)
Basic and diluted net loss per common share	$ (1.07)	$ (1.48)	$ (1.54)
Weighted average common shares outstanding	38,187,662	30,956,889	24,913,087
*includes the following amounts of stock-based compensation expense:			
Research and development	$ 1,180	$ 397	$ —
Selling, general and administrative	4,857	2,685	272

See accompanying notes to consolidated financial statements.

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity and Comprehensive Loss

Year Ended December 31, 2007

(In thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Treasury stock		Accumulated other comprehensive income (loss)	Total
	Shares	Amount			Shares	Cost		
Balance, December 31, 2006	35,677,008	$ 357	$ 225,577	$ (183,463)	13,377	$ (113)	$ (29)	42,329
Net loss				(40,705)			—	(40,705)
Foreign currency translation adjustment				—			5	5
Total comprehensive loss				(40,705)			5	(40,700)
Public offering, net of transaction costs	3,672,000	37	50,061	—	—	—	—	50,098
Exercise of common stock warrants	12,751	—	74	—	—	—	—	74
Issuance of restricted stock	15,000	—	—	—	—	—	—	—
Cashless exercise of common stock warrants	460,295	5	(5)	—	—	—	—	—
Exercise of common stock options	826,034	8	5,228	—	—	—	—	5,236
Employee Stock Purchase Plan purchases	106,451	1	1,150	—	—	—	—	1,151
Cancellation of restricted stock	(730)	—	—	—	—	—	—	—
Stock based compensation	—	—	6,037	—	—	—		6,037
Treasury stock acquisition	—	—	—	—	12,899	(209)		(209)
Balance, December 31, 2007	40,768,809	$ 408	$ 288,122	$ (224,168)	26,276	$ (322)	$ (24)	$ 64,016

See accompanying notes to consolidated financial statements.

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity and Comprehensive Loss

Year Ended December 31, 2006

(In thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Treasury stock		Deferred compensation	Accumulated other comprehensive income (loss)	Total
	Shares	Amount			Shares	Cost			
Balance, January 1, 2006	29,241,482	$ 292	$ 177,429	$ (137,515)	—	$ —	$ (437)	$ 104	39,873
Net loss				(45,948)				—	(45,948)
Foreign currency translation adjustment				—				2	2
Unrealized loss on available for sale securities				—				(135)	(135)
Total comprehensive loss				(45,948)				(133)	(46,081)
Public offering, net of transaction costs	5,500,000	55	43,245	—	—	—	—	—	43,300
Exercise of common stock warrants	178,523	2	1,041	—	—	—	—	—	1,043
Issuance of restricted stock	200,000	2	(2)	—	—	—	—	—	—
Cashless exercise of common stock warrants	310,602	3	(3)	—	—	—	—		—
Exercise of common stock options	185,970	2	984	—	—	—	—		986
Employee Stock Purchase Plan purchases	60,544	1	238	—	—	—	—	—	239
Cancellation of restricted stock	(113)	—	—	—	—	—	—	—	—
Stock based compensation	—	—	3,082	—	—	—	—		3,082
Reclassification of deferred compensation	—	—	(437)	—	—	—	437	—	—
Treasury stock acquisition	—	—	—	—	13,377	(113)	—		(113)
Balance, December 31, 2006	35,677,008	$ 357	$ 225,577	$ (183,463)	13,377	$ (113)	—	$ (29)	$ 42,329

See accompanying notes to consolidated financial statements.

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Stockholders' Equity and Comprehensive Loss

Year Ended December 31, 2005

(In thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Notes receivable from stockholders	Deferred compensation	Accumulated other comprehensive income	Total
	Shares	Amount						
Balance, January 1, 2005	20,648,988	$ 206	$ 135,856	$ (99,257)	$ (17)	$ (565)	$ 21	$ 36,244
Net loss				(38,258)			—	(38,258)
Unrealized gain on available for sale securities				—			83	83
Total comprehensive loss				(38,258)			83	(38,175)
Private placement, net of transaction costs	8,242,796	83	32,955	—	—	—	—	33,038
Issuance of private placement warrants	—	—	7,151	—	—	—	—	7,151
Exercise of common stock options	210,687	2	738	—	—	—	—	740
Employee Stock Purchase Plan purchases	125,127	1	501	—	—	—	—	502
Issuance of restricted stock	25,000	—	120	—	—	(120)	—	—
Cancellation of restricted stock	(11,116)	—	(83)	—	—	83	—	—
Amortization of deferred compensation	—	—	—	—	—	165	—	165
Compensation on stock option grants to	—	—	84	—	—	—	—	84
Compensation on stock option grants	—	—	107	—	—	—	—	107
Interest income accrued on notes receivable	—	—	—	—	(1)	—	—	(1)
Repayment of notes receivable	—	—	—	—	18	—	—	18
Balance, December 31, 2005 ..	29,241,482	$ 292	$ 177,429	$ (137,515)	$ —	$ (437)	$ 104	$ 39,873

See accompanying notes to consolidated financial statements.

AUXILIUM PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flow

(In thousands, except share and per share amounts)

(In thousands)

	Years Ended December 31,		
	2007	2006	2005
Cash flows from operating activities:			
Net loss	$ (40,705)	$ (45,948)	$ (38,258)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,404	1,068	1,087
Stock-based compensation	6,037	3,082	356
Change in fair value of financing related liability	—	—	990
Unrealized gain on available for sale cash equilvalents	—	—	83
Changes in operating assets and liabilities:			
Decrease (increase) in accounts receivable	(2,522)	(4,960)	172
Decrease (increase) in inventories	(2,335)	1,580	(373)
Decrease (increase) in prepaid expenses and other current assets	(935)	186	(602)
Increase in accounts payable and accrued expenses	9,105	3,479	6,474
Increase (decrease) in deferred revenue	(731)	(2,603)	1,048
Increase in deferred rent	226	547	192
Net cash used in operating activities	(30,456)	(43,569)	(28,831)
Cash flows from investing activities:			
Purchases of property and equipment	(4,478)	(1,739)	(1,246)
Purchases of short-term investments	(16,902)	(63,335)	(47,275)
Redemptions of short-term investments	21,011	78,775	36,025
Purchases of other assets	—	(1,900)	—
Net cash used in investing activities	(369)	11,801	(12,496)
Cash flows from financing activities:			
Proceeds from common shares, and in 2005 warrants, issued in equity offerings, net of transaction costs	50,098	43,300	39,198
Proceeds from warrant exercises	74	1,043	—
Payments on debt financings	(61)	(261)	(427)
Employee Stock Purchase Plan purchases	1,150	239	502
Proceeds from exercise of common stock options	5,236	986	740
Purchases of treasury stock	(209)	(113)	—
Collection of notes receivable from stockholders	—	—	18
Net cash provided by financing activities	56,288	45,194	40,031
Effect of exchange rate changes on cash	(8)	29	(31)
Increase (decrease) in cash and cash equivalents	25,455	13,455	(1,327)
Cash and cash equivalents, beginning of period	44,835	31,380	32,707
Cash and cash equivalents, end of period	$ 70,290	$ 44,835	$ 31,380

See accompanying notes to consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Organization and Description of Business

(a) The Company

Auxilium Pharmaceuticals, Inc. along with its subsidiaries, or the Company, is a specialty biopharmaceutical company with a focus on developing and marketing products to urologists, endocrinologists, orthopedists and select primary care physicians. The Company has one marketed product, Testim, a proprietary, topical 1% testosterone gel indicated for the treatment of hypogonadism. In the fourth quarter of 2002, the Company received approval from the U.S. Food and Drug Administration, or FDA, to market Testim. The Company launched Testim in the first quarter of 2003. The Company currently markets Testim in the U.S. through its own sales force. Testim is also approved for marketing in Belgium, Canada, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom. The Company currently relies on third parties to market, sell and distribute Testim outside of the U.S.

The Company has four projects in clinical development. XIAFLEX™ (clostridial collagenase for injection), formerly referred to as AA4500, is in phase III of development for the treatment of Dupuytren's contracture and is in phase II of development for the treatment of Peyronie's disease and Frozen Shoulder syndrome (also known as Adhesive Capsulitis). The Company's transmucosal film product candidate for the treatment of overactive bladder (AA4010) is in phase I of development. The Company expects to seek a partner to further develop this product candidate. The Company has one pain product using its transmucosal film delivery system in pre-clinical development and rights to seven additional pain products and products for hormone replacement and urologic disease using its transmucosal film delivery system. The Company also has options to all indications using XIAFLEX for non-topical formulations.

(b) Liquidity

The Company commenced operations in the fourth quarter of 1999. Since inception, it has incurred losses and negative cash flows from operations. The Company has been dependent upon external financing, including primarily private and public sales of securities, to fund operations. As of December 31, 2007, the Company had an accumulated deficit of approximately $224,168,000, and expects to incur additional operating losses.

The Company may require additional financing in the future to execute its intended business strategy. There can be no assurances that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, when and if needed. Failure to raise needed funds on satisfactory terms could have a material impact on the Company's business, operating results or financial condition.

(2) Summary of Significant Accounting Policies

(a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Auxilium Pharmaceuticals, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

(b) Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and disclosure of contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

(c) Translation of Foreign Financial Statements

The Company established a foreign subsidiary in the United Kingdom in 2000, which uses the pound sterling as its functional currency. Assets and liabilities of the Company's foreign subsidiary are translated at the year-end rate of exchange. The statements of operations for this subsidiary are translated at the average rate of exchange for the year. Gains or losses from translating foreign currency financial statements are accumulated in other comprehensive income (loss) in stockholders' equity.

(d) Fair Value of Financial Instruments

Management believes that the carrying amounts of the Company's financial instruments, including cash, cash equivalents, short-term investments, accounts receivable, restricted cash deposits, accounts payable, accrued expenses and notes payable approximate fair value due to the short-term nature of those instruments.

(e) Revenue Recognition

The Company sells Testim to pharmaceutical wholesalers, who have the right to return purchased product prior to the units being dispensed through patient prescriptions. Revenue for this product is recognized in accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists*, and the SEC's Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104 (together SAB No. 101). Among its criteria for revenue recognition from sale transactions where a buyer has a right of return, SFAS No. 48 requires the amount of future returns to be reasonably estimated. In order to develop a methodology, and provide a basis, for estimating future product returns on sales to its customers at the time of shipment, the Company has been tracking the Testim product return history, taking into consideration product expiration dating at time of shipment and inventory levels in the distribution channel. Based on the product return history gathered through the end of the first quarter of 2006, the Company determined it had the information to reasonably estimate customer returns and, therefore, in the first quarter of 2006, began recognizing revenue for Testim sales at the time of shipment of the product to customers. Revenue is also reduced for estimates of allowances for cash discounts, rebates and patient coupons based on historical experience, and current contract prices and terms with customers. If actual, or expected, customer returns and revenue allowances differ from previous estimates, adjustments of these estimates would be recognized in the period such facts become known.

Prior to 2006, the Company was unable to reasonably estimate customer returns and, therefore, deferred the recognition of revenue on product shipments of Testim units until the units were dispensed through patient prescriptions because units dispensed are not subject to return. The Company estimated prescription units dispensed based on distribution channel data provided by external, independent sources.

As a result of the above-described change in revenue recognition, net revenues for the year ended December 31, 2006 include a one-time benefit of $1,198,000 (representing revenue previously deferred, net of estimated returns and allowances of $1,019,000) and the net loss for the year ended December 31, 2006 includes a one-time benefit of $702,000, or $0.02 per share (representing the one-time benefit in net revenues partially offset by the related cost of sales).

The following individual customers each accounted for at least 10% of total product shipments for any of the respective periods:

	Years Ended December 31,		
	2007	2006	2005
Customer A	50.1%	48.0%	31.3%
Customer B	27.9%	27.0%	31.2%
Customer C	15.2%	18.0%	18.7%
	93.2%	93.0%	81.2%

For revenues associated with licensing agreements, we use revenue recognition criteria outlined in Staff Accounting Bulletin (SAB) No. 101 and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the underlying agreement. We currently have license and distribution agreements with Paladin to distribute Testim in Canada and with Ipsen, as amended, to market and distribute Testim worldwide, except for the U.S., Canada, Mexico, Japan, Poland, Russia, South Korea and China, their territories and possessions. Under these agreements, the distributor and the licensee are each required to purchase Testim from us and make up-front, milestone and royalty payments. Further, the distributor and the licensee may each cancel the agreements if there is a breach of contract or if any party files for bankruptcy. Only milestone payments for product supply price reductions are refundable if we subsequently increase the supply price; otherwise, no up-front or milestone payments are refundable in any instance. Product shipments are subject to return and refund only if the product does not comply with technical specifications or if any of the agreements are terminated due to our nonperformance. We are obligated under the agreements to provide multiple deliverables, including the license/product distribution rights, regulatory filing services and commercial product supply. Under EITF No. 00-21, all deliverables under each of these agreements are treated as single units of accounting as the Company does not have evidence to support that the consideration for the undelivered item, Testim units to be shipped, is at fair value. We have deferred revenue recognition for non-refundable up-front and milestone payments until at least the first product shipment under each agreement.

Upon product shipment, non-refundable up-front and milestone revenue is recognized as revenue on a straight line basis over the remaining contract term. The amortization period is based upon contractual terms of the respective agreement and is currently estimated to be 17 years for the Ipsen agreement and 10 years for the Paladin agreement. The Company has started to amortize milestones received over these periods since the first product shipment under the respective agreement. When earned by us in future periods, additional milestone payments achieved will be amortized over the remaining period. Refundable milestone payments will be deferred and only included in the revenue recognition equation with non-refundable milestone consideration when the refund right effectively lapses. .

(f) Cash, Cash Equivalents and Short-term Investments

Cash, cash equivalents and short-term investments are stated at market value. Cash equivalents include only securities having a maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash, cash equivalents and short-term investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, U.S. government securities, or short-term commercial paper. The Company considers its investments, including securities with maturities in excess of one year, as "available for sale" under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and accordingly classifies them as current, as management can sell these investments at any time at their option.

(g) Accounts Receivable

Accounts receivable, trade consist of amounts due from wholesalers for the purchase of Testim. Ongoing credit evaluations of customers are performed and collateral is generally not required.

Accounts receivable, trade are net of allowances for cash discounts, actual returns and bad debts of $302,000 and $296,000 at December 31, 2007 and 2006, respectively.

The following individual customers each accounted for at least 10% of accounts receivable, trade on either of the respective dates:

	December 31,	
	2007	2006
Customer A	47.0%	41.0%
Customer B	27.0%	25.0%
Customer C	19.0%	28.0%
	93.0%	94.0%

(h) Inventories

Inventories are stated at the lower of cost or market, as determined using the first-in, first-out method.

(i) Concentration of Supply

The Company has a single source of supply for CPD and only two sources of supply for testosterone. In addition, a single source contract manufacturer produces Testim. The Company attempts to mitigate the risk of supply interruption by maintaining adequate safety stock of raw materials and by scheduling production runs to create safety stock of finished goods. The Company evaluates secondary sources of supply for all its raw materials and finished goods. The Company does not have any long-term minimum commitments for finished goods production or raw materials (see Note 6).

(j) Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred, and costs of improvements are capitalized. Depreciation is recognized using the straight-line method based on the estimated useful life of the related assets. Amortization of leasehold improvements is recognized using the straight-line method based on the shorter of the estimated useful life of the related assets or the lease term.

(k) Long-Lived Assets

The Company reviews long-lived assets, such as property and equipment, and purchased intangibles subject to amortization, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated

undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset. As of December 31, 2007, the Company has not revised the remaining useful lives of any significant assets.

Included in other assets is the unamortized balance of a license agreement milestone payment. This payment is being amortized over the 67-month estimated useful life of the related product which is consistent with the remaining lives of the underlying patents.

(l) Research and Development Costs

Research and development costs include salaries and related expenses for development personnel as well as fees and costs paid to external service providers. Costs of external service providers include both clinical trial costs and the costs associated with non-clinical support activities such as toxicology testing, manufacturing process development and regulatory affairs. External service providers include contract research organizations, contract manufacturers, toxicology laboratories, physician investigators and academic collaborators. Research and development costs, including the cost of product licenses prior to regulatory approval, are charged to expense as incurred.

(m) Income Taxes

On January 1, 2007 the Company adopted FASB Interpretation No. 48 (FIN 48), "*Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*", which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation did not have any material impact on the Company's results of operation or financial position.

Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Deferred tax assets and liabilities are measured at the balance sheet date using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted. Interest and penalties related to uncertain tax positions are classified as income tax expense.

(n) Stock-Based Compensation

On January 1, 2006, the Company adopted SFAS No. 123R (revised 2004), *Share-Based Payments*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors, including employee stock options and employee stock purchases related to the Company's employee stock purchase plan, based on estimated fair values. In its adoption of SFAS No. 123R, the Company applied the provisions of SAB No. 107 which was issued by the SEC in March 2005. Prior to January 1, 2006, the Company accounted for employee stock-based compensation using the intrinsic value method under Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, as permitted by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. SFAS No. 148 amended the transition and disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*.

The Company adopted SFAS No. 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's calendar year. The Company's consolidated financial statements as of, and for the years ended, December 31, 2007 and 2006 reflect the impact of the application of SFAS No.123R. In accordance with the modified prospective method, the Company's consolidated financial statements for periods prior to 2006 have not been restated for, and therefore do not include, the effect of SFAS No. 123R.

SFAS No. 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized over the requisite service period as compensation expense in the consolidated statement of operations. The Company uses the Black-Scholes option pricing model (Black-Scholes model) to estimate the fair value of share-based grants and the straight-line method to amortize compensation expense over their vesting period. These methods were also utilized by the Company in preparing pro forma disclosures required under SFAS No. 123 (see Note 11). Under the intrinsic value method, except for compensation expense related to restricted stock awards, no stock-based compensation expense had been recognized in the Company's consolidated statements of operations prior to 2006.

Stock-based compensation expense recognized in the Company's consolidated statements of operations for the years ended December 31, 2007 and 2006 includes compensation expense for share-based payment awards granted prior to, but not vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS No. 123, and the compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R and SAB No. 107. SFAS No. 123R requires forfeitures of stock-based awards prior to vesting to be estimated at the time of grant and revised, if necessary, in subsequent periods if the actual forfeitures differ from the estimates. Therefore, stock-based compensation expense for 2007 and 2006 reflects management's estimate of forfeitures. However, in the Company's pro forma information for the year ended December 31, 2005, the Company accounted for forfeitures as they occurred.

Total stock-based compensation expense recorded for the year ended December 31, 2007, 2006 and 2005 amounted to $6,037,000, $3,082,000 and $272,000, respectively. As a result of adoption of SFAS No. 123R, the Company's net loss for the year ended December 31, 2006 is $2,571,000, or $(0.08) per share, greater than if the Company had continued to account for share-based compensation under APB No. 25. As required by SFAS No. 123R, the $437,000 balance of deferred compensation of January 1, 2006 relating to prior restricted stock grants was reclassified to additional paid-in capital.

(o) Comprehensive Income (Loss)

The Company follows SFAS No. 130, *Reporting Comprehensive Income*. SFAS No. 130 established standards for the reporting and presentation of comprehensive income and its components in financial statements. The Company's comprehensive loss consists of net loss, foreign currency translation adjustments and unrealized gains on available for sale securities. The Company's comprehensive loss is presented within the accompanying consolidated statements of stockholders' equity (deficit). For the years ended December 31, 2007, 2006 and 2005 the Company had foreign currency translation adjustments of $5,000, $2,000 and $0, respectively. Unrealized gains (losses) on available for sale securities were $0, $(135,000) and $83, 000, respectively.

(p) Net Loss Per Common Share

Net loss per common share is calculated in accordance with SFAS No. 128, *Earnings per Share*, and SAB No. 98. Under the provisions of SFAS No. 128 and SAB No. 98, basic net loss per common share is computed by dividing the net loss applicable to common stockholders for the period by the weighted average number of common shares outstanding during the period reduced, where applicable, for unvested outstanding restricted shares.

The following table sets forth the computation of basic and diluted net loss per common share (in thousands, except share and per share amounts):

	Years Ended December 31,		
	2007	2006	2005
Numerator:			
Net loss	$ (40,705)	$ (45,948)	$ (38,258)
Denominator:			
Weighted-average common shares outstanding	38,408,314	31,104,053	24,997,747
Weighted-average unvested restricted common shares subject to forfeiture	(220,652)	(147,164)	(84,660)
Shares used in calculating net loss applicable to common stockholders per share	38,187,662	30,956,889	24,913,087
Basic and diluted net loss per common share	$ (1.07)	$ (1.48)	$ (1.54)

Diluted net loss per common share is computed giving effect to all dilutive potential common stock, including options, and warrants. Diluted net loss per common share for all periods presented is the same as basic net loss per common share because the potential common stock is anti-dilutive. Anti-dilutive common shares not included in diluted net loss per common share are summarized as follows:

	December 31,		
	2007	2006	2005
Common stock options	3,776,105	3,548,903	2,101,498
Warrants	2,281,939	2,903,257	3,793,363
Restricted common stock	198,072	232,544	81,451
	6,256,116	6,684,704	5,976,312

(q) Segment Information

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas and does not have separately reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

(r) Advertising Costs

Advertising costs, included in selling, general and administrative expenses, are charged to expense as incurred. Advertising expenses for the years ended December 31, 2007, 2006 and 2005 were $926,000, $600,000 and $461,000, respectively.

(s) New Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*", which becomes effective, in part, for financial statements issued for fiscal years beginning after November 15, 2007. SFAS No. 157 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This statement is applicable to other accounting literature that requires fair value measurement and does not require any new fair value measurements. The Company is currently evaluating the effect, if any, the adoption of SFAS No. 157 will have on the Company's consolidated financial statements.

In February 2007, The FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities"*, which becomes effective for fiscal years beginning after November 15, 2007. SFAS No. 159 will provide companies the option to measure at fair value many financial instruments and certain other assets and liabilities on an instrument-by-instrument basis. The Company is currently evaluating the effects, if any, SFAS No. 159 could have on the Company's consolidated financial statements.

(3) Cash, Cash Equivalents and Short-term Investments

Cash and cash equivalents include only securities having a maturity of three months or less at the time of purchase. At December 31, 2007 and 2006 demand deposits, money market accounts, commercial paper, U.S. Treasury and agency obligations, and corporate notes comprised all of the Company's cash and cash equivalents.

Short-term investments consist of corporate auction-rate securities, or ARS, with original maturities ranging up to 40 years and, in 2006, floating rate corporate notes. ARS have interest reset dates of 28 or 35 days. The reset date is the date in which the underlying interest rate is revised based on a Dutch auction and the underlying security may be sold. The Company classifies ARS as current as they are available for sale under SFAS No. 115 since the Dutch auctions have historically provided a liquid market for the type of ARS owned by the Company. However, with liquidity issues experienced in global credit and capital markets, all ARS held by the Company as of March 10, 2008 experienced failed auctions, beginning on February 11, 2008, as the amount of securities submitted for sale exceeded the amount of purchase orders. The cost value of these securities held as of March 7, 2008 amounts to $5.8 million, of which $3.6 million were held as of December 31, 2007. The Company will continue to assess the balance sheet classification of its short-term investments if uncertainties in the credit and capital markets continue.

The following summarizes cash, cash equivalents and short-term investments (in thousands):

	December 31,	
	2007	2006
Cash and Cash Equivalents		
Demand deposits	$ 2,745	$ 1,165
Money market accounts	61	3,169
Commercial paper	30,813	16,660
Obligations of U.S. Government	22,615	14,317
Corporate notes	14,056	9,524
	$ 70,290	$ 44,835
Short-term Investments		
Auction rate securities	$ 5,800	$ 2,900
Corporate notes	—	7,009
	$ 5,800	$ 9,909

(4) Inventories

Inventories consist of the following (in thousands):

	December 31, 2007	December 31, 2006
Raw materials	$ 2,371	$ 1,519
Work-in-process	1,508	194
Finished goods	1,263	1,094
	$ 5,142	$ 2,807

(5) Property and Equipment

Property and equipment consists of the following (in thousands):

	Estimated useful life	December 31, 2007	December 31, 2006
Office furniture, computer equipment and software	3 to 5 years	$ 2,910	$ 2,532
Manufacturing equipment	3 to 10 years	2,673	2,505
Laboratory equipment	7 years	353	260
Leasehold improvements	lease term	3,240	1,208
		9,176	6,505
Less accumulated depreciation and amortization		(3,711)	(2,475)
		5,465	4,030
Construction-in-progress—laboratory and manufacturing equipment		2,438	702
		$ 7,903	$ 4,732

Depreciation expense was $1,315,000, $975,000 and $883,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

(6) Supply Agreement

The Company has a supply agreement for the production of Testim with DPT Laboratories, Ltd., or DPT. In connection with the agreement, the Company purchased approximately $1.1 million of packaging equipment that is used by DPT in Testim production. The Company owns the equipment. The packaging equipment was placed in service at the end of 2003 and is being amortized over the estimated life of the equipment. Although the Company is not required to purchase any minimum amount of Testim from DPT, it is required to pay a minimum annual manufacturing fee of $190,000.

(7) Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2007	December 31, 2006
Payroll and related expenses	$ 6,757	$ 4,971
Royalty expenses	3,236	2,228
Research and development expenses	5,121	3,646
Sales and marketing expenses	1,564	1,392
Testim rebates, discounts and returns accrual	7,430	5,743
Other expenses	2,634	1,542
	$ 26,742	$ 19,522

(8) Commitments and Contingencies

(a) Leases

The Company leases its main office space and a manufacturing facility under noncancellable operating leases that expire in 2012 and 2017, respectively. The Company also leases office equipment and automobiles. Rent expense was $3,482,000, $1,606,000 and $782,000 for the years ended December 31, 2007, 2006, and 2005, respectively.

On December 31, 2004, the Company entered into a 90-month lease agreement to move its headquarters facility to Malvern, Pennsylvania. The Company moved into the new office space in June 2005. In June, 2006, the lease agreement was amended to include additional headquarters office space. The Company paid a $400,000 security deposit under the lease, which is included in other assets, and received allowances to improve the leased facility of approximately $1,068,000. The Company has recorded the cost of the improvements as a fixed asset and the allowance as a deferred rent credit. The Company amortizes the leasehold improvement asset over the shorter of the life of the improvements or the life of the lease. The Company amortizes the deferred rent credit as a reduction of rent expense on a straight-line basis over the life of the lease. The new lease includes a period of free rent and escalating minimum rent payments. The Company records rent expense for the minimum lease payments on a straight-line basis.

As of February 22, 2008, the Company amended the Malvern lease agreement to further expand its headquarters office space and extend the lease to December 31, 2013. Under the amendment, the Company received an additional $397,000 improvement allowance for the leased space.

On September 1, 2006, the Company entered into a lease agreement for an existing biological manufacturing facility that has an initial term ending January 1, 2017 and that may be extended for two consecutive five-year periods. The Company maintains a bank letter of credit in the amount of $1,900,000 as a security deposit which is collateralized by a bank deposit of equal amount. This $1,900,000 bank deposit is included in other long-term assets at December 31, 2007 and 2006. The lease provides free rent for the first three months and, thereafter, for escalating minimum rent payments. The Company records rent expense for the minimum lease payments on a straight-line basis. In addition, the lease provides an allowance for tenant improvements of up to $3,750,000 which would be amortized, including an interest factor, over the initial term of the lease. As of December 31, 2007, the Company had not requested any allowances for tenant improvements.

Future minimum lease payments under noncancellable operating leases for manufacturing facilities, office space, equipment and automobiles as of December 31, 2007, and as adjusted for the February 2008 Malvern lease amendment, are as follows (in thousands):

January 1, 2008 to December 31, 2008	$ 3,730
January 1, 2009 to December 31, 2009	$ 3,322
January 1, 2010 to December 31, 2010	$ 3,228
January 1, 2011 to December 31, 2011	$ 3,303
January 1, 2012 to December 31, 2012	$ 3,400
January 1, 2013 and thereafter	$ 10,730

(b) Research, Development and License Agreements

The Company has entered into various licensing agreements. Through December 31, 2007, the Company has made aggregate milestone payments under all agreements of $9,625,000. The Company could make an additional $27,725,000 of contingent milestone payments under all agreements if all underlying events occur over the life of the agreements.

Bentley Pharmaceuticals, Inc.

In May 2000, the Company entered into a license agreement with Bentley Pharmaceuticals, Inc., or Bentley, for its patented transdermal gel technology. Under the agreement, as amended, the Company was granted an exclusive, worldwide, royalty-bearing license to make and sell products incorporating Bentley's formulation technology that contain testosterone. The Company produces Testim under this agreement. The term of this agreement is determined on a country-by-country basis and extends until the later of patent right termination in a country or 10 years after the first sale of product in that country. In May 2001, the Company entered into a license agreement with Bentley granting similar rights for a product containing another hormone, the term of which is perpetual. In May 2001, the Company also entered into a separate license granting similar rights for a product containing a therapeutic drug.

In addition to its royalty obligations, the Company is obligated to pay certain upfront payments and milestones under the license agreements with Bentley. Through December 31, 2007, the Company has made aggregate upfront and milestone payments under the three license agreements with Bentley of $625,000. If all events under the Bentley license agreements occur, the Company would be obligated to pay a maximum of an additional $1,025,000 in milestone payments.

BioSpecifics Technologies Corp.

In June 2004, the Company entered into a development and license agreement with BioSpecifics Technologies Corp., or BioSpecifics, and amended such agreement in May 2005 (the BioSpecifics Agreement). Under the BioSpecifics Agreement, as amended, the Company was granted exclusive worldwide rights to develop, market and sell certain products containing BioSpecifics' enzyme XIAFLEX. The Company's licensed rights concern the development of products, other than dermal formulations labeled for topical administration. Currently, the Company is developing XIAFLEX for the treatment of Dupuytren's contracture, Peyronie's disease and Frozen Shoulder syndrome. The Company may expand the BioSpecifics Agreement, at its option, to cover other indications as they are developed by the Company or BioSpecifics.

The BioSpecifics Agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. The Company may terminate the BioSpecifics Agreement with 90 days written notice.

The Company must pay BioSpecifics on a country-by-country and product-by-product basis a specified percentage of net sales for products covered by the BioSpecifics Agreement. Such percentage may vary depending on whether BioSpecifics exercises the supply option. In addition, the percentage may be reduced if (i) BioSpecifics fails to supply commercial product supply in accordance with the terms of the BioSpecifics Agreement; (ii) market share of a competing product exceeds a specified threshold; or (iii) the Company is required to obtain a license from a third party in order to practice BioSpecifics' patents without infringing such third party's patent rights.

In addition to the payments set forth above, the Company must pay BioSpecifics an amount equal to a specified mark-up of the cost of goods sold for products sold by the Company that are not manufactured by or on behalf of BioSpecifics, provided that, in the event BioSpecifics exercises the supply option, no payment will be due for so long as BioSpecifics fails to supply the commercial supply of the product in accordance with the terms of the BioSpecifics Agreement.

Finally, the Company is obligated to make contingent milestone payments upon contract initiation, receipt of technical data, the one-year anniversary of the BioSpecifics Agreement, filing of regulatory applications and receipt of regulatory approval. Through December 31, 2004, the Company paid up-front and milestone payments under the BioSpecifics Agreement of $5,000,000. The Company recorded two payments of $2,500,000 each as an in-process research and development expense in each of the second and third quarters of 2004 because XIAFLEX was in the early stages of phase II clinical trials and there was no alternative future use for XIAFLEX prior to FDA approval. In March 2005, the Company accrued the one-year contract anniversary payment of $3,000,000 which was paid in June 2005. The Company recorded this accrual as an additional in-process research and development expense in the first quarter of 2005 because XIAFLEX was in the early stages of phase II clinical trials and there was no alternative future use for XIAFLEX prior to FDA approval. In December 2005, the Company paid and expensed the option exercise fee of $500,000 for the Frozen Shoulder syndrome indication. The Company could make up to an additional $5,500,000 of contingent milestone payments under the BioSpecifics Agreement if all existing conditions are met. Additional milestone obligations may be due if the Company exercises an option to develop and license XIAFLEX for additional medical indications.

Formulation Technologies, L.L.C., d/b/a PharmaForm

In June 2003, the Company expanded its drug delivery technology portfolio by entering into a license agreement with Formulation Technologies, L.L.C., d/b/a PharmaForm, or PharmaForm. Under this agreement, as amended, the Company was granted an exclusive, worldwide, royalty-bearing license to develop, make and sell products that contain hormones or that are used to treat urologic disorders incorporating PharmaForm's oral transmucosal film technology for which there is an issued patent in the U.S. The term of this license agreement is for the life of the licensed patents.

In February 2005, the Company entered into an additional license agreement with PharmaForm. Under this agreement, the Company was granted exclusive, worldwide royalty-bearing rights to develop, manufacture and market eight compounds using PharmaForm's proprietary transmucosal film technology for the management of pain, including acute and chronic pain. The compounds that may be developed include opioids as well other types of analgesics. In 2005, the Company paid an up-front payment of $500,000 and could make up to an additional $21,200,000 in contingent milestone payments if all underlying events for these eight products occur. In addition, the Company will have on-going royalty payment obligations to PharmaForm. The timing of the remaining payments, if any, is uncertain.

The Company entered into a research and development agreement with PharmaForm on a fee for service basis. The Company will be the sole owner of any intellectual property rights developed in connection with this agreement.

(c) Manufacturing Agreement

In July 2005, the Company entered into an agreement Cobra Biologics Ltd., or Cobra**,** for the process development, scale up and manufacture of XIAFLEX for phase II/III clinical trials (the Manufacturing Agreement). Through an agreement dated July 14, 2006 (the Amended Manufacturing Agreement), the Company terminated the Manufacturing Agreement and agreed that Cobra will manufacture the XIAFLEX batches needed for clinical trials and for the biological license application (BLA) to be filed under the U.S. Federal Food, Drug and Cosmetic Act and related applicable regulations and will provide related services upon our request. In November 2006, the Company entered into a letter agreement with Cobra (the Amendment) that further amended the Amended Manufacturing Agreement. Under the Amendment, the Company paid $1.1 million to Cobra and Cobra agreed to complete only one BLA batch of the active ingredient for XIAFLEX and perform certain other services as may be agreed to by the parties.

(d) Co-promotion Agreement

In April 2005, the Company entered into a co-promotion agreement (the Oscient Agreement) with Oscient Pharmaceuticals, Inc., or Oscient. The Oscient Agreement provided that Oscient would have the exclusive right to co-promote Testim to primary care physicians in the U.S., while the Company would continue to promote Testim using its specialty sales force that calls on urologists, endocrinologists and select primary care physicians. Oscient compensation for its services was based on a specified percentage of gross profit from Testim sales attributable to primary care physicians in the U.S. (the Oscient co-promotion fees). In, addition, Oscient and the Company agreed to utilize a joint marketing and promotion plan and to share equally in such expenses. The initial term of the Oscient Agreement extended to April 30, 2007. On September 1, 2006, the Company entered into a letter agreement with Oscient which sets forth the terms and conditions upon which Oscient and Auxilium mutually agreed to terminate the Oscient Agreement prior to the expiration of its initial term. Pursuant to the Termination Agreement, the Company paid Oscient the sum of $1,800,000 for the early termination and the Oscient Agreement terminated at the close of business on August 31, 2006, with certain specified provisions surviving termination, and Oscient ceased all promotion activities related to Testim at that time. Oscient co-promotion fees incurred in 2006 and 2005 were $4,508,000 and $3,536,000, respectively.

For the period in 2005 and 2006 during which the Oscient Agreement was in effect, the Company invoiced and recorded in its financial statements all sales of Testim, including those sales to primary care physicians that exceed the specified threshold in the Oscient Agreement, as well as the gross profit earned on all sales. The Company also recorded its share of promotional expenses incurred and the Oscient co-promotion fees as “Selling, general and administrative” operating expenses in its consolidated statement of operations.

(9) Income Taxes

At December 31, 2007, the Company had Federal net operating loss carryforwards of approximately $194.6 million, which will expire in 2019 through 2027, if not utilized. In addition, the Company had state net operating loss carryforwards of approximately $165.8 million, of which $77.7 million relate to Pennsylvania, which expires in 2010 through 2027 if not utilized. Future utilization of Pennsylvania net operating loss carryforwards are limited to the greater of 12.5% of Pennsylvania taxable income or $3.0 million per year. At December 31, 2007, the Company had Federal research and development credits of approximately $4.3 million that will expire in 2020 through 2027, if not utilized.

The Tax Reform Act of 1986 (the Act) provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company’s ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company’s ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for Federal income tax purposes.

The components of the net deferred tax assets are as follows (in thousands):

	December 31,	
	2007	2006
Net operating losses	$ 71,896	$ 56,596
Research and development credit	4,341	2,977
Depreciation and amortization	2,539	3,033
Accruals and reserves	3,154	4,342
Deferred profit	3,835	4,096
Stock compensation	2,826	935

	December 31,	
	2007	2006
Other temporary differences	83	139
Gross deferred tax assets	88,674	72,118
Deferred tax assets valuation allowance	(88,674)	(72,118)
	$ —	$ —

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance at December 31, 2007 and 2006. The valuation allowance in 2007 increased by $16.6 million over 2006 related primarily to additional net operating losses incurred by the Company.

The Company and its subsidiaries file income tax returns in the United Kingdom, United States and local tax jurisdictions in the United States. Presently, the Company has not been contacted by the Internal Revenue Service or any state tax jurisdictions for examination of its income tax returns for open periods. As the Company has generated losses since inception, all periods from 1999 through 2007, are open to examination.

As of December 31, 2007, the Company believes that there are no significant uncertain tax positions, and no amounts have been recorded for interest and penalties. The Company does not anticipate any events that would require it to record a liability related to any uncertain tax position as prescribed by FIN 48.

(10) Common Stock and Redeemable Convertible Preferred Stock

(a) Common Stock

The Company is authorized to issue 120,000,000 shares of common stock, with a par value of $0.01 per share.

On June 30, 2005, the Company completed a private placement financing in which the Company issued 8,242,796 shares of common stock and warrants to purchase an aggregate of 2,060,687 shares of common stock with an exercise price of $5.84 per share resulting in gross proceeds to the Company of approximately $40,400,000. The terms of the Company's securities purchase agreements by which the private placement was consummated permit settlement of the warrant in unregistered shares; however, the damages payable in cash arising from failure to register or failure to keep the registration statement effective for up to two years are so significant that they precluded equity treatment. In connection with the private placement financing, the Company paid $1,242,000 in placement agent fees and incurred approximately $175,000 in other transaction costs. Approximately $216,000 of the placement agent fees and transaction costs which were allocated to the warrants were expensed by the Company during the quarter ended June 30, 2005. The net proceeds to the Company were approximately $38,983,000.

The $5.84 warrants have a five-year life and are fully vested and exercisable. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's own stock," ("EITF 00-19") the warrants were recorded as a long-term liability and valued at fair value on the date of issuance. The fair value of the warrants on the date of issuance was $6,161,000 and was determined using the Black-Scholes model with the following assumptions: dividend yield of 0%; estimated volatility of 80%; risk free interest rate of 3.76% and a contractual life of five years.

On December 30, 2005, the Company and the purchasers amended the securities purchase agreements (the Amendments). The Amendments delete in its entirety the liquidated damages provision discussed above. The estimated fair value of the warrants on December 30, 2005 of $7,151,000 was reclassified to additional paid-in capital since the equity derivative qualifies as permanent equity under EITF 00-19. The non-cash change in the fair value of the warrants of $990,000 was recorded as other expense for the year ended December 31, 2005.

On September 14, 2006, the Company completed a registered direct offering in which the Company issued 5,500,000 shares of common stock at a price of $8.50 per share resulting in gross proceeds to the Company of approximately $46,750,000. In connection with the registered direct offering, the Company paid $2,805,000 in placement agent fees and incurred approximately $645,000 in other transaction costs, resulting in net proceeds to the Company of $43,300,000.

On June 8, 2007, the Company completed a registered direct offering in which the Company issued 3,672,000 shares of common stock at a price of $14.50 per share resulting in gross proceeds to the Company of approximately $53,244,000. In connection with the registered direct offering, the Company paid $2,928,000 in placement agent fees and incurred approximately $450,000 in other transaction costs, resulting in net proceeds to the Company of $49,866,000.

(b) Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock, with a par value of $0.01 per share. No preferred stock is issued or outstanding.

(11) Warrants

As of December 31, 2007, the Company had the following common stock warrants outstanding:

Expiration date	Number of warrants	Exercise price
May 2008	5,817	$ 7.50
June 2010	1,219,581	5.84
Oct. 2010	1,056,541	5.63
	2,281,939	

(12) Employee Stock Benefit Plans

(a) Employee Stock Purchase Plan

Under the Company's 2006 Employee Stock Purchase Plan, as approved by the stockholders of the Company, employees may purchase shares of the Company's common stock at a 15% discount through payroll deductions. Employees may contribute up to 10% of their compensation to the 2006 Employee Stock Purchase Plan. The purchase price is 85% of the fair value per share of common stock on the date the purchase period begins or the date on which the purchase period ends, whichever is lower. The plan restricts the maximum number of shares that an employee may purchase to 15,000 shares during each semi-annual purchase period and to $25,000 worth of common stock during each year. There is a maximum of 300,000 shares issuable under the 2006 Employee Stock Purchase Plan. In January, July and December, 2007, employees purchased 39,721, 37,920 and 28,810 shares of common stock at a price of $6.8595, $12.4865 and $14.0505 per share, respectively, representing 85% of the closing price of the common stock on July 3, 2006, January 2, 2007 and July 2, 2007, respectively, the first day at the beginning of each respective purchase period on which the market was open.

The 2004 Employee Stock Purchase Plan, which was terminated in 2006, permitted employees to purchase shares of the Company's common stock at a 15% discount through payroll deductions. Employees were enrolled in a two-year option period and purchased stock in half-year intervals at 85% of the lower of the fair market value of common stock on the date of purchase or the beginning of the two-year option period. In May 2005, employees purchased an aggregate amount of 66,530 shares of common stock at a price of $4.063 per share. In November 2005, employees purchased an aggregate of 58,597 shares of common stock at a price of $3.9525 per share. In June 2006, employees purchase an aggregate amount of 60,544 shares at a price of $3.95.

(b) Stock Options and Stock Awards

Under the Company's 2004 Equity Compensation Plan, amended and restated June 13, 2007, (the 2004 Plan), as approved by the stockholders of the Company, qualified and nonqualified stock options and stock awards may be granted to employees, non-employee directors and service providers. In June 2007, the stockholders authorized the increase of shares authorized for issuance under the 2004 Plan to 8,000,000 shares. The Compensation Committee of the Board of Directors (the Compensation Committee) administers the 2004 Plan and has delegated to each of the Company's Chief Executive Officer and Chief Financial Officer the authority to grant stock options to newly hired employees and promoted employees below the Vice President level within specified parameters. To date, the Company has granted only nonqualified stock options and restricted stock awards under the 2004 Plan. Stock options are granted with an exercise price equal to 100% of the market value of the common stock on the date of grant, and generally have a ten-year contractual term and vest no later than four years from the date of grant (with some providing for automatic vesting upon a change of control of the Company). The Company issues new shares of common stock upon exercise of stock options. At December 31, 2007, there were 2,567,396 shares available for future grants under the 2004 Plan.

(c) General Stock Option Information

The following tables summarize stock option activity for the three years ended December 31, 2007:

	Years Ended December 31,		
	2007	2006	2005
Options outstanding:			
Outstanding at beginning of period	3,548,903	2,101,498	1,858,700
Granted	1,339,240	1,864,323	1,070,592
Exercised	(826,034)	(185,970)	(210,687)
Cancelled	(286,004)	(230,948)	(617,107)
Outstanding at end of period	3,776,105	3,548,903	2,101,498
Exercisable at end of period	1,153,052	1,293,361	1,186,909
Weighted average exercise prices:			
Outstanding at beginning of period	$ 7.40	$ 5.92	$ 6.55
Granted	15.29	8.94	5.01
Exercised	6.34	5.30	3.52
Cancelled	9.53	7.98	6.93
Outstanding at end of period	10.27	7.40	5.92
Exercisable at end of period	7.21	6.26	6.56

Of the 286,004 options cancelled during 2007, 279,377 represented unvested options forfeited with an average exercise price of $9.46 and 6,627 represented vested options cancelled with a weighted average exercise price of $12.22. The aggregate intrinsic value of options outstanding and of exercisable options as of December 31, 2007 was $74,457,000 and $26,270,000, respectively. These aggregate intrinsic values represent the total pretax intrinsic value, based on the Company's stock closing price of $29.99 as of December 31, 2007, that would have been received by the option holders had all option holders exercised their options as of that date.

The weighted-average grant date fair value of the options issued in 2007, 2006 and 2005 was $8.30, $5.84 and $3.40, respectively. The total fair value of options vested in 2007, 2006 and 2005 was $3,663,000, $1,143,000 and $3,144,000, respectively. The total intrinsic value of options exercised in 2007, 2006 and 2005 was $9,119,000, $901,000 and $355,000, respectively. As of December 31, 2007, the weighted average remaining contractual life of outstanding options and of exercisable options was 8.27 and 7.10 years, respectively.

The total number of in-the-money options exercisable as of December 31, 2007 was 1,153,052.

(d) Restricted Stock Information

The compensation cost of restricted stock awards is determined by their intrinsic value on the grant date. The following table summarizes the restricted stock activity for the three years ended December 31, 2007:

	Years Ended December 31,		
	2007	2006	2005
Nonvested shares:			
At beginning of period	232,544	81,451	88,055
Granted	15,000	200,000	25,000
Vested	(48,742)	(48,794)	(20,488)
Forfeited	(730)	(113)	(11,116)
At end of period	198,072	232,544	81,451
Weighted average grant date fair value:			
At beginning of period	$ 7.47	$ 6.67	$ 7.50
Granted	13.39	7.81	4.78
Vested	7.48	7.50	7.50
Forfeited	7.50	7.50	7.50
At end of period	7.92	7.47	6.67

(e) Valuation and Expense Information under SFAS No. 123R

On January 1, 2006, the Company adopted SFAS No. 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors, including stock options and employee stock purchases under the Company's employee stock purchase plan, based on estimated fair values. Prior to the adoption of SFAS No. 123R, the Company accounted for stock-based awards to employees and directors using the intrinsic value method under APB No. 25 and provided pro forma information in accordance with SFAS No. 123 concerning the impact of a fair value measurement of share-based compensation. The fair value of each share-based award was estimated on the date of grant using the Black-Scholes model and applying the assumptions in the following table. The expected volatility is based on the blended historical volatility of peer group companies and, for 2007 and 2006, the historical volatility of the Company. The Company uses the simplified calculation of expected option life, described in SAB No. 107, because the Company's history is inadequate to determine a reasonable estimate of the option life. The dividend yield is determined based on the Company's history to date and management's estimate of dividends over the option life. The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of the grant.

	Year Ended December 31,		
	2007	2006	2005
Weighted average assumptions:			
Expected life of options (in years)	6.09	6.25	5.50
Risk-free interest rate	4.59%	4.90%	4.02%
Expected volatility	50.18%	66.47%	80.00%
Expected dividend yield	0.00%	0.00%	0.00%

Pre-vesting forfeitures are estimated in the determination of total stock-based compensation cost based on Company experience. The estimate on pre-vesting forfeitures will be adjusted in future periods to the extent actual pre-vesting forfeitures differ, or are expected to differ, from such estimates. As of December 31, 2007, there was approximately $13,389,000 of total unrecognized stock-based compensation cost related to all share-based payments that will be recognized over the weighted-average period of 2.57 years. Future grants will add to this total, whereas future amortization and the vesting of existing grants will reduce this total.

(f) Pro Forma Disclosures

The pro forma information presented in the following table assumes that compensation cost for employee and director service option grants and purchase rights under the Company's 2004 Employee Stock Purchase Plan had been determined based on the fair value at the grant dates for those options, consistent with SFAS No. 123. On this basis, the net loss and net loss per common share for the years ended December 31, 2005 would have increased to the pro forma amounts indicated below (in thousands, except per share amounts):

	Year Ended December 31, 2005
Net loss applicable to common stockholders, as reported	$ (38,258)
Add: total stock based employee compensation expense recognized under the intrinsic value based method	272
Deduct: total stock based employee compensation expense determined under fair value based method	(3,685)
Pro forma net loss applicable to common stockholders	$ (41,671)
Net loss per common share:	
Basic and diluted, as reported	$ (1.54)
Basic and diluted, pro forma	$ (1.67)

The above pro forma disclosure is not representative of the effects of stock-based compensation for years subsequent to 2005. In September 2005, the Compensation Committee of the Board of Directors of the Company approved the acceleration of the vesting of the unvested portion of "out-of-the-money" stock options then held by employees, including executive officers. All other terms and conditions of these "out-of-the-money" options remained unchanged. As a result of this acceleration, approximately $1.9 million of compensation cost applicable to these "out-of-the-money" stock options is reflected in the above pro forma table.

(13) Testim Marketing and Distribution Agreements

In December 2003, the Company entered into an exclusive marketing and distribution agreement with Bayer, Inc. or, Bayer, in Canada. In December 2006, this agreement was mutually terminated and the previously deferred amount of $600,000 of non-refundable receipts from Bayer was recognized as revenue.

In March 2004, the Company signed a sublicense agreement, as later amended, with Ipsen to use and sell Testim on a worldwide basis outside the U.S., Canada, Mexico, Japan, Poland, Russia, South Korea and China, their territories and possessions. Ipsen has launched Testim in Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the U.K. Ipsen is obligated to purchase product from the Company and to pay royalty and certain milestone payments. The milestone payments are due upon contract signing, regulatory approval, product launch in various countries and supply price reductions. The license is exclusive and royalty-bearing for the longer of ten years from market launch or the expiration of patent protection in any particular country.

In December 2006, the Company entered into an exclusive marketing and distribution agreement with Paladin Labs, Inc., or Paladin, in Canada. Paladin agreed to purchase product and pay certain royalty and milestone payments. Milestones payments were due upon contract signing and upon achieving specified sales levels. The term of the agreement is for the life of the patent covering Testim in Canada.

Through December 31, 2007, the Company collected $12,200,000 of license payments under the Ipsen and Paladin agreements. Of this amount, $11,200,000 relates to non-refundable milestones. The remaining $1,000,000 represents refundable milestone from Ipsen that cannot be recognized at this time. During the years ended December 31, 2007 and 2006, the Company recorded revenue of $732,000 and $685,000, respectively, for up-front and milestone amounts received from Ipsen. At December 31, 2007, $748,000 was classified as current deferred revenue and $9,500,000 was classified as long-term deferred revenue.

(14) Employee Benefit Plans

The Company sponsors a 401(k) defined contribution plan covering substantially all U.S. employees. The board of directors determines contributions made by the Company annually. The Company made matching contributions of $274, 000, $170,000, and $136,000 in 2007, 2006, and 2005, respectively.

In 2001, the Company adopted a defined contribution plan covering substantially all United Kingdom employees. The Company made contributions of $63,000, $80,000, and $70,000 in 2007, 2006, and 2005, respectively.

(15) Unaudited Quarterly Financial Information (in thousands, except share and per share amounts):

	2007			
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Net revenues	$ 18,420	$ 23,340	$ 26,236	$ 27,738
Cost of goods sold	5,078	5,872	6,421	7,239
Research and development expenses*	8,711	9,711	9,833	14,545
Selling, general and administrative expenses*	17,207	18,503	18,159	18,902
Loss from operations	(12,576)	(10,746)	(8,177)	(12,948)
Net loss	(11,877)	(10,022)	(6,950)	(11,858)
Basic and diluted net loss per common share (1)	(0.33)	(0.27)	(0.17)	(0.29)
Weighted average basic and diluted common shares outstanding	35,778,015	36,724,292	39,850,584	40,331,967
*includes the following amounts of stock-based compensation expense:				
Research and development	$ 222	$ 272	$ 308	$ 378
Selling, general and administrative	959	1,187	1,333	1,378

	2006			
	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Net revenues	$ 14,893	$ 16,471	$ 17,640	$ 19,486
Cost of goods sold	3,850	4,386	4,484	4,971
Research and development expenses*	8,368	8,859	8,450	12,223
Selling, general and administrative expenses*	12,906	15,473	17,120	15,777
Loss from operations	(10,231)	(12,247)	(12,414)	(13,486)
Net loss	(9,673)	(11,746)	(11,770)	(12,758)
Basic and diluted net loss per common share (1)	(0.33)	(0.40)	(0.39)	(0.36)
Weighted average basic and diluted common shares outstanding	29,187,794	29,244,903	30,081,510	35,234,484
*includes the following amounts of stock-based compensation expense:				
Research and development	$ 52	$ 71	$ 109	$ 165
Selling, general and administrative	337	558	874	916

(1) The sum of the quarterly loss per share amounts may differ from the full year amount due to changes in the number of shares outstanding during the year.

ITEM 9. ***Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

ITEM 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer have concluded, based on their respective evaluations as of the end of the period covered by this Report, that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Report are effective to provide reasonable assurance that the information required to be disclosed in the reports we file under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosures. A controls system cannot provide absolute assurances, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our 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:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors of our company; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework. Based on this assessment and those criteria, management concluded that our internal control over financial reporting was effective as of December 31, 2007.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers, LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting occurred during our fiscal year ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. ***Other Information***

None

PART III

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

The information required by this item is incorporated herein by reference to the sections captioned "Election of Directors," "Executive Officers," "Corporate Governance," and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive Proxy Statement relating to our 2008 Annual Meeting of Stockholders.

We have adopted a Code of Conduct that applies to all of our directors, officers and employees. Our Code of Conduct contains provisions that satisfy the standards for a "code of ethics" set forth in Item 406 of Regulation S-K of the rules and regulations of the Securities and Exchange Commission. Our Code of Conduct also contains a special Code of Ethics that is applicable to our Chief Executive Officer and our senior financial officers. Our Code of Conduct is available under the heading "Investor Relations — Corporate Governance" on our Internet Web site, the address of which is www.auxilium.com. The information contained on our Internet Web site is not incorporated by reference into this Report and should not be considered part of this or any other report that we file with or furnish to the SEC.

To the extent that we amend any provision of our Code of Conduct or grant a waiver from any provision of our Code of Conduct that is applicable to any of our directors or our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, we intend to satisfy our disclosure obligations under applicable SEC rules by posting such information on our Internet Web site under the heading "Investor Relations — Corporate Governance."

ITEM 11. *Executive Compensation*

The information required by this item is incorporated herein by reference to the section captioned "Executive Compensation" in our definitive Proxy Statement relating to our 2008 Annual Meeting of Stockholders.

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

The information required by this item is incorporated herein by reference to the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our definitive Proxy Statement relating to our 2008 Annual Meeting of Stockholders.

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

The information required by this item is incorporated herein by reference to the section captioned "Certain Relationships and Related Transactions" in our definitive Proxy Statement relating to our 2008 Annual Meeting of Stockholders.

ITEM 14. *Principal Accountant Fees and Services*

The information required by this item is incorporated herein by reference to the section captioned "Ratification of Selection of Independent Registered Public Accounting Firm" in our definitive Proxy Statement relating to our 2008 Annual Meeting of Stockholders.

PART IV

ITEM 15. ***Exhibits and Financial Statement Schedules***

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

(1) Consolidated Financial Statements

See Index to Consolidated Financial Statements on page 68.

(2) Financial Statement Schedules

All schedules to the consolidated financial statements are omitted as the required information is either inapplicable or presented in the consolidated financial statements.

(3) Exhibits

The information required by this Item is set forth in the Exhibit Index hereto which is incorporated herein by reference.

(b) Exhibits

The information required by this Item is set forth in the Exhibit Index hereto which is incorporated herein by reference.

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.

AUXILIUM PHARMACEUTICALS, INC.

Date: March 10, 2008

By: /s/ Armando Anido
Armando Anido
Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Armando Anido and James E. Fickenscher as true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities to sign this Report filed herewith and any or all amendments to said Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission granting unto said attorneys-in-fact and agents the full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the foregoing, as to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Armando Anido **Armando Anido**	Chief Executive Officer and President (Principal Executive Officer) and Director	March 10, 2008
/s/ James E. Fickenscher **James E. Fickenscher**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2008
/s/ Rolf A. Classon **Rolf A. Classon**	Chairman	March 10, 2008
/s/ Al Altomari **Al Altomari**	Director	March 10, 2008
/s/ Edwin A. Bescherer Jr. **Edwin A. Bescherer Jr.**	Director	March 10, 2008
/s/ Philippe O. Chambon **Philippe O. Chambon**	Director	March 10, 2008
/s/ Oliver S. Fetzer **Oliver S. Fetzer**	Director	March 10, 2008
/s/ Renato Fuchs **Renato Fuchs**	Director	March 10, 2008
/s/ Dennis H. Langer **Dennis H. Langer**	Director	March 10, 2008
/s/ Dennis J. Purcell **Dennis J. Purcell**	Director	March 10, 2008

EXHIBIT INDEX

Exhibit No.	Description
3.1	Fifth Restated Certificate of Incorporation of the Registrant (filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004, File No. 000-50855, and incorporated by reference herein).
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004, File No. 000-50855, and incorporated by reference herein).
4	Third Amended and Restated Investors Rights Agreement, dated October 31, 2003, by and among the Registrant and parties listed therein (filed as Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.1*	License Agreement, dated May 31, 2000, as amended, between Bentley Pharmaceuticals, Inc. and the Registrant (filed as Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.2*	License Agreement, dated May 31, 2001, as amended, between Bentley Pharmaceuticals, Inc. and the Registrant (filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.3*	License Agreement, dated June 20, 2003, between Formulation Technologies L.L.C. d/b/a PharmaForm and the Registrant (filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.4	Amendment, dated April 19, 2004, to License Agreement between Formulation Technologies, L.L.C. d/b/a PharmaForm and the Registrant, dated June 20, 2003 (filed as Exhibit 10.20 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.5	Amendment No. 2, dated June 17, 2004, to License Agreement between Formulation Technologies L.L.C. d/b/a PharmaForm and the Registrant, dated June 20, 2003 (filed as Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.6*	Research and Development Agreement, dated June 20, 2003, between Formulation Technologies L.L.C. d/b/a PharmaForm and the Registrant (filed as Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.7*	Amendment, dated February 8, 2005, to Research and Development Agreement between Formulation Technologies L.L.C. d/b/a PharmaForm and the Registrant, dated June 20, 2003 (filed as Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the years ended December 31, 2004 and incorporated by reference herein).
10.8*	License Agreement, dated February 8, 2005, between Formulation Technologies, L.L.C. d/b/a PharmaForm and the Registrant (filed as Exhibit 10.8 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004, File No. 000-50855, and incorporated by reference herein).
10.9*	Development and License Agreement, dated June 3, 2004, by and between BioSpecifics Technologies Corp. and the Registrant.
10.10*	Amendment No. 1, dated May 10, 2005, to the Development and License Agreement by and between BioSpecifics Technologies Corp. and the Registrant, dated June 3, 2004 (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2005, File No. 000-50855, and incorporated by reference herein).
10.11*	License and Distribution Agreement, dated March 26, 2004, between Ipsen Farmaceutica B.V. and the Registrant (filed as Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.12*	Manufacturing Agreement, dated April 23, 2002, between DPT Laboratories, Ltd. and Registrant (filed as Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).

Exhibit No.	Description
10.13*	First Amendment, dated May 28, 2002 to Manufacturing Agreement between DPT Laboratories, Ltd. and the Registrant, dated April 23, 2002 (filed as Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.14*	Third Amendment, dated September 14, 2005, to Manufacturing Agreement between DPT Laboratories, Ltd. and the Registrant, dated April 23, 2002 (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on September 20, 2005, File No. 000-50855, and incorporated by reference herein).
10.15*	Process Development and cGMP Manufacture of Phase III CTM Agreement, dated June 28, 2005, by and between Cobra Biomanufacturing Plc and the Registrant (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2005, File No. 000-50855, and incorporated by reference herein).
10.16	Agreement of Lease, dated December 31, 2004, between Liberty Property Limited Partnership, as landlord, and Auxilium Pharmaceuticals, Inc., as tenant, as amended by the First Amendment to Agreement of Lease, dated as of June 1, 2006, by and between Auxilium Pharmaceuticals, Inc. and Liberty Property Limited Partnership and the Second Amendment to Agreement of Lease, dated February 22, 2008, between Auxilium Pharmaceuticals, Inc. and Liberty Property Limited Partnership (filed as Exhibit 99.1 to the Registrant's Current Report on Form 8-K filed on February 28, 2008, File No. 000-50855, and incorporated by reference herein).
10.17	Promissory Note, dated June 13, 2003, made by the Registrant in favor of General Electric Capital Corporation (filed as Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.18	Master Security Agreement, dated June 16, 2002, between General Electric Capital Corporation and the Registrant (filed as Exhibit 10.10 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.19*	Commercial Outsourcing Services Agreement, dated November 13, 2002, between Integrated Commercialization Solutions Inc. and the Registrant (filed as Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.20	Form of Securities Purchase Agreement, dated June 28, 2005 (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on July 1, 2005, File No. 000-50855, and incorporated by reference herein).
10.21	Form of Amendment to Securities Purchase Agreement, dated December 30, 2005 (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on January 6, 2006, File No. 000-50855, and incorporated by reference herein).
10.22#	Registrant's 2004 Equity Compensation Plan, amended and restated as of June 13, 2007 (filed as Exhibit A to the Registrant's Definitive Proxy Statement, dated April 30, 2007, for its 2006 Annual Meeting of Stockholders, and incorporated by reference herein).
10.23#	Form of Nonqualified Stock Option Agreement for awards under the Registrant's 2004 Equity Compensation Plan, including provision for immediate vesting upon a change of control of the Registrant (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 22, 2005, File No. 000-50855, and incorporated by reference herein).
10.24#	Form of Nonqualified Stock Option Agreement for awards under the Registrant's 2004 Equity Compensation Plan (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 22, 2005, File No. 000-50855, and incorporated by reference herein).
10.25#	Form of Incentive Stock Option Agreement for awards under the Registrant's 2004 Equity Compensation Plan, including provision for immediate vesting upon a change of control of the Registrant (filed as Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on March 22, 2005, File No. 000-50855, and incorporated by reference herein).
10.26#	Form of Incentive Stock Option Agreement for awards under the Registrant's 2004 Equity Compensation Plan (filed as Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on March 22, 2005, File No. 000-50855, and incorporated by reference herein).

Exhibit No.	Description
10.27#	Form of Amendment to Stock Option Grant Agreement for the acceleration of vesting of "out-of-the-money" stock options (filed as filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on September 26, 2005, File No. 000-50855, and incorporated by reference herein).
10.28#	Registrant's 2004 Employee Stock Purchase Plan (filed as Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.29#	Employment Agreement, dated May 18, 2005, between James E. Fickenscher and the Registrant (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on May 20, 2005, File No. 000-50855, and incorporated by reference herein).
10.30#	Employment Agreement, dated April 19, 2004, between Dr. Jyrki Mattila and the Registrant (filed as Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, Registration No. 333-114685, and incorporated by reference herein).
10.31#	Employment Agreement, dated March 22, 2005, between Jennifer Evans Stacey and the Registrant (filed as Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on March 22, 2005, File No. 000-50855, and incorporated by reference herein).
10.32*	Manufacturing and Clinical Supply Agreement, dated February 28, 2006, between the Registrant and Althea Technologies, Inc. (filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on May 12, 2006, File No. 000-50855, and incorporated by reference herein).
10.33	Indemnification Agreement, dated March 31, 2006, between KPMG LLP and the Registrant (filed as Exhibit 10.44 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005, File No. 000-50855, and incorporated by reference herein).
10.34	Indemnification Agreement, dated as of April 21, 2006, between the Registrant and KPMG LLP (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on April 27, 2006, file No. 000-50855, and incorporated by reference herein).
10.35	Indemnification Agreement, dated as of May 23, 2006, between the Registrant and KPMG LLP (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on June 6, 2006, File No. 000-50855, and incorporated by reference herein).
10.36#	Employment Agreement, dated June 27, 2006, between the Registrant and Armando Anido (filed as Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2006, File No. 000-50855, and incorporated by reference herein).
10.37*	Exhibit No. 11 to the Research and Development Agreement, dated as of July 14, 2006, by and between the Registrant and Cobra Biologics Ltd. (filed as Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2006, File No. 000-50855, and incorporated by reference herein).
10.38	Lease Agreement, dated September 1, 2006, between the Registrant and ARE-PA Region No. 6, LLC (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 5, 2006, File No. 000-50855, and incorporated by reference herein).
10.39	Letter Agreement, dated November 22, 2006, by and between the Registrant and Cobra Biologics Ltd. (filed as Exhibit 10 to the Registrant's Current Report on Form 8-K filed on November 29, 2006, File No. 000-50855, and incorporated by reference herein).
10.40	Letter Agreement, dated December 1, 2006, between the Registrant and Bayer Inc. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 12, 2006, File No. 000-50855, and incorporated by reference herein).
10.41#	2006 Cash Bonus Awards, 2007 Base Salary, 2007 Target Cash Bonus Awards and 2007 Stock Option Awards for Named Executive Officers (filed with the Registrant's Current Report on Form 8-K filed on March 1, 2007, File No. 000-50855, and incorporated by reference herein).
10.42#	Employment Agreement dated March 13, 2007, between the Registrant and Roger D. Graham, Jr. (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 7, 2007, File No. 000-50855, and incorporated by reference herein).

Exhibit No.	Description
10.43#	Form of Restricted Stock Grant Agreement for awards under the Registrant's 2004 Equity Compensation Plan, as amended (filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on May 7, 2007, File No. 000-50855, and incorporated by reference herein).
10.44	Placement Agency Agreement, dated June 7, 2007, by and among the Registrant, Banc of America Securities LLC and Thomas Weisel Partners LLC (filed as Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed on June 8, 2007, File No. 000-50855, and incorporated by reference herein).
10.45#	Form of Nonqualified Stock Option Agreement for awards to Non-Employee Directors under the Registrant's 2004 Equity Compensation Plan, as amended (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 6, 2007, File No. 000-50855, and incorporated by reference herein).
10.46#**	Employment Agreement dated January 31, 2008, between the Registrant and Anthony DelConte
21**	Subsidiaries of the Registrant.
23**	Consent of PricewaterhouseCoopers LLP.
24**	Power of Attorney (included on signature page).
31.1**	Certification of Armando Anido, the Registrant's Principal Executive Officer, required by Rule 13a-14(a) or Rule 15d-14(a).
31.2**	Certification of James E. Fickenscher, the Registrant's Principal Financial Officer, required by Rule 13a-14(a) or Rule 15d-14(a).
32**	Certification of Armando Anido, the Registrant's Principal Executive Officer, and James E. Fickenscher, the Registrant's Principal Financial Officer, required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the U.S. Code (18 U.S.C. 1350).

* Certain information in this exhibit has been omitted pursuant to an Order Granting Confidential Treatment issued by the SEC.

** Filed herewith.

\# Indicates management contract or compensatory plan or arrangement.

Exhibit 10.9

DEVELOPMENT AND LICENSE AGREEMENT
dated as of June 3, 2004

by and between

BIOSPECIFICS TECHNOLOGIES CORP.
(a Delaware corporation)

and

AUXILIUM PHARMACEUTICALS, INC.
(a Delaware corporation)

SCHEDULES

Schedule 1.7 BTC Patents
Schedule 1.16 Cost of Goods
Schedule 1.21 Enzyme
Schedule 3.2 Clinical Trials

DEVELOPMENT AND LICENSE AGREEMENT

This DEVELOPMENT AND LICENSE AGREEMENT (this "Agreement") dated the 3rd day of June, 2004 (the "June 3, 2004") is by and between BioSpecifics Technologies Corp., a corporation organized and existing under the laws of Delaware and having its principal office at 35 Wilbur Street, Lynbrook, New York 11563, and its Affiliates ("BTC"), and Auxilium Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 160 West Germantown Pike, Norristown, PA 19401 ("Auxilium"). BTC and Auxilium shall sometimes be referred to herein individually as a "Party" and collectively as "Parties."

INTRODUCTION

WHEREAS, BTC controls certain BTC Patents and BTC Know-How (each as defined below) related to the Enzyme and the Product (each as defined below), and has the right to grant certain rights and licenses thereunder as set forth herein, and

WHEREAS, Auxilium has certain expertise in the development and commercialization of pharmaceutical products, and Auxilium wishes to obtain certain licenses and options to develop and commercialize the Product for certain therapeutic uses in humans, and

WHEREAS, BTC wishes to convey such licenses to Auxilium.

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the sufficiency of which is hereby acknowledged, the Parties to this Agreement mutually agree as follows:

ARTICLE 1
DEFINITIONS

For purposes of this Agreement, the following initially capitalized terms in this Agreement, whether used in the singular or plural, shall have the following meanings:

1.1 "Additional Indication" shall mean any Indication for a Product outside of the Field.

1.2 "Additional Indication Option" has the meaning set forth in Section 2.2(b).

1.3 "Adverse Drug Experience" shall mean any of the following as such terms are defined at either 21 C.F.R. § 312.32 or 21 C.F.R. § 314.80: an "adverse drug experience," a "life-threatening adverse drug experience," a "serious adverse drug experience," or an "unexpected adverse drug experience" and the foreign counterparts thereof.

1.4 "Affiliate" shall mean any corporation, company, partnership, joint venture or firm which controls, is controlled by, or is under common control with a specified person or entity. For purposes of this Section 1.4, "control" shall be presumed to exist if one of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such cases such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

1.5 "Auxilium Remaining Indication" shall mean an Additional Indication for a Product that Auxilium believes has a reasonable probability of obtaining Regulatory Approval and achieving commercial success, but for which BTC does not wish to undertake Stage I Development.

1.6 "BTC Know-How" shall mean any proprietary information or materials related to the Manufacture, preparation, formulation, use or development of the Enzyme or the Product Controlled by BTC during the Term and shall include formulations, processes, techniques, formulas, biological, chemical, assay control and manufacturing, technical, pre-clinical, clinical or other data, methods, know-how, and trade secrets.

1.7 "BTC Patents" shall mean those Patents Controlled by BTC with at least one claim directed to the Enzyme or the Product (or processes, improvements, uses and intermediates for the foregoing) including those listed on Schedule 1.7 attached hereto as it may be amended from time to time.

1.8 "BTC Product" shall mean any pharmaceutical product that includes Enzyme as an active ingredient and is under development for an Indication (or is indicated for use) outside the Field.

1.9 "Business Day" shall mean any day on which banking institutions in New York, New York are open for business.

1.10 "Clinical Trials" shall mean tests and studies in human subjects or patients that are required to obtain, maintain, or sustain Regulatory Approval in a country in the Territory.

1.11 "Commercialization" or "Commercialize" shall mean activities directed to marketing, promoting, co-promoting, distributing, importing, exporting, offering for sale and selling the Product. When used as a verb, "Commercialize" means to engage in Commercialization.

1.12 "Commercially Reasonable Efforts" means, with respect to a Party, the efforts and resources which would be used by that Party relating to a certain activity or activities, consistent with its normal business practices, which are consistent with the general level of effort and resources in the pharmaceutical industry for a company similar in size and scope.

1.13 "Competing Product" shall mean a product that contains Enzyme and is sold in a country by a Person (other than Auxilium) in an Indication for which Auxilium is marketing a Product in such country.

1.14 "Confidential Information" has the meaning set forth in Section 10.1

1.15 "Controlled" or "Controls", when used in reference to intellectual property, shall mean the legal authority or right of a Party hereto (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to another Party, or to otherwise disclose proprietary or trade secret information to such other Party, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party.

1.16 "Cost of Goods" shall mean the total cost of Product in Final Packaging, including, but not limited to, the sum of the following actual costs: (i) manufacturing, shipping and storage of Enzyme; (ii) manufacturing, shipping and storage of Product, prior to sale to a Third Party; (iii) commercial packaging and labeling; (iv) routine quality compliance and quality assurance programs; and (v) customs or excise taxes, import duties, sales taxes and other taxes or duties (other than those taxes resulting from sales to a Third Party of Product in finished packaged and labeled form). In the event that BTC manufactures Enzyme or Products, Cost of Goods shall be calculated in accordance with Schedule 1.16.

1.17 "Develop" or "Development" shall mean Stage I Development and Stage II Development. When used as a verb, "Developing" means to engage in Development. For purposes of clarity, in no event shall Development include Manufacture.

1.18 "Development Costs" shall mean costs associated with Development activities.

1.19 "Effective Date" shall mean the date specified in the first paragraph of this Agreement.

1.20 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

1.21 "Enzyme" shall mean an enzyme more particularly described on Schedule 1.21, and any variants or derivatives thereof.

1.22 "European Union" shall mean the countries of the European Union, as it is constituted as of the Effective Date and as it may be expanded from time to time.

1.23 "Exercised Indication" has the meaning set forth in Section 2.2(c).

1.24 "Exercised Indication Date" has the meaning set forth in Section 2.2(c).

1.25 "Exercise Period" has the meaning set forth in Section 2.2(c).

1.26 "FDA" shall mean the U.S. Food and Drug Administration or its successor agency.

1.27 "Field" shall mean, subject to expansion pursuant to Section 2.2, the prevention or treatment of Dupuytren's Disease and Peyronie's Disease.

1.28 "Final Packaging" means the labeling and packaging to be used in connection with the Product labeled for use in the Field in the Territory, including the packaging of package inserts and components reasonably necessary for sale of the finished Product to the ultimate consumer.

1.29 "Indemnified Party" has the meaning set forth in Section 12.3.

1.30 "Indemnifying Party" has the meaning set forth in Section 12.3.

1.31 "Indication" shall mean a pharmaceutical application for the Product.

1.32 "Infringement Claim" has the meaning set forth in Section 8.2(a).

1.33 "Law" shall mean any applicable statute, law, ordinance, regulation, order, or rule of any federal, state, local, foreign, or other governmental agency or body or of any other type of regulatory body (including common law) or securities exchange, including those covering pharmaceutical sales, environmental, pollution, energy, safety, health, transportation, bribery, record-keeping, zoning, antidiscrimination, antitrust, wage and hour, and price and wage control matters.

1.34 "Licensed Technology" shall mean the BTC Patents and the BTC aKnow-How.

1.35 "Loss" has the meaning set forth in Section 12.1.

1.36 "Major Market Country" shall mean the **[**]**.

1.37 "MAA" shall mean an application seeking Regulatory Approval of the Regulatory Authority in the European Union to market and sell a Product in the Field in the European Union.

1.38 "MAA Acceptance" shall mean the written notification by the applicable Regulatory Authority that the MAA has met all the criteria for filing acceptance.

1.39 "Manufacture" or "Manufacturing" shall mean manufacturing, filling, processing, testing, engineering, designing, redesigning, packaging, storing, quality control, quality assurance, releasing, disposing, handling, shipping, and all other activities undertaken or required to be undertaken in order to manufacture and supply the Product in its Final Packaging and related devices and apparatus for administration thereof, in the case of commercial supplies, or packaged in accordance with Laws, in the case of clinical supplies.

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

1.40 "NDA" or "New Drug Application" shall mean a new drug application filed with the FDA pursuant to 21 C.F.R. §314, seeking permission to market the Product for a particular Indication in the Field in interstate commerce in the United States.

1.41 "NDA Filing Acceptance" shall mean the written notification by the FDA that the NDA has met all the criteria for filing acceptance.

1.42 "Net Sales" shall mean the gross amount invoiced by Auxilium and its Affiliates or Sublicensees on account of sales of the Product in Final Packaging to Third Parties in the Territory, less the total of: (a) trade, cash or quantity discounts not already reflected in the amount invoiced; (b) excise, sales and other consumption taxes and customs duties to the extent included in the invoice price; (c) freight, insurance and other transportation charges to the extent specifically included in the invoice price; (d) returns or retroactive price reductions; and (e) compulsory payments and rebates directly related to the sale of the Product accrued, paid or deducted pursuant to governmental regulations.

1.43 "Orphan Drug Designation" shall mean the special designation of Product by FDA's Orphan Product Division which provides the Product with the opportunity to obtain additional market exclusivity from the date the drug receives FDA approval and also possible tax and regulatory approval benefits. The term "Orphan Drug Designation" shall include any foreign counterparts of the foregoing.

1.44 "Patents" shall mean any patents or patent applications and any continuations, continuations-in-part, divisions, provisionals, substitutions, patents of addition, reissues, reexamination, renewals or extensions thereof (including any supplemental patent certificates) and any confirmation patent or registration patent and all foreign counterparts of any of the foregoing.

1.45 "Person" shall mean any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

1.46 "Phase II Clinical Trials" shall mean a Clinical Trial for the Product on a number of patients, no fewer than the number required to allow for the detection of statistical differences between the control and treated patients, for the purposes of determining dose and evaluating safety and efficacy in the proposed therapeutic indication, conducted in accordance with current good clinical practices and in accordance with a protocol that has been reviewed by the FDA and reflects any comments or concerns raised by the same.

1.47 "Phase III Clinical Trials" shall mean a Clinical Trial for the Product on sufficient numbers of patients to generate safety and efficacy data to support Regulatory Approval in the proposed therapeutic indication, conducted in accordance with current good clinical practices and in accordance with a protocol that has been reviewed by the FDA and reflects any comments or concerns raised by the same.

1.48 "Product" shall mean pharmaceutical product containing Enzyme as an active ingredient and any reformulation, improvement, enhancement, combination, refinement, or modification thereof; provided however, Product shall specifically exclude dermal formulations labeled for topical administration.

1.49 "Product Data" shall mean the physical embodiment, to the extent available of: (a) the know-how, including relevant laboratory notebook information, screening data and synthesis schemes, including descriptions in any form, data and other information, and (b) all other data including Regulatory Data and any other pre-clinical and clinical data and information, technical, chemical, safety and scientific data, information and know-how, obtained or generated in connection with Development of the Product in the Field.

1.50 "Product Details" shall mean a face-to-face meeting, in an individual or group practice setting, between a healthcare professional with prescribing authority who is a target prescriber of a Product in the Field and a professional representative of the applicable Party during which the key attributes of a Product are verbally presented to such healthcare professional. When used as a verb, "detail" or "detailing" shall mean to engage in a Detail.

1.51 "Regulatory Approval" shall mean, with respect to a country or group of countries in the Territory, all authorizations by the appropriate governmental entity or entities necessary for commercial sale of the Product in the Field for a particular Indication in that country or group of countries including, where applicable, approval of labeling, price, reimbursement and manufacturing.

1.52 "Regulatory Authority" shall mean the FDA or any foreign counterpart or additional governmental or regulatory agencies in the Territory responsible for applicable Regulatory Approvals.

1.53 "Regulatory Data" shall mean any and all research data, pharmacology data, chemistry, manufacturing, and control data, preclinical data, clinical data or all other documentation submitted, or required to be submitted, to Regulatory Authorities in

association with regulatory filings for the Product in the Field (including any Drug Master Files (DMFs), Chemistry, Manufacturing and Control ("CMC") data, or similar documentation).

1.54 "Remaining Indication" shall mean an Additional Indication for which Auxilium has not exercised an Additional Indication Option within the Exercise Period.

1.55 "Stage I Development" shall mean pre-clinical and clinical drug development activities reasonably necessary to completing all development activities up to and including the completion of Phase II Clinical Trials for the Product in the Field, including pre-clinical studies, test method development, statistical analysis, Clinical Trials, regulatory affairs, and activities directed to seeking Regulatory Approvals.

1.56 "Stage I Development Costs" shall mean costs associated with Stage I Development activities.

1.57 "Stage II Development" shall mean non-clinical and clinical drug development activities reasonably necessary to the development and submission of Regulatory Data to a Regulatory Authority for the purpose of achieving Regulatory Approval, including non-clinical studies, test method development, statistical analysis, Clinical Trials, regulatory affairs, and activities directed to seeking Regulatory Approvals.

1.58 "Stage II Development Costs" shall mean costs associated with Stage II Development activities.

1.59 "Standard Terms" has the meaning set forth in Section 6.4(d).

1.60 "Sublicense Income" shall mean (a) the upfront payment, if any, actually received from a Sublicensee by Auxilium upon execution of an agreement with such Sublicensee, and (b) any milestone payments actually received from a Sublicensee by Auxilium in consideration for the grant of a sublicense to such Sublicensee under the Licensed Technology in the Field; provided, however, that Sublicense Income shall not include any such consideration received by Auxilium from any such Sublicensee in return for, as payment for or otherwise in respect of: (i) equity or debt of Auxilium (provided, however, that the exclusion contained in this sub-clause (i) shall not apply to transactions between Auxilium and its Affiliates), (ii) the manufacture or supply of ingredients or products, (iii) the performance of services (including research and development services other than screening services performed on behalf of a Sublicensee) or other similar payments, (iv) reimbursement of Auxilium's out of pocket costs and expenses, including patent expenses, or (v) the sale of Auxilium in whole or in part.

1.61 "Sublicensee" shall mean a Person to whom Auxilium grants any right or license to use the Licensed Technology to make, use or sell the Product in the Field in the Territory.

1.62 "Supply Agreement" has the meaning set forth in Section 6.4.

1.63 "Term" has the meaning set forth in Section 11.1(a).

1.64 "Territory" shall mean all the countries and territories of the world.

1.65 "Third Party" shall mean any Person or other entity other than Auxilium, BTC or their respective Affiliates.

1.66 "Vial" shall means a single dose unit of Product.

ARTICLE 2

LICENSE AND OPTION

2.1 License Grant to Auxilium

(a) Subject to the terms and conditions of this Agreement, on the Effective Date, BTC hereby grants to Auxilium an exclusive license under the Licensed Technology to research, Develop, use, Commercialize, market, sell and distribute the Product for the Field in the Territory.

(b) Subject to the terms and condition of this Agreement, BTC hereby grants to Auxilium a non-exclusive right and license under the Licensed Technology to Manufacture or have Manufactured the Product for the Field in the Territory. Notwithstanding the foregoing provisions of this Section 2.1(b), Auxilium shall not exercise its license pursuant to this Section 2.1(b) to Manufacture the Product except as permitted by, and solely for the purposes set forth in, Article 6.

(c) The licenses granted under Sections 2.1(a) and 2.2(b) shall include the right to grant sublicenses (and in the case of Section 2.1(a), distribution rights); provided, however, that all such sublicenses shall contain terms and conditions which are consistent with the terms and conditions contained in this Agreement.

2.2 Option to License Additional Indications

(a) Development of Additional Indications for Products. The Parties shall cooperate in good faith in generating ideas and concepts for Additional Indications for Products. BTC shall use Commercially Reasonable Efforts to conduct Stage I Development for the use of the Product for the treatment of Frozen Shoulder. BTC shall summarize such efforts in reports to be submitted to the Joint Development Committee on a quarterly basis.

(b) Option Grant. Subject to the terms and conditions of this Agreement, BTC hereby grants to Auxilium an exclusive option to an exclusive license to Products in the Territory for each Additional Indication on the same terms and conditions as provided for Indications in the Field (each, an "Additional Indication Option").

(c) Exercise Period; Exercise of Option. The period during which Auxilium may exercise an Additional Indication Option (the "Exercise Period") shall commence on the date on which BTC submits a Phase II Clinical Trial report to Auxilium for the Product for such Additional Indication and ends one hundred and twenty (120) days thereafter. BTC shall provide Auxilium with a copy of a Phase II Clinical Trial report and, any additional data or results in its control. Auxilium may exercise the Additional Indication Option at any time during the Exercise Period by delivering to BTC a written notice of exercise with regard to such Additional Indication (each, an "Exercised Indication") that sets forth the effective date of the exercise (the "Exercised Indication Date"). Upon receipt, BTC shall counter-sign the exercise notice which shall then be appended to and incorporated by reference into this Agreement effective the Exercised Indication Date.

(d) License Grant Upon Exercise of Option. Effective on the Exercised Indication Date, the Field definition shall be amended and expanded to include the relevant Exercised Indication.

(e) Auxilium Remaining Indications. Auxilium shall have the right to Develop and Commercialize Auxilium Remaining Indications at its sole cost and expense. Upon notification to BTC of Auxilium's intent to Develop and Commercialize an Auxilium Remaining Indication, the Field definition shall be amended and expanded to include such Auxilium Remaining Indication.

2.3 Remaining Indications BTC may offer Third Parties the right under the Licensed Technology to research, Develop, use Commercialize, market, sell and distribute the Product for any Remaining Indication (the "Remaining Indication Rights"), provided that, prior to executing a definitive agreement with a Third Party for one or more Remaining Indications, BTC must (a) provide Auxilium with a written summary of the material terms of the proposed agreement (the "Offer Terms"), and (b) grant Auxilium an option, exercisable for seventy-five (75) days after Auxilium's receipt of the written summary, to agree to equivalent terms, in which case the Parties shall negotiate in good faith an exclusive license agreement on such terms as promptly as possible thereafter. In the event that Auxilium does not exercise an option to license a Remaining Indication within such seventy-five (75) day period, the Remaining Indication Rights may be licensed to such Third Party on terms and conditions no less favorable to BTC than the Offer Terms.

2.4 Transfer of BTC Know-How Within forty-five (45) days of the Effective Date, BTC shall, or shall cause its Affiliates to, transfer to Auxilium all material Product Data relating to Dupuytren's Disease and Peyronie's Diseases, including but not limited to preclinical, clinical data, clinical trial protocols, study data tabulations, reports, the right of cross-reference and permission to use in Auxilium Regulatory Data and regulatory filings, investigator-generated data granted by the owners of such data, etc., in reasonably satisfactory form. Promptly, but in no event more than thirty (30) days, after the Exercised Indications Date, BTC shall, or shall cause its Affiliates to, transfer to Auxilium all Product Data relating to such Exercised Indication, in reasonably satisfactory form.

2.5 Exclusivity During the Term and any extension thereof, and for two years thereafter, neither BTC nor any of its Affiliates shall, except as otherwise set forth and provided in this Agreement, (a) directly or indirectly develop, manufacture, market, sell, detail or promote any Competing Product or (b) encourage off-label use of a Competing Product that could affect labeled usage of the Product in the Field. In addition, in the event that BTC markets a BTC Product outside the Field within a country in the Territory where Auxilium is promoting the Product within the Field, BTC shall promote the BTC Product under a trademark different from the Auxilium Trademark, and will not knowingly market, ship, distribute, promote, sell or otherwise put into circulation the BTC Products within the Field in such country or in any other country within the Territory. In the event that BTC enters into any agreements with its distributors or wholesalers for the BTC Products in a country in the Territory, it shall include in any and all said agreements appropriate provisions providing, to the extent not prohibited by Law, that the BTC Products must be distributed and sold solely outside the Field within such country in the Territory. In the event that Auxilium enters into any agreements with its distributors or wholesalers for the Product in the Field, it shall include in any and all said agreements appropriate provisions providing, to the extent not prohibited by Law, that the Product must be distributed and sold solely within the Field within such country in the Territory.

ARTICLE 3
PRODUCT DEVELOPMENT

3.1 Joint Development Committee

(a) Formation. As soon as practicable after the execution of this Agreement, BTC and Auxilium will establish a Joint Development Committee (the "JDC") made up of two (2) representatives designated by each Party hereto to assist in coordinating scientific interactions and resolving potential disagreements between BTC and Auxilium during the course of the Development of

Product. The JDC Chair will be appointed by Auxilium from among the members of the committee designated by Auxilium. Each of BTC and Auxilium shall have one vote on the JDC and, in the event of a deadlock with respect to any action, the vote of Auxilium , rendered after reasonable and open discussion among the members of the JDC, shall be final and controlling. BTC shall not take any action with respect to Remaining Indications that would be detrimental to the Product or damaging to Auxilium. Notwithstanding the foregoing, BTC will advise the JDC of all Development and Commercialization of Remaining Indications. The JDC shall have the right to discuss and comment on such activities but shall not have the final vote with respect to such activities as they relate to Remaining Indications.

(b) Quarterly Meetings. While a Product is under Development, the JDC shall meet formally at least quarterly, or with such other frequency, and at such time and location, as may be established by the JDC, for the following purposes, among others: (i) to oversee and coordinate Development activities of the Parties for Products; (ii) to receive and review reports by the Parties as may be submitted to the JDC on a quarterly basis; and (iii) to discuss matters relating to Patents related to the Product, including but not limited to issues of inventorship and decisions relating to the filing, prosecution and maintenance of such Patents, provided however, when the JCC is established, the JCC and the JDC will coordinate responsibility on such matters. Meetings of the JDC may be held in person or by teleconference, as may be determined by the JDC.

3.2 Auxilium's Stage II Development Activities.

(a) Dupuytren's Disease and Peyronie's Disease. As soon as it has received the relevant Product Data pursuant to Section 2.4, Auxilium shall assume all responsibility for (including financial responsibility), and have sole discretion over, all continuing Development of the Product for Dupuytren's Disease and Peyronie's Disease including all Clinical Trials underway as of the Effective Date and listed on Schedule 3.2. Auxilium shall not have financial responsibility for Development Costs or any other costs incurred in connection with Development related to Dupuytren's Disease and Peyronie's Disease prior to the Effective Date.

(b) Exercised Indications On each Exercised Indication Date, Auxilium shall be entitled to assume responsibility for, and have sole discretion over, all continuing Development activities for the Product for each such Exercised Indication. Auxilium shall have one (1) year after the relevant Exercised Indication Date to initiate Stage II Development for such Exercised Indication, provided, however, that such obligations shall not be binding upon Auxilium to the extent that BTC fails to (i) deliver material Product Data to Auxilium in accordance with Section 2.4, or (ii) supply Auxilium with material amounts of clinical supplies of the Product for use in the Field in accordance with the delivery scheduled specified by Auxilium under the terms of Section 6.3.

(c) Cooperation The Parties agree to cooperate with respect to the transfer of Development activities from BTC to Auxilium including transferring Clinical Trials and making introductions of Auxilium to clinical investigators and opinion leaders.

(d) Stage II Development Costs.

(i) Dupuytren's Disease and Peyronie's Disease. Auxilium shall be responsible for all the Development Costs related to the Product for Dupuytren's Disease and Peyronie's Disease and incurred by Auxilium after the Effective Date; provided, however, that BTC shall continue to be responsible for all Development Costs which are which are incurred prior to the Effective Date.

(ii) Exercised Indications. In the event Auxilium assumes responsibility for Stage II Development of the Product for an Exercised Indication, Auxilium shall be responsible for all Development Costs related to the Product for such Exercised Indication and incurred by Auxilium after the Exercised Indication Date; provided, however, that BTC shall continue to be responsible for all Development Costs which are incurred prior to the Exercised Indication Date.

(iii) Right of Set-Off. To the extent that Auxilium pays any Stage I Development Costs resulting from additional Stage I Development that is requested or required by a Regulatory Authority after assuming responsibility for Development of the Product for any Indication, Auxilium shall be entitled to set-off the amount of such Stage I Development Costs against any amounts due to BTC pursuant to Section 7.1.

3.3 Data and Records

(a) Ownership of Data. Auxilium shall retain ownership of all Product Data, information and results related to Development activities for the Product, provided, however, that Auxilium hereby grants to BTC a right of reference with respect to Remaining Indications to the Regulatory Data contained in Regulatory Approvals Controlled by Auxilium for the Product in the Field. Notwithstanding the foregoing, (a) if Auxilium's license rights to the Product terminate with respect to an Indication within the Field, Auxilium shall assign BTC its right, title and interest in and to the Product and Regulatory Data for that Indication, and (b) if Auxilium's license rights to a Product hereunder terminate entirely, Auxilium shall assign BTC its right, title and interest in and to all such Product and Regulatory Data; provided, however, that Auxilium may maintain a copy of such Regulatory Data for legal and archival purposes.

(b) Development Records. Each Party shall each maintain records in sufficient detail and in good scientific manner appropriate for patent purposes and as will properly reflect all work done and results achieved in the performance of Development activities hereunder (including all Regulatory Data in the form required to be maintained under any applicable governmental regulations). Such records shall include books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof, computer information storage means, samples of materials and other graphic or written data generated in connection with the Development activities. Subject to the terms and conditions of

Article 10 below, each Party shall provide the other the right to inspect (no more than once a year) such records upon reasonable request and during normal business hours, and shall provide copies of all requested records, to the extent reasonably required for the performance of the requesting Party's obligations under this Agreement.

ARTICLE 4
REGULATORY MATTERS

4.1 Efforts Within twelve (12) months of filing for Regulatory Approval in any Major Market Country, Auxilium will file for Regulatory Approval in all the Major Market Countries. Notwithstanding the foregoing, if a different dossier is required for any such other Major Market Country(ies), Auxilium will exercise Commercially Reasonable Efforts to seek Regulatory Approval with respect to such country(ies). Auxilium may develop additional formulations, dosage forms or delivery systems for the Product in the Field as may be commercially practicable at its own expense. For purposes of clarity, Remaining Indications shall not be subject to this Article 4; provided, however, that BTC shall not conduct Development or Commercialization of Product in such Remaining Indication in a manner that jeopardizes Auxilium's Development or Commercialization of Product in the Field.

4.2 Regulatory Matters in the Territory. As between the Parties, Auxilium shall be responsible in the Territory for ensuring compliance with all regulatory requirements relating to the Product labeled for use in the Field (i.e., obtaining, maintaining, and updating all required any Regulatory Approvals). Without limiting the foregoing, Auxilium shall (i) file all regulatory filings and supporting documentation; (ii) serve as the designated regulatory official for purposes of receiving communications from the Regulatory Authority; and (iii) report any Adverse Drug Experience to Regulatory Authorities.

4.3 Ownership. All Regulatory Approvals relating to the Products labeled for use in the Field shall be the property of Auxilium and held in the name of Auxilium or its designee. BTC shall promptly take whatever steps necessary to transition any existing regulatory filings to Auxilium. As promptly as possible after the Effective Date, BTC shall cause the Investigational New Drug ("IND") **[**]** and IND **[**]**, and all foreign counterparts thereof, to be assigned to Auxilium.

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4.4 Regulatory Interactions for Product.

(a) Communications with Regulatory Authority; Advice of Counsel. BTC shall not communicate with Regulatory Authorities, or take any action regarding an investigation or a request by a Regulatory Authority with respect to a Product in the Field, except (i) with the prior written consent of Auxilium, or (ii) upon the advice of legal counsel that such communication is required by Law. BTC shall cooperate with Auxilium and provide all reasonable assistance and take all actions reasonably requested by Auxilium that are necessary to comply with any Law applicable to a Product in the Field. If BTC is advised by its legal counsel that it must communicate with any Regulatory Authority, then BTC shall promptly, but in no event more than two (2) Business Days, advise Auxilium of the same and provide Auxilium in advance with a copy of any proposed written communication with such Regulatory Authority and comply with any and all reasonable requests of Auxilium concerning any such communication with such Regulatory Authority.

(b) Receipt of Correspondence; Inspections. Each Party shall promptly, but in any event within three (3) Business Days, (i) provide to the other copies of any material documents or correspondence received from any Regulatory Authority related to Development activities for a Product and (ii) inform the other Party of any inspections, proposed regulatory actions, investigations or requests for information or a meeting by any Regulatory Authority with respect to a Product. In the event BTC does not have advance notice of an inspection by a Regulatory Authority, it shall immediately notify Auxilium of such inspection and it shall cooperate with such Regulatory Authority.

(c) Recalls and Withdrawals. Subject to the terms and conditions of the Supply Agreement, Auxilium shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawals or any other corrective action related to the Products labeled for use in the Field in the Territory; provided however, (i) Auxilium shall immediately notify BTC of any decision to initiate a recall or withdrawal of such Product; (ii) all costs and expenses with respect to a recall, market withdrawal or other corrective action for such Product shall be borne by Auxilium unless such recall, market withdrawal or other corrective action was due to the negligence, willful misconduct or material breach of this Agreement or the Supply Agreement by BTC; and (iii) BTC shall immediately notify Auxilium of any decision to initiate a recall or withdrawal of a Product outside of the Field. Each Party shall provide the other Party with recall information received by it in sufficient detail to allow the Parties to comply with Law.

(d) Notice. Each Party shall provide the other Party with notice, in a sufficiently timely basis to enable the other Party to comply in all material respects with Laws, of notification or other information which it receives (directly or indirectly) from, any Regulatory Authority (and providing, as soon as reasonably possible, copies of any associated written requests) that (i) raises any material concerns regarding the safety or efficacy of a Product; (ii) indicates or suggests a claim of a Third Party arising in connection with a Product, or (iii) is reasonably likely to lead to a recall or market withdrawal of a Product, provided that neither Party shall be obliged to disclose information in breach of any contractual restriction which it could not reasonably have avoided or which disclosure would waive any legal privilege.

4.5 Inquiries, Adverse Events, etc. As between the Parties, Auxilium shall be responsible for the surveillance, receipt and evaluation of product complaints for Product labeled for use in the Field in the Territory and reporting to Regulatory Authorities Adverse Drug Experiences for the Products in the Field. As between the Parties, BTC shall be responsible for the surveillance, receipt and evaluation of product complaints for Product labeled for use outside the Field and reporting to Regulatory Authorities Adverse Drug Experiences for the Products outside the Field. Each Party shall ensure that, in the Development or Commercialization of the Product, it will record, investigate, summarize, notify, report and review all Adverse Drug Experiences in accordance with Law. Each Party shall (i) adhere to all requirements of Laws which relate to the reporting and investigation of Adverse Drug Experiences, and (ii) keep the Parties informed of such events.

(a) Each Party shall submit reports of all Adverse Drug Experiences associated with the use of the Product and other required safety information (e.g., PSUR's or annual safety reports) to the Regulatory Authorities in accordance with Law. Each Party shall submit a copy of each such report to the other Party in advance of such submission to permit the other Party to comply with legal requirements applicable to it and comment on such reports.

(b) Each Party shall submit reports of all Adverse Drug Experiences associated with the use of Product for which Regulatory Approval has not been achieved and other required safety information to the Regulatory Authorities in accordance with Law. Each Party shall submit a copy of each such report to the other Party in advance of such submission to permit the other Party to comply with legal requirements applicable to it and comment on such reports.

(c) In order to accomplish the objectives of this Section and to the extent required by Law, within one hundred and eighty (180) days of the Effective Date, the Parties shall discuss and develop an agreement containing mutually acceptable guidelines and procedures for the receipt, recordation, communication, exchange and reporting of Adverse Drug Experiences for the Product.

4.6 Approval of Labeling and Promotional Materials. Auxilium shall be responsible to seek or obtain any necessary Regulatory Authority approvals of any label, labeling, package inserts or outserts, monographs and packaging, and promotional materials for use in connection with the Products labeled for use in the Field and for determining whether the same requires approval from Regulatory Authority. The Parties shall cooperate in such efforts to seek and obtain such approvals.

4.7 Cooperation. The Parties shall cooperate to provide each other all reasonable assistance and take all actions reasonably requested that are necessary to comply with Laws, including safety updates, amendments, annual reports, pharmacovigilance filings, investigator notifications, facility inspections, and certifications and maintenance and updates for regulatory filings and Regulatory Approvals. Unless otherwise provided under the terms of this Agreement, the Parties will cooperate, communicate and provide reasonable assistance to each other with regard to all CMC matters related to the Product.

ARTICLE 5
COMMERCIALIZATION

5.1 Joint Commercialization Committee.

(a) Formation. Not later than the commencement of Phase III Clinical Trials for any Product, BTC and Auxilium will establish a Joint Commercialization Committee (the "JCC") made up of two (2) representatives designated by each Party hereto to assist in coordinating interactions and resolving potential disagreements between BTC and Auxilium during the course of the Commercialization of Product. The JCC shall meet each and every calendar quarter. The JCC Chair will be appointed by Auxilium from among the members of the committee designated by Auxilium. Auxilium and BTC shall each have one vote on the JCC. The objective of the JCC shall be to reach agreement by consensus on all matters falling within its authority hereunder. In the event of a deadlock with respect to any action, the vote of Auxilium, after reasonable opportunity for open discussion among the members of the JCC, shall control. Notwithstanding the foregoing, the JCC shall not have authority to commit the financial resources of either party.

(b) Patent Position. The JCC will coordinate with the JDC in discuss matters relating to Patents related to the Product, including but not limited to issues of inventorship and decisions relating to the filing, prosecution and maintenance of such Patents.

(c) Coordinated Strategy. The JCC shall meet at least quarterly or with such frequency and at such time and location as may be established by the JCC and will monitor the overall strategy and oversee the global marketing of all Products. The JCC will have the opportunity to review market research plans and research results, clinical development results and similar items for each Product, including Products Developed for Remaining Indications, for the purpose of advising and assisting in communicating a unified global marketing strategy; provided, however, that with respect to Remaining Indications, the JCC shall not have the final vote.

5.2 Commercialization. Auxilium shall use Commercially Reasonable Efforts to Commercialize the Product in the Field in each country in the Territory. Subject to Section 5.4 below, Auxilium shall be responsible for and have sole discretion over all aspects of Commercialization of the Product for use in the Field in the Territory.

5.3 Orders, Booking Sales. Auxilium shall have the sole right and responsibility for Product in the Field in each country in the Territory to (a) receive, accept, and fill orders for such Product, (b) control invoicing, order processing, and collection of accounts receivable for such Product sales, and (c) record such Product sales in its books of account. If, for any reason, BTC receives orders for such Product, BTC shall forward such orders to Auxilium (or, if directed by Auxilium, to Auxilium' wholesalers) as soon as practicable. If any quantities of such Product are returned to BTC, BTC shall immediately notify Auxilium and ship them to the facility designated by Auxilium.

5.4 BTC Co-Promotion Rights. In the event that BTC provides written notice of its intent within ninety (90) days after an NDA Acceptance for a Product in the Field in the Territory indicated for use for any Exercised Indication, BTC will be allowed to provide up to ten percent (10%) of the Product Details for such Indication. In addition, in the event that BTC provides written notice of its intent within ninety (90) days after an NDA Acceptance for Frozen Shoulder, BTC will be allowed to provide up to ten percent (10%) of the Product Details for Dupuytren's Disease. Notwithstanding Section 13.10, BTC's co-promotion rights granted pursuant to this Section shall not be assignable or transferable to any other Person.

ARTICLE 6
MANUFACTURE AND SUPPLY

6.1 Joint Manufacturing Committee.

(a) Within forty-five (45) days after the Effective Date, BTC and Auxilium will establish a Joint Manufacturing Committee (the "JMC") made up of two (2) representatives designated by each Party hereto to which shall oversee the manufacturing of Product on a worldwide basis, including the planning, manufacturing and supply (including supply chain management). The JMC Chair will be appointed by BTC from among the members of the committee designated by BTC. Each of BTC and Auxilium shall have one vote on the JMC. The objective of the JMC shall be to reach agreement by consensus on all matters falling within its authority hereunder. In the event of a deadlock with respect to any action, the vote of BTC, after reasonable opportunity for open discussion among the members of the JMC, shall control.

(b) Specific Responsibilities of the JMC. In support of its responsibility for overseeing the Manufacturing of Product on a worldwide basis the JMC shall meet at least quarterly or with such higher frequency, and at such time and location as may be established by the JMC, and the JMC shall perform the following activities:

(i) delineate requirements and responsibilities for development and licensure of manufacturing processes and facilities for Product and for supply of Product in the Territory;

(ii) together with the Joint Development Committee, develop a manufacturing strategy to enable development and licensure of manufacturing processes and facilities for Product in the Territory that includes all aspects of manufacture and release, including but not limited to formulations, intermediate, dosage form, devices, product characterization studies, stability studies and manufacturing plans and forecasts;

(iii) review quality assurance efforts, including but not limited to those efforts with respect to the establishment of specifications and quality standards for Product;

(iv) together with the Joint Development Committee review and comment on the process for Product Development and the drafting and contents of the CMC section of a Drug Approval Application for Product;

(v) review technology transfer plans for any changes in manufacturing sites, testing sites, and responsibilities in the supply chain for Product, it being understood that decisions regarding the selection of which of a Party's own manufacturing and testing sites shall be used to manufacture any component of a Product, if a Party manufactures any component of a Product pursuant to this Agreement or any related supply agreement, shall remain in the sole control of such Party;

(vi) prepare for regulatory inspections and ensure adherence to compliance standards with respect to Product; and

(vii) review quality compliance and manufacturing related regulatory issues concerning the Product or any component thereof as important issues arise through meetings and review of relevant written material produced by Auxilium, BTC or any Regulatory Authority.

6.2 Development and Scale-Up. BTC shall, at its own cost and expense, develop the formulation and the finished dosage form and scale-up the Manufacture for commercial supply of the Enzyme and the Product for each Indication for use in the Field, including the **[**]**, to be registered with Regulatory Authorities in accordance with Law and in sufficient time prior to anticipated commercial launch of a Product to provide for sufficient supply of Product for use in the Field. Notwithstanding the foregoing, Auxilium will have the sole right and responsibility for selecting the finished dosage form and presentation for the Product in the Field.

6.3 Clinical Supply.

(a) Supply by BTC. BTC shall be responsible for supplying or arranging for the supply of the Product suitable for use by Auxilium in Clinical Trials. All the Product shall be Manufactured in accordance with applicable specifications, all Laws, and shall be subject to the Standard Terms set forth in below. BTC will supply Auxilium, free of charge, with bulk vials containing sufficient quantities of the Product to treat up to five hundred **[**]** patients per year in Clinical Trials. If Auxilium requires additional clinical supplies, BTC will supply Auxilium with such clinical supplies at its Cost of Goods. Auxilium will be entitled to qualify a back up supplier for the Manufacture of clinical and commercial supplies of Product in the Field (the "Back-Up Supplier") at any time after the Effective Date. BTC will use Commercially Reasonable Efforts to ensure that such Back-Up Supplier has sufficient know-how to Manufacture Product, including (i) providing all protocols, registration applications and other substantive regulatory documents, including, but not limited to, all data, scientific dossiers and governmental authorizations; (ii) providing access and reference to all regulatory dossiers and filings produced by BTC, its Affiliates and sublicensees relating to the Product; (iii) providing access to BTC Know-How in reasonably satisfactory form, and (iv) providing all technical assistance reasonably requested by the Back-Up Supplier related to the Manufacture of the Product. Auxilium will require that the Back-up Supplier execute a written confidentiality agreement with both Auxilium and BTC, in a form consistent with industry standards, which includes, among

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other things, an undertaking by the Back-up Supplier to keep confidential the manufacturing information and know-how disclosed to the Back-up Supplier by BTC. In the manufacturing information and know-how disclosed to the Back-up Supplier by BTC. In addition, Auxilium will use reasonable commercial efforts to seek the cooperation of the Back-up Supplier in sharing with BTC and Auxilium information concerning the Manufacture of the Product that Back-up Supplier may acquire in connection with such Manufacture.

(b) Notification of Requirements. Auxilium will provide BTC with one hundred and eighty (180) days notice of its requirements for clinical supplies of Product including a delivery schedule and address. BTC will provide notice within three (3) Business Days of receipt of such notice if BTC is unable to supply Auxilium with the quantities of clinical supplies of Product in accordance with the delivery schedule. In such event, the Parties shall cooperate but BTC shall be primarily responsible, at its sole cost and expense, for procuring such quantities of Product from the Back-Up Supplier as are necessary to compensate for any such deficiency.

(c) Late Delivery of Clinical Supply. In the event that BTC is more than thirty (30) days late in delivering such material amount of clinical supplies, in addition to any other remedies Auxilium may have in Law or equity, BTC will forgive Auxilium seven thousand five hundred dollars ($7500) per day for each additional day, such amounts to be creditable against any milestone payments due to BTC under Article 7.

6.4 Commercial Supply; Supply Agreement. BTC will supply or arrange for the supply of all necessary commercial quantities of the Product in the Territory. No later than three (3) months after the Effective Date, the Parties shall enter into a commercial supply agreement on customary and reasonable terms and conditions (the "Supply Agreement"), such Supply Agreement shall include the following:

(a) Royalty. Auxilium will pay BTC on a country-by-country and Product by Product basis a royalty payment of six percent **[**]** of Net Sales of Products in the Field for the Term. Such royalty may be reduced as follows:

(i) Competing Product Sales. If a Competing Product is sold in a country in the Territory with a unit based market share of **[**]**% or greater, then there shall be no royalty due for sales in that country in the Territory.

(ii) Third Party Royalties. If the Manufacturing, Development or Commercialization of the Product by the Parties in accordance with this Agreement would, but for a license from such Third Party, infringe on such Third Party Patents, any royalties or other payments due to Third Parties pursuant to a license acquired by Auxilium then the royalty may be reduced by up to **[**]**% by such the royalty amounts to a floor of not less than three percent **[**]**% in any case.

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(b) Supply Price.

(i) Basic Supply Price. Subject to the adjustments set forth below, the "Supply Price" for the Product shall be calculated as a percentage of Net Sales as follows:

Annual Sales Volume (# Vials)	Supply Price (as % of Net Sales)
[**]	**[**]%**
[**]	**[**]%**
[**]	**[**]%**
[**]	**[**]%**
[**]	**[**]%**

Provided, however, the Supply Price shall not equal less than **[**]**% of BTC's Cost of Goods for the Product as provided in Schedule 1.16 (the "Minimum Supply Price").

(ii) Adjustments to Supply Price.

(A) Most Favored Customer. Notwithstanding anything in this Agreement to the contrary, if at any time during the Term BTC sells or provides products including Enzyme as an active ingredient to any customer for commercial use at rates more favorable than those accorded to Auxilium, BTC shall promptly offer Auxilium the benefit of such more favorable terms and conditions or rates, which, upon acceptance, shall be retroactive to the date that such more favorable terms and conditions were first effective for such other customer. In order for Auxilium to receive more favorable cost rates, Auxilum must accept the same basic business deal conditions as those provided to a party receiving the more favorable rates. Upon Auxilium's reasonable request, BTC shall provide written confirmation that it is in compliance with the requirements of this Section.

(B) Reduction In Cost of Goods. If BTC is successful in reducing the Cost of Goods, the Supply Price to Auxilium will be reduced by **[**]**% of such dollar reduction.

(C) Supply of Samples. Product samples shall be provided at no charge to Auxilium for use in post-market clinical trials and for selected use as commercial samples for dispensing to patients by an appropriate health care provider, but in no event for direct distribution to patients. The number of Product samples to be provided to Auxilium shall be set forth in the Supply Agreement.

(D) Delay in Delivery. If, for any reason other than a force majeure, the BTC delivers any shipment of Product in accordance with this Article later than the date of delivery set out in the purchase order as agreed by the Parties pursuant to the Supply Agreement then:

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(1) a 5% reduction in the Supply Price of Product if the shipment is delivered more than thirty (30) days but less than sixty (60) days late;

(2) a 10% reduction in the Supply Price of Product if the shipment is delivered more than sixty (60) days but less than ninety (90) days late; and

(3) a 15% reduction in the Supply Price of Product if the shipment is delivered more than ninety (90) days late.

(4) Once the price has been reduced in accordance with this Section, it will not revert to the original price unless and until the deliveries are no longer delayed.

(c) Stand-By Rights; Back Up Supplier.

(i) Standby Rights. Auxilium will be entitled to seek from the Back-Up Supplier the greater of (a) 25% its requirements and (b) that quantity of Product that BTC is unable to provide, for a period of one (1) year following the occurrence of any of the events set forth in (A), (B) or (C) below (the "Standby Rights"). In the event that Auxilium exercises its Standby Rights, the amount of Product that Auxilium is obligated to source from BTC pursuant to the Supply Agreement shall be reduced by such quantity for such one (1) year period.

(A) Failure to Meet Firm Order. If, for any reason, including, without limitation, as a result of a force majeure, BTC is unable to supply at least 75% of the amount of Product specified under a Firm Order, then Auxilium may exercise its Standby Rights by providing written notice; provided, however, that in the event that BTC is unable to supply the full amount specified in Auxilium's Firm Order for two consecutive quarters (regardless of the amount of such material shortfall), Auxilium may exercise its Standby Rights by providing written notice to BTC. In addition, Auxilium shall be permitted to seek supply of any shortfall (regardless of amount of such shortfall or the number of times BTC has fulfill some or all of an Auxilium Firm Order) from the Back-Up Supplier on a per event basis without specifically invoking its Stand-By Rights.

(B) Egregious Delivery Delay. If, for any reason, other than a force majeure, BTC delivers any quantity of any Product more than ninety (90) days after the date such delivery was due, then Auxilium may exercise its Standby Rights by providing written notice.

(C) Nonconforming Product. If any three (3) consecutive shipments contain nonconforming Product and BTC (1) fails to replace any nonconforming Product with conforming Product in a timely manner or (2) fails to replace nonconforming Product within fifteen (15) Business Days after a dispute regarding whether any rejected quantity of any Product constitutes nonconforming Product is decided in Auxilium's favor, then Auxilium may exercise its Standby Rights by providing written notice.

(ii) Offset. Auxilium will be entitled to offset any royalties owed to BTC by the amount represented by the difference between the Back Up Supplier's supply price and BTC's supply price.

(iii) BTC's Use of the Back Up Supplier. If BTC opts to use the Back Up Supplier to provide Product to Auxilium, then BTC will either reimburse Auxilium for **[**]** of the documented costs and expenses Auxilium incurred in qualifying, sourcing and maintaining such Back Up Supplier or **[**]**.

(d) Maintenance of Inventory. The Supply Agreement will require that by the time of Commercialization of the Product, BTC will maintain at least a six (6) month supply of API Enzyme and such reserve supply of Product as may be set forth in the Supply Agreement.

(e) Allocation of Supply. In the event of a shortage of raw materials necessary to Manufacture the Product, BTC shall allocate ninety percent (90%) of the total available supply of raw materials and Product to Auxilium.

(f) Continuous Improvement and Reduction of Cost of Goods. BTC shall use reasonable efforts to continuously improve its performance, and any Product suppliers' performance in the supply of the Product, including but not limited to, reducing Cost of Goods, increasing yield, and optimizing delivery timing.

(g) Standard Terms of Supply. With respect to the supply of the Product, BTC shall make the following representations, warranties, and covenants (the "Standard Terms"):

(i) The Product shall be Manufactured in accordance with all Laws and, at the time of delivery of the Product, such the Product will comply with the specifications, shall be free from defects in materials and workmanship, shall be fit for the purpose for which it is intended, and shall not be adulterated or misbranded within the meaning of the Act, and shall not constitute an article which may not, under the Act, be introduced into interstate commerce. BTC provides no other warranties, express or implied, regarding the Product and disclaims all other express or implied warranties, including the implied warranties of merchantability and fitness for a particular purpose.

(ii) The Product sold and shipped shall be Manufactured in accordance with all Laws in effect at the time and place of Manufacture of the Product, and all waste, including all hazardous waste, generated at the time of Manufacture of the Product shall be disposed of in accordance with all Laws;

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(iii) All records as are necessary and appropriate to demonstrate compliance with Laws shall be maintained by BTC and such Manufacture of the Product shall be performed in a facility maintaining a current drug establishment registration with the FDA as set forth in 21 C.F.R. § 207;

(iv) BTC shall ensure that it, its Affiliates, and its subcontractors maintain all Governmental Permits that may be necessary to Manufacture and ship the Product;

(v) BTC shall advise Auxilium of any information which arises out of BTC's, its Affiliates, and its subcontractors, as applicable, Manufacturing, relating to the Product, which have adverse regulatory compliance or reporting consequences concerning such the Product;

(vi) BTC shall provide to Auxilium any information reasonably requested by Auxilium and shall consult Auxilium before providing any information to any Regulatory Authority in connection with Manufacture of the Product. BTC shall as promptly as possible, but in no event later than within ten (10) days, advise Auxilium of any requests by any Regulatory Authority for inspections at the premises of BTC or any of its Affiliates or subcontractors with respect to the Product;

(vii) In the event BTC, its Affiliates, or its subcontractors are inspected by the FDA or any similar or related Regulatory Authority relating to the Product, BTC agrees to notify Auxilium of any such inspection and will use Commercially Reasonable Efforts to ensure that Auxilium shall have the right to be present during such inspection. BTC shall promptly notify Auxilium of any alleged violations or deficiencies relating to a Manufacturing facility at which the Product are Manufactured, packaged, or stored, and shall promptly disclose to Auxilium all relevant portions of any notice of observations or potential violations as well as a copy of its response thereto;

(viii) Neither BTC, its Affiliates nor subcontractors shall use, in the Manufacture of any the Product, in any capacity the services of any person, including any firm or individual, debarred or subject to debarment under the Generic Drug Enforcement Act of 1992, amending the Act at 21 U.S.C. § 335a. BTC agrees to notify Auxilium immediately in the event any person providing services to BTC, its Affiliates, or subcontractors relating to this Agreement is debarred or becomes subject to debarment; and

(ix) For the purpose of permitting a quality and compliance audit, BTC, its Affiliates, and subcontractors shall grant to authorized representatives of (or a Third Party hired on behalf of Auxilium who is reasonably acceptable to BTC), in general not more than once per month, upon reasonable notice, access to areas of each of its plants to the extent permitted by Law. Auxilium shall have the right, subject to any Third Party confidentiality obligations and at its sole expense, to examine those technical records made by BTC, its Affiliates or subcontractors that relate to the Manufacture of the Product.

(h) Customary Terms. The Supply Agreement shall also include provisions for: forecasting and ordering, inventory maintenance requirements; packaging obligations; back-up suppliers, compliance with applicable regulatory requirements, Auxilium guidelines, and specifications, and all Laws.

ARTICLE 7
PAYMENTS

7.1 Milestone Payments by Auxilium.

(a) Amount of Milestone Payments.

#	Milestone	United States Dollars	
1	The Effective Date	$[**]	
2	The delivery to Auxilium of the Product Data relating to Dupuytren's Disease and Peyronie's Disease in accordance with Section 2.4 of this Agreement.	$[**]	
3	The one (1) year anniversary of the Effective Date	$[**]	
4	Upon first of either NDA Acceptance or MAA Acceptance for the following Indications on an Indication by Indication basis:	Dupuytren's Disease	$[**]
		Peyronie's Disease	$[**]
5	Receipt by Auxilium or its Affiliate of first Regulatory Approval in the United States or three or more of the United Kingdom, Spain, Germany, France or Italy with labeling approved for the following Indications on an Indication by Indication basis:	Dupuytren's Disease	$[**]
		Peyronie's Disease	$[**]

(b) Timing of Milestone Payments. For milestones 1, 2 and 3, payment shall be made within ten (10) Business Days after the occurrence of the event giving rise to a payment obligation hereunder. For milestones 4 and 5, payment shall be made within thirty (30) days after the occurrence of the event giving rise to a payment obligation hereunder. All payments shall be made by wire transfer in United States Dollars to the credit of such bank account as may be designated, from time to time, by BTC in writing.

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7.2 Process Development Milestones Within thirty (30) days following the Effective Date, BTC will provide Auxilium with a plan for the scale-up of Manufacturing for clinical and commercial supplies of Product (the "Manufacturing Plan") which is acceptable to Auxilium. The Manufacturing Plan shall contain, among other things, a schedule setting forth a timeline for the achievement of certain manufacturing process development milestones (the "Process Development Milestones"). Auxilium shall pay to BTC the amount of $**[**]** monthly upon achieving the Process Development Milestones (the "Process Development Payments"); provided, however, that Auxilium may suspend the Process Development Payments at anytime if it determines, in its reasonable judgement that BTC has not consistently met the Process Development Milestones. For purposes of clarification, in no event will the Process Development Payments exceed $**[**]** in the aggregate.

7.3 Payments for Exercised Indications.

(a) Upon Exercise of Option. Within ten (10) Business Days of the inclusion on Exercised Indications in the Field, Auxilium shall make the following one-time license fee payments to BTC on a per Indication basis:

Amount	Indication
$1,000,000	Cellulite reduction
$ 500,000	Frozen Shoulder
$ 500,000	Each Additional Indication

(b) Upon Approval. Within ten (10) Business days of receipt by Auxilium of the first Regulatory Approval from the FDA for an Exercised Indication, Auxilium shall make the following milestone payments to BTC on a per Indication basis:

Amount	Labeling Approved for the following Indication
$[**]	[**]
$[**]	[**]
$[**]	[**]
$[**]	[**]
$[**]	Each Additional Indication

7.4 Payments Related to Sublicense Income. Within thirty (30) Business Days of receiving Sublicense Income, Auxilium shall make a payment to BTC in the following amount:

7.4.1 If Auxilium has not conducted a Clinical Trial for Product in the relevant Indication prior to the effective date of the relevant sublicense, then Auxilium will remit **[**]**% of the Sublicense Income actually received.

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7.4.2 If Auxilium has conducted Clinical Trials for a Product in the relevant Indication prior to the date of the relevant sublicense, then Auxilium will remit **[**]**% of Sublicense Income actually received.

7.4.3 Auxilium has obtained Regulatory Approval for a Product in the relevant Indication prior to the date of the relevant sublicense, then Auxilium will remit **[**]**% of Sublicense Income actually received.

7.4.4 If the field of use of the sublicense to the Product is non-human use, then Auxilium will remit **[**]**% of the Sublicense Income actually received for that field of use.

7.5 Currency. All payments shall be payable in United States Dollars.

7.6 Books and Records. Auxilium agrees to maintain and retain, in accordance with generally accepted accounting practices, complete and accurate records showing all transactions and information relating to this Agreement for a period of three (3) years from the date of entry to which they pertain.

7.7 Audit Rights. Upon the written request of BTC and not more than once in each calendar year, Auxilium shall permit an independent certified public accounting firm (other than on a contingency fee basis) selected by BTC and acceptable to Auxilium (which acceptance by Auxilium shall not be unreasonably withheld) to have access during normal business hours to such records of Auxilium as may be reasonably necessary to verify Auxilium's compliance with the payment terms of this Article 7. The accounting firm shall enter into an acceptable and customary confidentiality agreement with Auxilium obligating the accounting firm to retain in confidence all information of Auxilium which it obtains in performing such audits hereunder, and such audit shall be subject to Auxilium's third Party confidentiality obligations. Any audit under this Section 7.7 shall be at the expense of BTC, unless a particular audit reveals an underpayment of five percent (5%) or more of the amount that should have been paid to BTC for the period audited, in which case, Auxilium shall bear the expense of such audit.

7.8 Taxes. Auxilium shall be entitled to deduct from its payments to BTC the amount of any withholding taxes required to be withheld by Auxilium or its Affiliates or sublicensees to the extent BTC or sublicensees pay to the appropriate governmental authority on behalf of BTC such taxes. Auxilium shall deliver to BTC, upon BTC's request, proof of payment of all such taxes. Each Party shall provide assistance to the other Party in seeking any benefits available to such Party with respect to government tax withholdings by any relevant law or double tax treaty.

7.9 Interest. Any payments payable by either party which are not paid on or before the date such payments are due under this Agreement (other than such payments which are the subject of a good faith dispute between the Parties) shall bear interest at the prime rate of interest plus 1%, calculated on the number of days that payment is delinquent.

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7.10 Blocked Payments. In the event that, by reason of Laws or regulations in any country, it becomes impossible or illegal for Auxilium or an Affiliate or sublicensee of Auxilium, to transfer, or have transferred on its behalf, distribution fees or other payments to BTC, Auxilium shall promptly notify BTC of the conditions preventing such transfer and such distribution fees or other payments shall be deposited in local currency in the relevant country to the credit of BTC in a recognized banking institution designated by BTC or, if none is designated by BTC within a period of thirty (30) days, in a recognized banking institution selected by Auxilium or its Affiliate or sublicensee, as the case may be, and identified in a notice given to BTC.

ARTICLE 8
INTELLECTUAL PROPERTY

8.1 BTC Patentable Inventions and Know-How.

(a) BTC Patent Prosecution.

(i) During the term of the Agreement, BTC shall, diligently and in the reasonable exercise of its commercial discretion, prepare, file, prosecute, maintain, renew and defend BTC Patents in the countries where such BTC Patents are filed as of the Effective Date; provided, however, that BTC shall select patent counsel with Auxilium's consent, such consent not to be unreasonably withheld.

(ii) If BTC does not intend to file for patent protection or does not wish to continue preparation, prosecution, or maintenance of a BTC Patent, then it shall give at least thirty (30) days advance notice, and in no event less than a reasonable period of time for Auxilium to act in its stead.

(A) In such case, Auxilium may elect at its sole discretion to continue preparation, filing and prosecution or maintenance of the discontinued BTC Patent at its sole expense.

(B) Ownership of any such discontinued BTC Patent shall at the request of Auxilium be assigned to Auxilium and BTC shall execute such documents and perform such acts as may be reasonably necessary for assigning such ownership to Auxilium.

(C) Discontinuance may be elected on a country-by-country basis or for a patent application or patent series in total.

(b) Cooperation. BTC will consult Auxilium and will keep Auxilium continuously informed of all matters relating to the filing, prosecution and maintenance of BTC Patents including, but not limited to, disclosing to Auxilium the complete text of all such BTC Patents.

(i) BTC shall provide Auxilium with a copy of any BTC Patents relating to Enzyme or Product withing thirty (30) days of the Effective Date. Prior to filing the first of any new Patents in any jurisdiction, BTC shall provide Auxilium with a copy of any such Patent applications and copies of all material correspondence with the relevant patent office pertaining to the BTC Patents and directly relating to Enzyme or Product.

(ii) BTC shall consider all of Auxilium's comments in good faith and take all steps reasonably necessary to optimize the patent position for the Product.

(iii) In no event shall BTC relinquish control of the prosecution of BTC Patents to a Third Party.

8.2 Infringement Claims by Third Parties.

(a) Notice. If the manufacture, use or sale of the Product under the BTC Patents results in a claim or a threatened claim by a Third Party against a Party hereto for patent infringement or for inducing or contributing to patent infringement ("Infringement Claim"), the Party first having notice of an Infringement Claim shall promptly notify the other in writing. The notice shall set forth the facts of the Infringement Claim in reasonable detail.

(b) Third Party Licenses. In the event that practicing under the BTC Patents in connection with manufacture, use or sale of the Product in a country would infringe a Third Party Patent and a license to such Third Party Patent is available and Auxilium in its sole discretion seeks such a license, the Parties agree:

(i) Auxilium will be responsible for all costs associated with acquiring any Third Party license to the extent required for Auxilium to continue to make, use and sell the Product and the Enzyme, provided however, Auxilium may offset such costs against the Royalty, with a minimum floor of **[**]**% in accordance with Section 6.4 or, prior to commercial launch, offset such costs against any milestones due to BTC pursuant to Article 7; and

(ii) Auxilium will use Commercially Reasonable Efforts to obtain any such required licenses under the Third Party's Patents with a right to sublicense to BTC and if requested by BTC will grant such sublicense, under reasonable sublicense terms mutually acceptable to both BTC and Auxilium.

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(c) Litigation. In the event of the institution of any suit by a Third Party against Auxilium as a result of Auxilium's Development or Commercialization of the Product or the Enzyme, Auxilium shall have the right but, not the obligation, to defend such suit at its expense; BTC shall cooperate and assist Auxilium in any such litigation at Auxilium' expense. In the event of the institution of any suit by a Third Party against BTC as a result of BTC's Manufacture of the Product or the Enzyme, BTC shall have the right but, not the obligation, to defend such suit at its expense. Auxilium shall cooperate and assist BTC in any such litigation at BTC's expense. For purposes of clarity, notwithstanding anything to the contrary in Article 12, to the extent applicable, Auxilium will be entitled to seek indemnification from BTC for Losses arising in connection with such suit.

8.3 Infringement Claims Against Third Parties.

(a) Cooperation. BTC and Auxilium each agree to take reasonable actions to protect BTC Patents from infringement. If one Party brings any such action or proceeding, the second Party may be joined as a Party plaintiff if necessary for the action or proceeding to proceed and, in case of joining, the second Party agrees to give the first Party reasonable assistance and authority to file and to prosecute such suit.

(b) Notice. If any BTC Patents are infringed by a Third Party, the Party to this Agreement first having knowledge of such infringement, or knowledge of a reasonable probability of such infringement, shall promptly notify the other in writing. The notice shall set forth the facts of such infringement in reasonable detail.

(c) Institution of Proceedings. BTC, shall have the primary right, but not the obligation, to institute, prosecute, and control with its own counsel at its own expense any action or proceeding with respect to infringement of the claims of such BTC Patents and Auxilium shall have the right, but not the obligation at its own expense, to be represented in such action by its own counsel.

(d) Failure to Institute Proceedings. If BTC fails to institute, prosecute, and control such action or prosecution and fails to do so within a period of one hundred twenty (120) days after receiving notice of the infringement, Auxilium shall have the right to bring and control any such action by counsel of its own choice, and BTC shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(e) Division of Damages Award. Any recovery made in connection with such infringement claim shall be divided as follows:

(i) the Party that initiated and prosecuted such action shall recoup all of its costs and expenses (including reasonable attorney's fees) incurred in connection with such action, whether the recovery is by settlement or otherwise;

(ii) the other Party then shall, to the extent possible, recover its costs and expenses (including reasonable attorney's fees) incurred in connection with such action;

(iii) if BTC initiated and prosecuted the action, the amount of any recovery remaining shall be retained by BTC; and

(iv) if Auxilium initiated and prosecuted the action, the amount of any recovery remaining shall be retained by Auxilium, except that BTC shall receive a portion equivalent to the amount it would have received in accordance with the terms of Section 6.4 as if such amount were Net Sales of Auxilium.

(f) Settlement. The Parties shall keep each other informed of the status of and of their respective activities regarding any litigation or settlement thereof concerning Product; provided, however, that no settlement or consent judgment or other voluntary final disposition of a suit under this Section may be undertaken without the consent of the other Party if such settlement would require the other Party to be subject to an injunction or to make a monetary payment or would otherwise adversely affect the other Party's rights under this Agreement or the validity of BTC Patents.

8.4 Notice of Certification. BTC and Auxilium each shall immediately give notice to the other of any certification filed under the "U.S. Drug Price Competition and Patent Term Restoration Act of 1984" (or its foreign equivalent) claiming that a BTC Patent is invalid or that infringement will not arise from the manufacture, use or sale of any Product by a Third Party.

(a) If BTC decides not to bring infringement proceedings against the entity making such a certification, BTC shall give notice to Auxilium of its decision not to bring suit within twenty one (21) days after receipt of notice of such certification.

(b) Auxilium may then, but is not required to, bring suit against the Party that filed the certification; provided, however, that the costs incurred by Auxilium in connection with such suit shall be creditable against milestone payments payable by Auxilium in accordance with Article 7.

(c) Any suit by Auxilium or BTC shall either be in the name of Auxilium or in the name of BTC, or jointly in the name of Auxilium and BTC, as may be required by law.

(d) For this purpose, the Party not bringing suit shall execute such legal papers necessary for the prosecution of such suit as may be reasonably requested by the Party bringing suit.

8.5 Patent Term Extensions. The Parties shall cooperate in good faith with each other in gaining patent term extension wherever applicable to BTC Patents covering Enzyme or Product.

(a) Auxilium and BTC shall jointly determine which BTC Patents shall be extended.

(b) All filings for such extension shall be made by the Party responsible for prosecution and maintenance of the BTC Patent, provided, however, that in the event that the Party who is responsible for prosecution and maintenance of the BTC Patent elects not to file for an extension, such Party shall (i) inform the other Party of its intention not to file and (ii) grant the other Party the right to file for such extension.

8.6 Trademarks.

(a) Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.

(b) Auxilium shall be solely responsible for selecting a trademark (the "Auxilium Trademark") to use for each country in the Territory. The Product shall be promoted and sold, in accordance with the provisions of this Agreement, in the Territory under the Auxilium Trademark. Auxilium (or its local Affiliates, as appropriate) shall own and retain all rights to Auxilium Trademark, and all goodwill associated therewith throughout the Territory. Auxilium shall also own rights to any internet domain names incorporating the Auxilium Trademark or any variation or part of Auxilium Trademark as its URL address or any part of such address.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1 BTC Represents and Warrants. BTC hereby represents and warrants to Auxilium that:

(a) This Agreement has been duly executed and delivered by BTC and constitutes the valid and binding obligation of BTC, enforceable against BTC in accordance with its terms except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of BTC, its officers and directors;

(b) As of the Effective Date BTC owns or possesses adequate licenses or other rights necessary to make, use and sell all technology covered by the BTC Patents, and to grant the licenses herein and the granting of the licenses to Auxilium hereunder does not violate any right known to BTC of any Third Party;

(c) BTC represents that to the best of its knowledge, as of the Effective Date it is not aware that the development, manufacture, use or sale of the Enzyme or the Product pursuant to this Agreement may infringe or conflict with any Third Party right or Patent, and BTC is not aware of any pending patent application that, if issued, would be infringed by the development, manufacture, use or sale of the Enzyme or the Product pursuant to this Agreement;

(d) The execution, delivery and performance of this Agreement by BTC does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, and, to the best of its knowledge, does not violate any material law or regulation of any court, governmental body or administrative or other agency having authority over it;

(e) BTC has disclosed to Auxilium all material information in its control pertaining to the suitability of Enzyme as a pharmaceutical candidate;

(f) The Product has valid and effective Orphan Drug Designation under the applicable FDA statutes, rules or regulations, effective, May 23, 1996, and March 12, 1996 BTC has no reason to believe such Orphan Drug Designation shall be terminated prior to the Effective Date.

(g) BTC is not currently a Party to, and during the Term will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

(h) BTC is duly organized and validly existing under the laws of the state of Delaware and has full legal power and authority to enter into this Agreement; and

(i) BTC is not subject to any order, decree or injunction by a court of competent jurisdiction which prevents or materially delays the consummation of the transactions contemplated by this Agreement.

9.2 Auxilium Represents and Warrants. Auxilium hereby represents and warrants to BTC that:

(a) The execution, delivery and performance of this Agreement by Auxilium does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, and, to the best of its knowledge,

does not violate any material law or regulation of any court, governmental body or administrative or other agency having authority over it;

(b) Auxilium is not currently a Party to, and during the Term will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;

(c) Auxilium is duly organized and validly existing under the laws of the state of Delaware and has full legal power and authority to enter into this Agreement; and

(d) Auxilium is not subject to any order, decree or injunction by a court of competent jurisdiction which prevents or materially delays the consummation of the transactions contemplated by this Agreement.

9.3 Disclaimer of Warranties. THE LIMITED WARRANTIES CONTAINED IN THIS ARTICLE ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. During the Term, and for a period of five (5) years thereafter, each Party hereto will maintain in confidence all information disclosed, and reasonably believed by the other party to be confidential whether orally or in writing, by the other Party hereto ("Confidential Information"). Neither Party shall use, disclose or grant use of such Confidential Information except as required under this Agreement. Each Party shall use at least the same standard of care as it uses to protect its own Confidential Information to ensure that its and its Affiliates' employees, agents, consultants, and clinical investigators only make use of Confidential Information for the purpose of this Agreement and do not disclose or make any unauthorized use of such Confidential Information. Each Party shall promptly notify the other upon discovery of any unauthorized use or disclosure of Confidential Information. Confidential Information shall not include any information which and to the extent:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the other Party;

(c) becomes generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the other Party not to disclose such information; or

(e) was independently developed by the receiving Party without reference to the disclosure by the other Party, as documented by written records.

10.2 Terms of Agreement. The Parties agree that the material financial terms of the Agreement shall be considered the Confidential Information of both Parties.

10.3 Permitted Disclosure. Each Party may disclose the Confidential Information to the extent such disclosure is reasonably necessary in filing or prosecuting patent applications, prosecuting or defending litigation, or complying with any applicable statute or governmental regulation provided such Party has given the disclosing Party prompt written notice allowing it to limit such disclosure. In addition, either Party may disclose Confidential Information to its Affiliates and to its Sublicensees; provided, however, in connection with any such disclosure the disclosing Party shall secure confidential treatment of such Confidential Information.

10.4 Employee Obligations. The Parties shall undertake to ensure that all their employees who have access to Confidential Information of the other Party are under obligations of confidentiality fully consistent with those provided in this Article.

10.5 Publication. No Party may publish confidential or proprietary information of the other Party, without the consent of the other Party. The reviewing Party shall have thirty (30) days from receipt of the proposed oral disclosure or written publication to provide comments or proposed changes to the disclosing Party. The review period may be extended for an additional two (2) months to permit the reviewing Party to file one or more patent applications as it deems appropriate. This Section 10.5 shall be inapplicable to the publication of information presented in substantially the same form in which was previously published or disclosed to the public, and to any other disclosures which, on the advice of counsel, are required by law to be disclosed.

10.6 Prior Agreements. The obligations of Confidentiality and Nondisclosure set forth in this Section 10 supersede any and all prior and contemporaneous communications, representations, agreements or understandings, whether oral or written concerning the subject matter of this Section 10.

ARTICLE 11
TERM AND TERMINATION

11.1 Term.

(a) Term. Unless earlier terminated as provided herein, the Term shall commence as of the Effective Date and shall remain in full force and effect on a Product by Product and country by country basis until the later of (i) the last to expire valid claim of a patent covering such Product, (ii) the expiration of the regulatory exclusivity period conveyed by Orphan Drug Designation with respect to such Product, and (iii) twelve (12) years (the "Term").

(b) Accrued Obligations. Except where explicitly provided elsewhere herein, termination of this Agreement for any reason, or expiration of this Agreement, will not affect: (i) obligations, including the payment of any royalties or other sums which have accrued as of the date of termination or expiration, and (ii) rights and obligations which, from the context thereof, are intended to survive termination or expiration of this Agreement.

11.2 Termination for Insolvency. Either Party may terminate this Agreement immediately upon delivery of written notice to the other Party (a) upon the institution by or against the other Party of insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of the other Party's debts; provided, however with respect to involuntary proceedings, that such proceedings are not dismissed within one hundred and twenty (120) days; (b) upon the other Party's making an assignment for the benefit of creditors; or (c) upon the other Party's dissolution or ceasing to do business.

11.3 Material Breach. Either Party may terminate this Agreement upon ninety (90) days prior written notice to the other Party upon the material breach by the other Party of any of its obligations under this Agreement; provided, however, that such termination shall become effective only if the other Party shall fail to remedy or cure the breach within such ninety (90) day period.

11.4 Termination by Auxilium. Auxilium may terminate this Agreement in its entirety or on a country-by-country basis or on an Indication by Indication basis or on a Product by Product basis at any time upon ninety (90) days prior written notice to BTC.

11.5 Effect Of Termination.

(a) Effect On License. Upon the expiration or earlier termination of this Agreement, the rights licensed under this Agreement shall be treated as follows:

(i) Upon the expiration of the Term or the termination of this Agreement by Auxilium pursuant to Section 11.2 or Section 11.3, Auxilium shall have a fully paid-up, perpetual, irrevocable, royalty-free, transferable, worldwide, non-exclusive right and license under the Licensed Technology existing as of the date of such expiration to make, have made, use, offer to sell, and sell the Product in the Territory.

(ii) Upon termination of this Agreement by BTC pursuant to Section 11.2 or 11.3, or by Auxilium pursuant to Section 11.4 all rights to Product shall revert to BTC.

(b) Ongoing Obligations.

(i) Upon expiration or termination of this Agreement for any reason, each Party shall no later than thirty (30) days after such termination return to the other Party or destroy any Confidential Information disclosed by the other Party, except for one copy which may be retained in its confidential files.

(ii) Upon termination of this Agreement by BTC pursuant to Sections 11.2 or 11.3 or by Auxilium pursuant to Section 11.4, Auxilium shall assign and deliver to BTC all Regulatory Data and information (including registration dossiers) obtained for or in pursuing Regulatory Approvals, and all Regulatory Approvals (e.g., to BTC; designee in the Territory as permitted under the Law) for Product in the Territory received as of such termination date.

11.6 Inventory. Notwithstanding the foregoing, upon early termination of this Agreement pursuant to Section 11.2, 11.3 or 11.4, Auxilium shall have the right to sell all remaining Product in its inventory within six (6) months after the date of termination, but shall be bound to the royalty payments provided by Article 7.4 herein. Thereafter, Auxilium agrees to destroy any remaining supply of Product or return it to BTC at BTC's request and direction.

ARTICLE 12
INDEMNIFICATION

12.1 Auxilium. Auxilium shall defend BTC at Auxilium' cost and expense, and will indemnify and hold BTC and their respective directors, officers, employees, consultants, contractors, representatives, and agents harmless from and against any and all losses, costs, damages, fees, or expenses (including reasonable attorney's fees and expenses) ("Losses") incurred in connection with

or arising out of any Third Party claim (a "Third Party Claim") directly relating to (i) any material breach by Auxilium of its representations or warranties or obligations pursuant to this Agreement, (ii) any gross negligence or willful misconduct of Auxilium, its Affiliates, or their respective directors, officers, employees, contractors, consultants, agents, representatives, or sublicensees in the exercise of any of Auxilium' rights or the performance of any of Auxilium' obligations under this Agreement, and (iii) the handling, packaging, storage, or Commercialization by Auxilium or any of its Affiliates or sublicensees of any Product in the Territory (excluding all intellectual property infringement or related claims, which are covered in Section 12.2); provided that notwithstanding the foregoing, in all cases referred to in this Section 12.1, Auxilium shall have no liability to BTC for any Losses to the extent that such Losses were caused by any item for which BTC is required to indemnify Auxilium pursuant to Section 12.2.

12.2 BTC. BTC shall defend Auxilium and its Affiliates at BTC's cost and expense, and will indemnify and hold Auxilium and its Affiliates and their respective directors, officers, employees, consultants, contractors, representatives, and agents harmless from and against any and all Losses incurred in connection with or arising out of any Third Party Claim directly relating to (i) material breach by BTC of any of its representations, warranties or obligations pursuant to this Agreement, (ii) gross negligence or willful misconduct of BTC in the exercise of any of its rights or the performance of any of its obligations under this Agreement, (iii) personal injury and other product liability resulting from BTC's Development, Manufacture, or Commercialization of any Product, (iv) intellectual property infringement or related claims, including any Third Party Claim and trade secret misappropriation liability relating to the Development, Manufacture, or Commercialization of any Product, (v) any liability or other claims from the Manufacture, handling, packaging, storage, sale, or other disposition of any Product by BTC or any of its Affiliates or sublicensees, and (vi) any liability or claims arising from Product supplied by or on behalf of BTC to Auxilium that was not Manufactured in accordance with current Good Manufacturing Practices, Good Clinical Practice and Good Laboratory Practices, the specifications or all Laws and regulations except for such Losses that are indemnified pursuant to the Supply Agreement; provided that notwithstanding the foregoing, in all cases referred to in this Section 12.2, BTC shall have no liability to Auxilium for any Losses to the extent (and only to the extent) that such Losses were caused by any item for which Auxilium is required to indemnify BTC pursuant to Section 12.1.

12.3 Claims Procedures. Each Party entitled to be indemnified by the other Party (an "Indemnified Party") pursuant to Section 12.1 or 12.2 hereof shall give notice to the other Party (an "Indemnifying Party") promptly after such Indemnified Party has actual knowledge of any threatened or asserted claim as to which indemnity may be sought, and shall permit the Indemnifying Party to assume the defense of any such claim or any litigation resulting therefrom; provided:

(a) That counsel for the Indemnifying Party, who shall conduct the defense of such claim or any litigation resulting therefrom, shall be approved by the Indemnified Party (whose approval shall not unreasonably be withheld) and the Indemnified Party may participate in such defense at such Party's expense (unless (i) the employment of counsel by such Indemnified Party has been authorized by the Indemnifying Party; or (ii) the Indemnified Party shall have reasonably concluded that there may be a conflict of interest between the Indemnifying Party and the Indemnified Party in the defense of such action, in each of which cases the Indemnifying Party shall pay the reasonable fees and expenses of one law firm serving as counsel for the Indemnified Party, which law firm shall be subject to approval, not to be unreasonably withheld, by the Indemnifying Party).

(b) The failure of any Indemnified Party to give notice as provided herein shall not relieve the Indemnifying Party of its obligations under this Agreement to the extent that the failure to give notice did not result in harm to the Indemnifying Party.

(c) No Indemnifying Party, in the defense of any such claim or litigation, shall, except with the approval of each Indemnified Party which approval shall not be unreasonably withheld, consent to entry of any judgment or enter into any settlement which (i) would result in injunctive or other relief being imposed against the Indemnified Party; or (ii) does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party of a release from all liability in respect to such claim or litigation.

(d) Each Indemnified Party shall furnish such information regarding itself or the claim in question as an Indemnifying Party may reasonably request in writing and shall be reasonably required in connection with the defense of such claim and litigation resulting therefrom.

12.4 Escrow. In the event of any Third Party Claim against Auxilium for which BTC is obligated to indemnify Auxilium in accordance with Section 12.2, Auxilium shall be entitled, until a final un-appealable decision has been rendered or a settlement has been reached (a "Final Decision"), to pay an amount equal to fifty percent (50%) of all amounts due to BTC on Net Sales of Products (such aggregate amount, the "Escrowed Amount") into an escrow account maintained by a Third Party reasonably acceptable to BTC. To the extent that Auxilium incurs any Losses in connection with such Third Party Claim, an amount equal to the amount of any such Losses shall be distributed to Auxilium out of such escrow account, with the remainder (if any) to be paid to BTC. In the event that the Escrow Amount is less than the amount of such Losses, BTC shall pay the difference to Auxilium within thirty (30) days of such Final Decision.

12.5 Insurance. During the Term, each of Auxilium and BTC shall maintain general liability and product liability insurance in the following amounts: (i) at all times prior to approval of a NDA for a Product, $3,000,000 per occurrence, and (ii) at all times after approval of a NDA for a Product, $5,000,000.

12.6 Compliance. The Parties shall comply fully with all Laws and regulations in connection with their respective activities under this Agreement.

ARTICLE 13
MISCELLANEOUS PROVISIONS

13.1 Dispute Resolution. In the event of any controversy or claim arising out of relating to or in connection with any provision of this Agreement, or the rights or obligations hereunder, the Parties shall try to settle their differences amicably between themselves. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and within ten (10) business days after such notice appropriate representatives of the Parties shall meet for attempted resolutions by good faith negotiations. If such representatives are unable to resolve such disputed matters, it shall be referred to the Chief Executive Officers of BTC and Auxilium, for discussion and resolution. If they are unable to resolve the dispute within thirty (30) days of initiating such negotiations, the Parties agree first to submit the dispute to non-binding mediation before resorting to litigation or other mutually agreed dispute resolution mechanism. The dispute resolution procedures set forth herein shall not limit a court from granting a temporary restraining order or a preliminary injunction in order to preserve the status quo of the Parties pending arbitration or to protect a Party's trademark or confidential or proprietary information.

13.2 Construction. Unless the context of this Agreement clearly requires otherwise, (a) references to the plural include the singular, the singular the plural, the part the whole, (b) references to any gender include all genders, (c) "or" has the inclusive meaning frequently identified with the phrase "and/or," (d) "including" has the inclusive meaning frequently identified with the phrase "including but not limited to" or "including", and (e) references to "hereunder" or "herein" relate to this Agreement. The section and other headings contained in this Agreement are for reference purposes only and shall not control or affect the construction of this Agreement or the interpretation thereof in any respect. Section, subsection, and Schedule references are to this Agreement unless otherwise specified. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP.

13.3 Governing Law; Jurisdiction. This Agreement shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding the provisions governing conflict of laws under such New York law to the contrary, except matters of intellectual property law which shall be determined in accordance with the intellectual property laws relevant to the intellectual property in question.

13.4 Post-Closing Access to Information. BTC shall afford to representatives of Auxilium reasonable access to offices, plants, properties, books and records of BTC relating to the Product, during normal business hours, in order that Auxilium may have an opportunity to make such reasonable investigations as it desires with respect to Product. At all times after the Effective Date, each Party will permit the other Party and its representatives (including its counsel and auditors) during normal business hours, for a proper purpose to have reasonable access to and examine and make copies of, at the expense of the copying Party, all books, records, files and documents in its possession which relate to the Product.

13.5 Section 365(n) of the Bankruptcy Code. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under section 365(n) of the Bankruptcy Code.

13.6 Waiver. The failure on the part of Auxilium or BTC to exercise or enforce any rights conferred upon it hereunder shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter. The observance of any Term may be waived (either generally or in a particular instance and either retroactively or prospectively) by the Party entitled to enforce such term, but any such waiver shall be effective only if in writing signed by the Party against whom such waiver is to be asserted.

13.7 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any Term, other than an obligation to make a payment, when such failure or delay is caused by or results from fire, floods, embargoes, government regulations, prohibitions or interventions, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts, acts of God, or any other cause beyond the reasonable control of the affected Party.

13.8 Severability. It is the intention of the Parties to comply with all Laws domestic or foreign in connection with the performance of its obligations hereunder. In the event that any provision of this Agreement, or any part hereof, is found invalid or unenforceable, the remainder of this Agreement will be binding on the Parties hereto, and will be construed as if the invalid or unenforceable provision or part thereof had been deleted, and the Agreement shall be deemed modified to the extent necessary to render the surviving provisions enforceable to the fullest extent permitted by law.

13.9 Government Acts. In the event that any act, regulation, directive, or law of a government, including its departments, agencies or courts, should make impossible or prohibit, restrain, modify or limit any material act or obligation of Auxilium or BTC under this Agreement, the Party, if any, not so affected shall have the right, at its option, to suspend or terminate this Agreement as

to such country, if good faith negotiations between the Parties to make such modifications to this Agreement as may be necessary to fairly address the impact thereof, after a reasonable period of time are not successful in producing mutually acceptable modifications to this Agreement.

13.10 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement, without the consent of the other Party, in connection with the transfer or sale of all or substantially all of its assets or business or in the event of its merger or consolidation with another company. In all cases the assigning Party shall provide the other Party with prompt notice of any such assignment. Any purported assignment in contravention of this Section shall, at the option of the nonassigning Party, be null and void and of no effect. No assignment shall release either Party from responsibility for the performance of any accrued obligation of such Party hereunder.

13.11 Counterparts. This Agreement may be executed in duplicate, both of which shall be deemed to be originals, and both of which shall constitute one and the same Agreement.

13.12 No Agency. Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership or similar relationship between BTC and Auxilium. Notwithstanding any of the provisions of this Agreement, neither Party shall at any time enter into, incur, or hold itself out to third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever, and all contracts, expenses and liabilities undertaken or incurred by one Party in connection with or relating to the development, manufacture or sale of Enzymes or Product shall be undertaken, incurred or paid exclusively by that Party, and not as an agent or representative of the other Party.

13.13 Notice. All communications between the Parties with respect to any of the provisions of this Agreement will be sent to the addresses set out below, or to other addresses as designated by one Party to the other by notice pursuant hereto, by internationally recognized courier or by prepaid certified, air mail (which shall be deemed received by the other Party on the seventh business day following deposit in the mails), or by facsimile transmission or other electronic means of communication (which shall be deemed received when transmitted), with confirmation by letter given by the close of business on or before the next following business day:

If to BTC, at:
Biospecifics Technologies Corp.
35 Wilbur Street
Lynbrook, New York 11563
Attn: _____

with a copy to:

Brown Raysman Millstein Felder & Steiner LLP
163 Madison Avenue
P.O. Box 1989
Morristown, New Jersey 07962-1989
Attn.: Leslie Gladstone Restaino, Esq.

If to Auxilium at:
Auxilium Pharmaceuticals Inc.
160 West Germantown Pike
Norristown, PA 19401
Attn: _____

with a copy to:

Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103
Attn: Manya S. Deehr, Esq.

13.14 Headings. The paragraph headings are for convenience only and will not be deemed to affect in any way the language of the provisions to which they refer.

13.15 Assurances. Neither Party will take any action, or fail to act in a manner, which would prejudice the rights intended to be granted to the other Party pursuant to this Agreement.

13.16 Entire Agreement. This Agreement contains the entire understanding of the Parties relating to the matters referred to herein, and may only be amended by a written document, duly executed on behalf of the respective Parties.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

AUXILIUM PHARMACEUTICALS, INC.

By: /s/ Gerri Henwood
Name: Gerri Henwood
Title: CEO

BIOSPECIFICS TECHNOLOGIES CORP.

By: /s/ Edwin H. Wegman
Name: Edwin H. Wegman
Title: Pres.

Schedule 1.7 BTC Patents

BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES
PATENT APPLICATIONS AND EXISTING PATENTS

1. U.S. Patent 5,393,792, patented February 28, 1995, inventors Dr. Harold Stern and Dr. David Yee, title: High Dosage Topical Forms of Collagenase

2. U.S. Patent 5,422,103, patented June 6, 1995, inventors Dr. Harold Stern and Dr. David Yee, title: High Dosage Topical Forms of Collagenase

3. U.S. Patent 5,514,370, patented May 7, 1995, inventors Dr. Harold Stern and Dr. David Yee, title: High Dosage Forms of Collagenase (Method of Treatment with...).

Note: Foreign patent applications corresponding to the above U.S. applications have been filed in **[**]** foreign countries (Australia, Canada, 9 countries of the European patent convention, (Austria, France, Germany, Ireland, Italy, Netherlands, Spain, Switzerland, United Kingdom, Hungary, **[**]**, Russia). Patents have issued in all countries except **[**]**, where the application is pending.

4. U.S. application inventors **[**]**. US Patent Application # 10/172601 pending.

5. U.S. Patent 6.086.872, patented July 11, 2000, inventor Thomas L. Wegman, Amelioration of Dupuytren's Disease.

Note: Foreign patents corresponding to the above patent have been granted in 4 countries. France (2,772,273 granted 4/25/03), Australia (733,208 granted 8/23/01), UK (98050503 granted 10/10/01) and Sweden (9800806-3 granted 3/2/04). Patents have been filed in **[**]**.

6. U.S. Patent 6.022,539, patented February 8, 2000, inventor Thomas L. Wegman, Amelioration of Peyronie's Disease.

Note: Foreign patent application corresponding to the above application have been filed in **[**]** countries. **[**]**, France, **[**]**. Corresponding patent French Patent 0006863 has issued.

7. U.S. Patent 5,173,295, patented December 22, 1992, inventor Peter Wehling, title: Method of Enhancing the Regeneration of Injured Nerves and Adhesive Pharmaceutical Formulation Therefor.

8. U.S. Patent 5,279,825, patented January 18, 1994, inventor Peter Wehling, title: Method of Enhancing the Regeneration of Injured Nerves and Adhesive Pharmaceutical Formulation Therefor.

Note: Foreign patent application corresponding to the above two cases filed in **[**]**.

9. European Patent Office Patent EPO721781B1 June 2002 – inventors Edwin H. Wegman, Burton Bronsther, and Erwin T. Jacob, title: Reduction of Adipose Tissue Using Collagenase. This patent is being extended into [**] additional countries.

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

Patents licensed to Advance Biofactures Corp.

10. US Patent 5,851,522, patented December 22, 1998 inventor Dr. I. M Herman titled "Enhancing Keratinocyte Migration. EPO, (9 countries), Canada

11. US Patent 5,718,897, patented on February 17, 1998. Inventor Dr. Ira Herman, Title: Enhancing Keratinocyte Migration and Proliferation.

Note: Foreign patent application corresponding to the above case has been filed in **[**]**.

Updated: May 24, 2004

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

Schedule 1.16
Cost of Goods

The cost of Enzyme or a Product manufactured by BTC shall mean the fully allocated cost of manufacturing, which shall include:

1. Materials cost, which means the price paid for raw material components and finished goods which are purchased from outside vendors as well as any freight and duty where applicable.

2. Direct labor costs, which means the employment costs including, salary and employee benefits within the relevant manufacturing operating unit.

3. Direct and factory overheads, which means the cost of specific activities that are provided by support functions. Overhead costs includes expenses associated with quality assurance testing, batch review, equipment maintenance costs, manufacturing energy and utilities, waste removal, storage, transportation, insurance, management and administrative expenses, general facilities costs, environmental engineering, interest expense and property taxes.

Cost of Goods shall be calculated in accordance with U.S. Generally Accepted Accounting Principles. BTC's Cost of Goods for Enzyme or Product shall in no event exceed **[**]**% of the cost of Enzyme or Product as supplied, or as could be supplied, by a Third Party, as measured at the request of Auxilium and no more frequently than once per calendar year.

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

Schedule 1.21
Enzyme

Schedule 1.2.1 Enzyme

The enzyme is **[**]**.

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

Schedule 3.2
Clinical Trials

Schedule 3.2 Clinical Trials

Dupuytren's Disease

[**]

Peyronie's Disease

[**]

** **CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED PURSUANT TO AN ORDER GRANTING CONFIDENTIAL TREATMENT ISSUED BY THE SECURITIES AND EXCHANGE COMMISSION.**

Exhibit 10.46

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is entered into this 29th day of January, 2008 by and between Auxilium Pharmaceuticals, Inc. (the "Company") and Dr. Anthony DelConte ("Executive").

WHEREAS, the Company desires to employ Executive, and Executive desires to be employed by the Company upon the terms and conditions hereinafter set forth;

NOW, THEREFORE, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Employment. The Company hereby agrees to employ Executive, and Executive hereby accepts such employment and agrees to perform Executive's duties and responsibilities, in accordance with the terms, conditions and provisions hereinafter set forth. This Agreement shall be effective as of January 31, 2008 (the "Effective Date") and shall continue until terminated in accordance with Section 2 hereof. Nothing in this Agreement shall be construed as giving Executive any right to be retained in the employ of the Company, and Executive specifically acknowledges that Executive shall be an employee-at-will of the Company, and thus subject to discharge at any time by the Company with or without cause and without compensation of any nature except as provided in Section 2 below.

1.1 Duties and Responsibilities. Commencing on the Effective Date, Executive shall serve as the Chief Medical Officer of the Company and shall perform all duties and accept all responsibilities incident to such position as may be reasonably assigned to Executive by the Company's Board of Directors (the "Board") or by the Chief Executive Officer of the Company and which are typically performed by a Chief Medical Officer.

1.2 Extent of Service. Executive agrees to use Executive's best efforts to carry out Executive's duties and responsibilities under Section 1.1 hereof and, consistent with the other provisions of this Agreement, to devote substantially all of Executive's business time, attention and energy thereto. The foregoing shall not be construed as preventing Executive from making investments in other businesses or enterprises, provided that Executive agrees not to become engaged in any other business activity which, in the reasonable judgment of the Board, is likely to interfere with Executive's ability to discharge Executive's duties and responsibilities to the Company.

1.3 Base Salary. For all the services rendered by Executive hereunder, the Company shall pay Executive a base salary ("Base Salary") at the annual rate of $300,000, payable bi-weekly in installments at such times as the Company customarily pays its other senior level executives. Executive's Base Salary shall be reviewed annually for appropriate increases by the Board or compensation committee pursuant to the normal performance review policies for senior level executives.

1.4 Restricted Stock and Stock Options. Executive shall be granted, upon approval of the Board of Directors of the Company, a non-qualified option to purchase 90,000 shares (the "Option Grant") of the Company's common stock at an exercise price per share equal to the last reported sale price of a share of the Company's common stock on the Nasdaq National market on the Effective Date of this Agreement. Vesting of the Option Grant will be over four years with twenty-five percent (25%) of the grant amount vesting in each of the four years and will begin on the Effective Date. The Option Grant will be subject to the terms of the Company's 2004 Equity Compensation Plan.

1.5 Incentive Compensation. The Executive shall participate in all short-term and long-term incentive programs established by the Company for its senior level executives generally, at levels determined by the Board or the Chief Executive Officer. Executive's incentive compensation shall be subject to the terms of the applicable plans and shall be determined based on Executive's individual performance and Company performance as determined by the Board or the Chief Executive Officer. Executive's bonus eligibility for 2008 shall be 35% of his base salary, subject to achievement of goals to be mutually agreed upon by Executive and the Chief Executive Officer.

1.6 Retirement and Welfare Plans. Executive shall participate in all employee retirement and welfare benefit plans made available to the Company's senior level executives as a group or to its employees generally, as such retirement and welfare plans may be in effect from time to time and subject to the eligibility requirements of the plans. Nothing in this Agreement shall prevent the Company from amending or terminating any retirement, welfare or other employee benefit plans or programs from time to time as the Company deems appropriate.

1.7 Reimbursement of Expenses; Vacation. Executive shall be provided with reimbursement of reasonable expenses related to Executive's employment by the Company on a basis no less favorable than that which may be authorized from time to time for senior level executives as a group, and shall be entitled to four (4) weeks of vacation and three (3) personal days in accordance with the Company's pay for time not worked policies.

2. Termination. Executive's employment shall terminate upon the occurrence of any of the following events:

2.1 Termination Without Cause Before A Change of Control.

(a) The Company may remove Executive at any time without Cause (as defined in Section 2.9) from the position in which Executive is employed hereunder upon not less than 30 days' prior written notice to Executive.

(b) If Executive's employment terminates as described in subsection (a) above and Executive executes and does not revoke a written release upon such removal, in a form provided by the Company, of any and all claims against the Company and all related parties with respect to all matters arising out of Executive's employment by the Company, or the termination thereof (the "Release"), Executive shall be entitled to receive the following severance compensation, as long as Executive complies with the terms of Sections 4, 5, 6 and 7 below:

(i) Executive shall receive severance payments in an amount equal to 0.75 times Executive's annual Base Salary at the rate in effect at the time of Executive's termination. The severance amount shall be paid in equal monthly installments over the nine- month period following Executive's termination of employment (the "Severance Period"). Monthly payments shall commence within 30 days after the effective date of the termination (or the end of the revocation period for the Release, if later).

(ii) The Company shall pay the monthly COBRA medical insurance cost (less any required employee payments calculated as if Executive had continued to be an employee) if Executive continues medical coverage under COBRA, for Executive, and, where applicable, his spouse and dependents, during the 9-month period following Executive's termination date. The Executive may elect COBRA continuation coverage according to the terms of the Company's applicable medical plan for the period permitted under such plan.

(iii) Executive shall receive any benefits accrued in accordance with the terms of any applicable benefit plans and programs of the Company.

(iv) Executive agrees that if Executive fails to comply with Section 4, 5, 6 or 7 below, all payments under this Section 2.1 shall immediately cease.

2.2 Termination Without Cause; Resignation for Good Reason After A Change of Control.

(a) If a Change of Control occurs and the Company terminates Executive's employment without Cause at any time upon or after a Change of Control or Executive resigns for Good Reason (as defined in Section 2.9) upon or at any time during the two-year period following the Change of Control, this Section 2.2 shall apply.

(b) If Executive's employment terminates as described in subsection (a) above and Executive executes and does not revoke a Release, Executive shall be entitled to receive the following severance compensation, as long as Executive complies with the terms of Sections 4, 5, 6 and 7 below:

(i) Executive shall receive a lump sum severance payment in an amount equal to (A) 1.25 times Executive's annual Base Salary at the rate in effect at the time of Executive's termination, plus (B) 1.25 times Executive's average annual bonus paid by the Company to Executive for the two fiscal years preceding Executive's termination of employment. The payment shall be made within 30 days after the effective date of the termination of employment (or the end of the revocation period for the Release, if later).

(ii) The Company shall pay the monthly COBRA medical insurance cost (less any required employee payments calculated as if Executive had continued to be an employee) if Executive continues medical coverage under COBRA, for Executive, and, where applicable, his spouse and dependents, during the 15-month period following Executive's termination date. The Executive may elect COBRA continuation coverage according to the terms of the Company's applicable medical plan for the period permitted under such plan.

(iii) All outstanding stock options held by Executive at the date of Executive's termination of employment shall become fully exercisable on the date of termination and all stock awards held by Executive at the date of Executive's termination of employment shall become fully vested and exercisable as of the date of termination.

(iv) Executive shall receive any benefits accrued in accordance with the terms of any applicable benefit plans and programs of the Company.

(c) Executive agrees that if Executive materially breaches Section 4, 5, 6 or 7 below, all payments under this Section 2.2 shall immediately cease.

2.3 Increase in Payments Upon a Change of Control.

(a) Anything in this Agreement to the contrary notwithstanding, in the event that it shall be determined that any payment or distribution by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "Payment"), would constitute an "excess parachute payment" within the meaning of Section 280G of the Code, the Company shall pay to Executive an additional amount (the "Gross-Up Payment") such that the net amount retained by Executive after deduction of any excise tax imposed under Section 4999 of the Code, and any federal, state and local income tax, employment tax and excise tax imposed upon the Gross-Up Payment, shall be equal to the Payment. For purposes of determining the amount of the Gross-Up Payment, unless Executive specifies that other rates apply, Executive shall be deemed to pay federal income tax and employment taxes at the highest marginal rate of federal income and employment taxation in the calendar year in which the Gross-Up Payment is to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of Executive's residence on Executive's termination date, net of the maximum reduction in federal income taxes that may be obtained from the deduction of such state and local taxes.

(b) All determinations to be made under this Section 2.3 shall be made by the Company's independent public accountant immediately prior to the Change of Control or by another independent public accounting firm mutually selected by the Company and Executive before the date of the Change of Control (the "Accounting Firm"), which firm shall provide its determinations and any supporting calculations both to the Company and Executive within 20 days after Executive's termination date. Any such determination by the Accounting Firm shall be binding upon the Company and Executive. Within 10 days after the Accounting Firm's determination, the Company shall pay the Gross-Up Payment to Executive.

(c) The Company shall pay the Gross-Up Payment as and when the related excise tax under section 4999 of the Code ("Excise Tax") is incurred. The Gross-Up Payment shall be paid in accordance with Section 409A of the Code, to the extent applicable. If required in order to comply with Section 409A of the Code, (i) the Gross-Up Payment attributable to Payments other than severance compensation shall be paid in a lump sum payment upon the closing of the Change of Control, subject to Section 2.10 below, if applicable, and (ii) the Gross-Up Payment attributable to severance compensation shall be paid in a lump sum payment on the first day on which severance compensation is paid. If the amount of a Gross-Up Payment cannot be fully determined by the date on which the applicable portion of the Payment becomes subject to the Excise Tax ("Payment Date"), the Company shall pay to the Executive by the Payment Date an estimate of such Gross-Up Payment, as determined by the Accounting Firm, and the Company shall pay to the Executive the remainder of such Gross-Up Payment (if any) as soon as the amount can be determined, but in no event later than 20 days after the Payment Date.

(d) All of the fees and expenses of the Accounting Firm in performing the determinations referred to in this Section 2.3 shall be borne solely by the Company. The Company agrees to indemnify and hold harmless the Accounting Firm from any and all claims, damages and expenses resulting from or relating to its determinations pursuant to this Section 2.3, except for claims, damages or expenses resulting from the gross negligence or willful misconduct of the Accounting Firm.

2.4 Voluntary Termination. Executive may voluntarily terminate Executive's employment for any reason upon 30 days' prior written notice. In such event, after the effective date of such termination, except as provided in Section 2.2 with respect to a resignation for Good Reason, no further payments shall be due under this Agreement, except that Executive shall be entitled to any benefits accrued in accordance with the terms of any applicable benefit plans and programs of the Company.

2.5 Disability. The Company may terminate Executive's employment if Executive has been unable to perform the material duties of Executive's employment for a period of 90 days in any 12-month period because of physical or mental injury or illness ("Disability"); provided, however, that the Company shall continue to pay Executive's Base Salary until the Company acts to terminate Executive's employment. Executive agrees, in the event of a dispute under this Section 2.5 relating to Executive's Disability, to submit to a physical examination by a licensed physician jointly selected by the Board and Executive. If the Company terminates Executive's employment for Disability, no further payments shall be due under this Agreement, except that Executive shall be entitled to any benefits accrued in accordance with the terms of any applicable benefit plans and programs of the Company.

2.6 Death. If Executive dies while employed by the Company, the Company shall pay to Executive's executor, legal representative, administrator or designated beneficiary, as applicable, any benefits accrued under the Company's benefit plans and programs. Otherwise, the Company shall have no further liability or obligation under this Agreement to Executive's executors, legal representatives, administrators, heirs or assigns or any other person claiming under or through Executive.

2.7 Cause. The Company may terminate Executive's employment at any time for Cause (as defined in Section 2.9) upon written notice to Executive, in which event all payments under this Agreement shall cease. Executive shall be entitled to any benefits accrued before Executive's termination in accordance with the terms of any applicable benefit plans and programs of the Company.

2.8 Notice of Termination. Any termination of Executive's employment shall be communicated by a written notice of termination to the other party hereto given in accordance with Section 11. The notice of termination shall (i) indicate the specific termination provision in this Agreement relied upon, (ii) briefly summarize the facts and circumstances deemed to provide a basis for a termination of employment and the applicable provision hereof, and (iii) specify the termination date in accordance with the requirements of this Agreement.

2.9 Definitions.

(a) "Cause" shall mean any of the following grounds for termination of Executive's employment:

(i) Executive shall have been convicted of, or entered a plea of guilty to, a felony,

(ii) Executive intentionally and continually fails to perform Executive's reasonably assigned material duties to the Company (other than a failure resulting from Executive's incapacity due to physical or mental illness), which failure has continued for a period of at least 30 days after a written notice of demand for substantial performance, signed by a duly authorized officer of the Company, has been delivered to Executive specifying the manner in which Executive has failed substantially to perform,

(iii) Executive engages in willful misconduct in the performance of Executive's duties, or

(iv) Executive materially breaches Section 4, 5, 6 or 7 below.

(b) "Change of Control" as used herein, a "Change of Control" shall be deemed to have occurred if:

(i) Any "person" (as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing more than 50% of the voting power of the then outstanding securities of the Company; provided that a Change of Control shall not be deemed to occur as a result of a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the parent corporation would be entitled in the election of directors; or

(ii) The consummation of (A) a merger or consolidation of the Company with another corporation where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger or consolidation, shares entitling such stockholders to more than 50% of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors, (B) a sale or other disposition of all or substantially all of the assets of the Company, or (C) a liquidation or dissolution of the Company.

(iii) After the Effective Date, directors are elected such that a majority of the members of the Board shall have been members of the Board for less than two years, unless the election or nomination for election of each new director who was not a director at the beginning of such two-year period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of such period.

(c) "Good Reason" shall mean the occurrence of any of the following events or conditions, unless Executive has expressly consented in writing thereto, or except as a result of Executive's physical or mental incapacity or as described in the last sentence of this subsection (c):

(i) a reduction in Executive's Base Salary;

(ii) a substantial reduction of Executive's duties and responsibilities hereunder; or

(iii) the Company requires that Executive's principal office location be moved to a location more than 50 miles from Executive's principal office location immediately before the change.

Notwithstanding the foregoing, Executive shall not have Good Reason for termination unless Executive gives written notice of termination for Good Reason within 15 days after the event giving rise to Good Reason occurs and the Company does not correct the action or failure to act that constitutes the grounds for Good Reason, as set forth in Executive's notice of termination, within 30 days after the date on which Executive gives written notice of termination.

2.10 Required Postponement for Specified Executives.

(a) If Executive is considered a Specified Executive (as defined below) and payment of any amounts under this Agreement is required to be delayed for a period of six months after separation from service pursuant to Section 409A of the Code, payment of such amounts shall be delayed as required by section 409A, and the accumulated postponed amounts, with

accrued interest as described below, shall be paid in a lump sum payment within five days after the end of the six month period. If Executive dies during the postponement period prior to the payment of benefits, the amounts postponed on account of Section 409A, with accrued interest as described in subsection (b) below, shall be paid to the personal representative of Executive's estate within 60 days after the date of Executive's death.

(b) If payment of any amounts under this Agreement is required to be delayed pursuant to section 409A of the Code, the Company shall pay interest on the postponed payments from the date on which the amounts otherwise would have been paid to the date on which such amounts are paid at an annual rate equal to the rate announced by Deutsche Bank (or its successor) as its "prime rate" as of Executive's Termination Date.

(c) The term "Specified Executive" means an employee who, at any time during the 12-month period ending on the identification date (defined below), is (i) an officer of the Company or a member of its controlled group (as determined for purposes of section 416(i) of the Code) who has annual compensation greater than $135,000 (or such other amount as may be in effect under Section 416(i)(1) of the Code), (ii) a 5% owner of the Company or (iii) a 1% owner of the Company who has annual compensation greater than $150,000. The identification date shall be each December 31, and the determination of Specified Executives as of such identification date shall apply for the 12-month period following April 1 after the identification date. The determination of Specified Executives, including the number and identity of persons considered officers, shall be made by the Company in accordance with the provisions of Sections 416(i) and 409A of the Code and the regulations issued thereunder.

3. Non-Exclusivity of Rights. Nothing in this Agreement shall prevent or limit Executive's continuing or future participation in or rights under any benefit, bonus, incentive or other plan or program provided by the Company and for which Executive may qualify; provided, however, that if Executive becomes entitled to and receives the payments provided for in Section 2 of this Agreement, Executive hereby waives Executive's right to receive payments under any severance plan or similar program applicable to all employees of the Company.

4. Confidentiality. Executive agrees that Executive's services to the Company and its subsidiaries and any successors or assigns (collectively, the "Employer") were and are of a special, unique and extraordinary character, and that Executive's position places Executive in a position of confidence and trust with the Employer's customers and employees. Executive also recognizes that Executive's position with the Employer will give Executive substantial access to Confidential Information (as defined below), the disclosure of which to competitors of the Employer would cause the Employer to suffer substantial and irreparable damage. Executive recognizes, therefore, that it is in the Employer's legitimate business interest to restrict Executive's use of Confidential Information for any purposes other than the discharge of Executive's employment duties at the Employer, and to limit any potential appropriation of Confidential Information by Executive for the benefit of the Employer's competitors and to the detriment of the Employer. Accordingly, Executive agrees as follows:

(a) Executive will not at any time, whether during or after the termination of Executive's employment, reveal to any person or entity any of the trade secrets or confidential information of the Employer or of any third party which the Employer is under an obligation to keep confidential (including but not limited to trade secrets or confidential information respecting inventions, products, designs, methods, know-how, techniques, systems, processes, software programs, works of authorship, customer lists, projects, plans and proposals) ("Confidential Information"), except as may be required in the ordinary course of performing Executive's duties as an employee of the Employer, and Executive shall keep secret all matters entrusted to Executive and shall not use or attempt to use any such information in any manner which may injure or cause loss or may be calculated to injure or cause loss whether directly or indirectly to the Employer.

(b) The above restrictions shall not apply to: (i) information that at the time of disclosure is in the public domain through no fault of Executive; (ii) information received from a third party outside of the Employer that was disclosed without a breach of any confidentiality obligation; (iii) information approved for release by written authorization of the Employer; or (iv) information that may be required by law or an order of any court, agency or proceeding to be disclosed; provided Executive shall provide the Employer notice of any such required disclosure once Executive has knowledge of it and will help the Employer to the extent reasonable to obtain an appropriate protective order.

(c) Further, Executive agrees that during Executive's employment Executive shall not take, use or permit to be used any notes, memoranda, reports, lists, records, drawings, sketches, specifications, software programs, data, documentation or other materials of any nature relating to any matter within the scope of the business of the Employer or concerning any of its dealings or affairs otherwise than for the benefit of the Employer. Executive further agrees that Executive shall not, after the termination of Executive's employment, use or permit to be used any such notes, memoranda, reports, lists, records, drawings, sketches, specifications, software programs, data, documentation or other materials, it being agreed that all of the foregoing shall be and remain the sole and exclusive property of the Employer and that, immediately upon the termination of Executive's employment, Executive shall deliver all of the foregoing, and all copies thereof, to the Employer, at its main office.

(d) Executive agrees that upon the termination of Executive's employment with the Employer, Executive will not take or retain without written authorization any documents, files or other property of the Employer, and Executive will return promptly to the Employer any such documents, files or property in Executive's possession or custody, including any copies thereof maintained in any medium or format. Executive recognizes that all documents, files and property which Executive has received and will receive from the Employer, including but not limited to scientific research, customer lists, handbooks, memoranda, product specifications, and other materials (with the exception of documents relating to benefits to which Executive might be entitled following the termination of Executive's employment with the Employer), are for the exclusive use of the Employer and employees who are discharging their responsibilities on behalf of the Employer, and that Executive has no claim or right to the continued use, possession or custody of such documents, files or property following the termination of Executive's employment with the Employer.

5. Intellectual Property.

(a) If at any time or times during Executive's employment Executive shall (either alone or with others) make, conceive, discover or reduce to practice any invention, modification, discovery, design, development, improvement, process, software program, work of authorship, documentation, formula, data, technique, know-how, secret or intellectual property right whatsoever or any interest therein (whether or not patentable or registrable under copyright or similar statutes or subject to analogous protection) (herein called "Developments") that (i) relates to the business of the Employer or any customer of or supplier to the Employer or any of the products or services being developed, manufactured or sold by the Employer or which may be used in relation therewith, (ii) results from tasks assigned to Executive by the Employer or (iii) results from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Employer, such Developments and the benefits thereof shall immediately become the sole and absolute property of the Employer and its assigns, and Executive shall promptly disclose to the Employer (or any persons designated by it) each such Development, and Executive hereby assigns any rights Executive may have or acquire in the Developments and benefits and/or rights resulting therefrom to the Employer and its assigns without further compensation and shall communicate, without cost or delay, and without publishing the same, all available information relating thereto (with all necessary plans and models) to the Employer.

(b) Upon disclosure of each Development to the Employer, Executive will, during Executive's employment and at any time thereafter, at the request and cost of the Employer, sign, execute, make and do all such deeds, documents, acts and things as the Employer and its duly authorized agents may reasonably require:

(i) to apply for, obtain and vest in the name of the Employer alone (unless the Employer otherwise directs) letters patent, copyrights or other analogous protection in any country throughout the world and when so obtained or vested to renew and restore the same; and

(ii) to defend any opposition proceedings in respect of such applications and any opposition proceedings or petitions or applications for revocation of such letters patent, copyright or other analogous protection.

(c) In the event the Employer is unable, after reasonable effort, to secure Executive's signature on any letters patent, copyright or other analogous protection relating to a Development, whether because of Executive's physical or mental incapacity or for any other reason whatsoever, Executive hereby irrevocably designates and appoints the Employer and its duly authorized officers and agents as Executive's agent and attorney-in-fact, to act for and on Executive's behalf and stead to execute and file any such application or applications and to do all other lawfully permitted acts to further the prosecution and issuance of letter patents, copyright and other analogous protection thereon with the same legal force and effect as if executed by Executive.

6. Non-Competition. While Executive is employed at the Employer and for a period of one year after termination of Executive's employment (for any reason whatsoever, whether voluntary or involuntarily), Executive will not, without the prior written approval of the Board, whether alone or as a partner, officer, director, consultant, agent, employee or stockholder of any company or other commercial enterprise, directly or indirectly engage in any business or other activity in the United States or Canada which competes with the Employer in the sale of the pharmaceutical or other products being manufactured, marketed, distributed or developed by the Employer while Executive is employed by Employer and at the time of termination of such employment. The foregoing prohibition shall not prevent Executive's employment or engagement after termination of Executive's employment by any company or business organization, as long as the activities of any such employment or engagement, in any capacity, do not involve work on matters related to the products being developed, manufactured, or marketed by the Employer at the time of termination of Executive's employment. Executive shall be permitted to own securities of a public company not in excess of five percent of any class of such securities and to own stock, partnership interests or other securities of any entity not in excess of five percent of any class of such securities and such ownership shall not be considered to be in competition with the Employer.

7. Non-Solicitation.

(a) While Executive is employed at the Employer and for a period of one (1) year after termination of such employment (for any reason, whether voluntary or involuntarily), Executive agrees that Executive will not:

(i) directly or indirectly solicit, entice or induce any customer to become a customer of any other person, firm or corporation with respect to products then sold or under development by the Employer or to cease doing business with the Employer, and Executive shall not approach any such person, firm or corporation for such purpose or authorize or knowingly approve the taking of such actions by any other person; or

(ii) directly or indirectly solicit or recruit any employee of the Employer to work for a third party other than the Employer (excluding newspaper or similar print or electronic solicitations of general circulation).

(b) This Section 7 does not apply to any general solicitation not focused to any group of customers itemized on a customer list of the Employer.

8. General Provisions.

(a) Executive acknowledges and agrees that the type and periods of restrictions imposed in Sections 4, 5, 6 and 7 of this Agreement are fair and reasonable, and that such restrictions are intended solely to protect the legitimate interests of the Employer, rather than to prevent Executive from earning a livelihood. Executive recognizes that the Employer competes worldwide, and that Executive's access to Confidential Information makes it necessary for the Employer to restrict Executive's post-employment activities in any market in which the Employer competes, and in which Executive's access to Confidential Information and other proprietary information could be used to the detriment of the Employer. In the event that any restriction set forth in this Agreement is determined to be overbroad with respect to scope, time or geographical coverage, Executive agrees that such a restriction or restrictions should be modified and narrowed, either by a court or by the Employer, so as to preserve and protect the legitimate interests of the Employer as described in this Agreement, and without negating or impairing any other restrictions or agreements set forth herein.

(b) Executive acknowledges and agrees that if Executive should breach any of the covenants, restrictions and agreements contained herein, irreparable loss and injury would result to the Employer, and that damages arising out of such a breach may be difficult to ascertain. Executive therefore agrees that, in addition to all other remedies provided at law or at equity, the Employer shall be entitled to have the covenants, restrictions and agreements contained in Sections 4, 5, 6, and 7 specifically enforced (including, without limitation, by temporary, preliminary, and permanent injunctions and restraining orders) by any state or federal court in the Commonwealth of Pennsylvania having equity jurisdiction and Executive agrees to subject Executive to the jurisdiction of such court.

(c) Executive agrees that if the Employer fails to take action to remedy any breach by Executive of this Agreement or any portion of the Agreement, such inaction by the Employer shall not operate or be construed as a waiver of any subsequent breach by Executive of the same or any other provision, agreement or covenant.

(d) Executive acknowledges and agrees that the payments and benefits to be provided to Executive under this Agreement are provided as consideration for the covenants in Sections 4, 5, 6, and 7 hereof.

9. Survivorship. The respective rights and obligations of the parties under this Agreement shall survive any termination of Executive's employment to the extent necessary to the intended preservation of such rights and obligations.

10. Mitigation. Executive shall not be required to mitigate the amount of any payment or benefit provided for in this Agreement by seeking other employment or otherwise and there shall be no offset against amounts due Executive under this Agreement on account of any remuneration attributable to any subsequent employment that Executive may obtain.

11. Notices. All notices and other communications required or permitted under this Agreement or necessary or convenient in connection herewith shall be in writing and shall be deemed to have been given when hand delivered or mailed by registered or certified mail, as follows (provided that notice of change of address shall be deemed given only when received):

If to the Company, to:

Auxilium Pharmaceuticals, Inc.
40 Valley Stream Parkway
Malvern, PA 19355

If to Executive, to:

Anthony DelConte, MD
18 Bayberry Drive
Broomall, PA 19008

or to such other names or addresses as the Company or Executive, as the case may be, shall designate by notice to each other person entitled to receive notices in the manner specified in this Section.

12. Contents of Agreement; Amendment and Assignment.

(a) This Agreement sets forth the entire understanding between the parties hereto with respect to the subject matter hereof and supercedes any and all prior agreements and understandings concerning Executive's employment by the Company, including that certain offer letter between the Company and Executive, dated as of December 11, 2007, and cannot be changed, modified, extended or terminated except upon written amendment approved by the Board and executed on its behalf by a duly authorized officer and by Executive.

(b) All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and assigns of the parties hereto, except that the duties and responsibilities of Executive under this Agreement are of a personal nature and shall not be assignable or delegatable in whole or in part by Executive. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) to all or substantially all of the business or assets of the Company, within 15 days of such succession, expressly to assume and agree to perform this Agreement in the same manner and to the same extent as the Company would be required to perform if no such succession had taken place.

13. Severability. If any provision of this Agreement or application thereof to anyone or under any circumstances is adjudicated to be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect any other provision or application of this Agreement which can be given effect without the invalid or unenforceable provision or application and shall not invalidate or render unenforceable such provision or application in any other jurisdiction. If any provision is held void, invalid or unenforceable with respect to particular circumstances, it shall nevertheless remain in full force and effect in all other circumstances.

14. Remedies Cumulative; No Waiver. No remedy conferred upon a party by this Agreement is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to any other remedy given under this Agreement or now or hereafter existing at law or in equity. No delay or omission by a party in exercising any right, remedy or power under this Agreement or existing at law or in equity shall be construed as a waiver thereof, and any such right, remedy or power may be exercised by such party from time to time and as often as may be deemed expedient or necessary by such party in its sole discretion.

15. Withholding. All payments under this Agreement shall be made subject to applicable tax withholding, and the Company shall withhold from any payments under this Agreement all federal, state and local taxes as the Company is required to withhold pursuant to any law or governmental rule or regulation. Except as otherwise provided by Section 2.3, Executive shall bear all expense of, and be solely responsible for, all federal, state and local taxes due with respect to any payment received under this Agreement.

16. Miscellaneous. This Agreement may be executed in counterparts, each of which is an original. It shall not be necessary in making proof of this Agreement or any counterpart hereof to produce or account for any of the other counterparts.

17. Governing Law. This Agreement shall be governed by and interpreted under the laws of the Commonwealth of Pennsylvania without giving effect to any conflict of laws provisions or canons of construction that construe agreements against the draftsperson.

18. Section 409A of the Code. This Agreement is intended to comply with Section 409A of the Code and its corresponding regulations, to the extent applicable. Notwithstanding anything in this Agreement to the contrary, payments may only be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable.

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have executed this Agreement as of the date first above written.

AUXILIUM PHARMACEUTICALS, INC.

By: /s/ Armando Anido

Name: Armando Anido
Title: Chief Executive Officer and President

EXECUTIVE

/s/ Anthony DelConte

ANTHONY DELCONTE, MD

Exhibit 21

SUBSIDIARIES OF AUXILIUM PHARMACEUTICALS, INC.

Subsidiary	Jurisdiction of Incorporation
Auxilium International Holdings, Inc.	Delaware
Auxilium UK Ltd.	United Kingdom
Auxilium US Holdings, LLC	Delaware

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-127489, No. 333-133477, No. 333-135344 and No. 333-145710) and in the Registration Statement on Form S-8 (No. 333-117595, No. 333-135347 and No. 333-144452) of Auxilium Pharmaceuticals, Inc. of our report dated March 10, 2008, relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Philadelphia, PA
March 10, 2008

Exhibit 31.1

CERTIFICATION

I, Armando Anido, certify that:

1. I have reviewed this annual report on Form 10-K of Auxilium Pharmaceuticals, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2008

/s/ Armando Anido

Armando Anido
Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION

I, James E. Fickenscher, certify that:

1. I have reviewed this annual report on Form 10-K of Auxilium Pharmaceuticals, Inc.;

2 Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

   (d) Disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2008

/s/ James E. Fickenscher

James E. Fickenscher
Chief Financial Officer

Exhibit 32

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the U.S. Code (18 U.S.C. § 1350), Armando Anido, the Chief Executive Officer and President of Auxilium Pharmaceuticals, Inc. (the "registrant"), and James E. Fickenscher, the Chief Financial Officer of the registrant, each hereby certifies that, to his knowledge:

1. The registrant's Annual Report on Form 10-K for the year ended December 31, 2007, to which this Certification is attached as Exhibit 32 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the registrant at the end of the period covered by the Periodic Report and results of operations of the registrant for the period covered by the Periodic Report.

These certifications accompany the Periodic Report to which they relate, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Periodic Report), irrespective of any general incorporation language contained in such filing.

Date: March 10, 2008

/s/ Armando Anido	/s/ James E. Fickenscher
Armando Anido Chief Executive Officer and President	James E. Fickenscher Chief Financial Officer

corporate information

BOARD OF DIRECTORS

Rolf Classon
Chairman of the Board, Auxilium
Chairman of the Board of Hillenbrand Industries Inc.,
Former Chairman of the Executive Committee of Bayer Health-Care AG

Al Altomari
Chief Executive Officer,
Barrier Therapeutics, Inc.

Armando Anido
Chief Executive Officer and President, Auxilium Pharmaceuticals, Inc.

Edwin A. Bescherer, Jr.
Retired Chief Financial Officer,
Dun & Bradstreet Corporation

Philippe O. Chambon, M.D., Ph.D.
Managing Director of New Leaf Venture Partners, LLC

Oliver Fetzer, Ph.D.
Former Senior Vice President,
Corporate Development,
and Research and Development,
Cubist Pharmaceuticals, Inc.

Renato Fuchs, Ph.D.
Retired Senior Vice President,
Manufacturing and Technical Operations,
Altus Pharmaceuticals, Inc.

Dennis H. Langer, M.D., J.D.
Managing Partner,
Phoenix IP Ventures, LLC

Dennis J. Purcell
Senior Managing Partner,
Aisling Capital LLC

CORPORATE OFFICERS

Armando Anido
Chief Executive Officer and President

James E. Fickenscher
Chief Financial Officer

Dr. Anthony DelConte
Chief Medical Officer

Roger D. Graham, Jr.
Executive Vice President,
Sales and Marketing

Dr. Jyrki Mattila
Executive Vice President,
Business Development,
Product Development and
Technical Operations

Jennifer Evans Stacey, Esq.
Executive Vice President,
General Counsel, Human Resources,
and Secretary

HEADQUARTERS

40 Valley Stream Parkway
Malvern, PA 19355
Phone: 484-321-5900
Fax: 484-321-5999

MANUFACTURING

102 Witmer Road
Horsham, PA 19044

EXCHANGE

NASDAQ Global Market—AUXL

INVESTOR CONTACT

William Q. Sargent, Jr.
Vice President, Investor Relations and Corporate Communications
484-321-5900
ir@auxilium.com

TRANSFER AGENT

StockTrans, Inc.
44 West Lancaster Avenue
Ardmore, PA 19003
610-649-7300

CORPORATE COUNSEL

Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, PA 19103

INDEPENDENT ACCOUNTANTS

PricewaterhouseCoopers LLP
Two Commerce Square, Suite 1700
2001 Market Street
Philadelphia, PA 19103

WEBSITE:

www.auxilium.com

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS
All statements other than historical facts are forward-looking and actual results may differ materially from those projected, anticipated or implied. Please refer to "Risk Factors" on page 21 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007 for a description of the substantial risks and uncertainties related to the forward-looking statements included in this Annual Report. Past performance of Auxilium Common Stock is not predictive of future returns.

Executive Team

From left to right: Seated – Jim Fickenscher, Chief Financial Officer; Armando Anido, Chief Executive Officer and President. *Standing –* Roger Graham, Executive Vice President, Sales and Marketing; Dr. Jyrki Mattila, Executive Vice President, Business Development, Product Development and Technical Operations; Dr. Tony DelConte, Chief Medical Officer; Jennifer Evans Stacey, Esq., Executive Vice President, General Counsel, Human Resources, and Secretary.

AUXILIUM
Innovations for Life™

Designed by The Fillit Group www.filliitgroup.com

Auxilium Pharmaceuticals, Inc.
40 Valley Stream Parkway
Malvern, PA 19355
Phone: 484-321-5900
Fax: 484-321-5999