UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2009

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 000-51934

BIOMIMETIC THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**62-1786244**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

389 Nichol Mill Lane, Franklin, Tennessee 37067
(Address of principal executive offices, including ZIP code)

(615) 844-1280
(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, $0.001 par value per share	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: 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 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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation only, that the registrant's directors, executive officers and greater than 10% shareholders are affiliates of the registrant), based upon the closing sale price of the registrant's common stock on June 30, 2009, the last business day of the registrant's most recently completed second fiscal quarter, was $115.6 million.

As of March 8, 2010, a total of 21,901,946 shares of the registrant's common stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the registrant's 2010 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III. The registrant intends to file such Proxy Statement with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2009. Except as expressly incorporated by reference, the registrant's Proxy Statement shall not be deemed to be a part of this report on Form 10-K.

BioMimetic Therapeutics, Inc.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, including but not limited to the notes to the consolidated financial statements and the sections titled ‘‘Business,’’ ‘‘Risk Factors’’ and ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations,’’ contains ‘‘forward-looking statements’’ within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended (the ‘‘Securities Act’’), and Section 21E of the Securities Exchange Act of 1934, as amended (the ‘‘Exchange Act’’). Statements in this Annual Report that are not historical facts are hereby identified as ‘‘forward-looking statements’’ for the purpose of the safe harbor provided by Section 21E of the Exchange Act and Section 27A of the Securities Act. Forward-looking statements convey our current expectations and forecasts of future events. Forward-looking statements include statements regarding our future results of operations and financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations that are not historical facts. The words ‘‘may,’’ ‘‘continue,’’ ‘‘estimate,’’ ‘‘intend,’’ ‘‘plan,’’ ‘‘will,’’ ‘‘believe,’’ ‘‘project,’’ ‘‘expect,’’ ‘‘anticipate’’ and similar expressions may identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking.

These forward-looking statements include, among other things, statements about:

- success, advancement and timing of clinical trials and studies and eventual regulatory approval of our product candidates or other new product introductions;
- market acceptance of and demand for Augment in Canada and our product candidates;
- regulatory actions that could adversely affect the price of or demand for our approved products;
- our intellectual property portfolio and licensing strategy;
- our marketing and manufacturing capacity and strategy;
- estimates regarding our capital requirements, and anticipated timing of the need for additional funds;
- product liability claims;
- economic conditions that could adversely affect the level of demand for Augment in Canada or our product candidates;
- financial markets, including the market for various investment securities;
- the competitive environment; and
- the current economic downturn.

Any or all of our forward-looking statements may turn out to be inaccurate. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Forward-looking statements may be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including the risks, uncertainties and assumptions described in ‘‘Risk Factors.’’ In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances contained in this Annual Report may not occur as contemplated and actual results could differ materially from those anticipated or implied by the forward-looking statements.

You should read this Annual Report with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report by these cautionary statements.

You should not unduly rely on these forward-looking statements, which speak only as of the date of this Annual Report. Unless required by law, we undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the Securities and Exchange Commission after the date of this Annual Report.

PART I

Item 1. BUSINESS

Overview

BioMimetic Therapeutics, Inc. is a biotechnology company which develops and commercializes innovative products to help stimulate the body's natural tissue regenerative process. We believe our protein therapeutic-device combination products have the potential to significantly improve the treatment of musculoskeletal injuries and conditions affecting bones, tendons, ligaments and cartilage. Our platform regenerative technology, which incorporates a potent version of one of the body's natural key stimulators of tissue repair, may offer physicians advanced biological solutions to actively stimulate tissue healing and regeneration.

We have already demonstrated that this technology is safe and effective in stimulating bone regeneration with the U.S. and Canadian regulatory approvals of our first periodontal product, *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), and with the Canadian regulatory approval of our first orthopedic product, Augment™ Bone Graft (''Augment''). We continue to focus on further developing this technology to stimulate tissue healing in orthopedic applications (such as certain types of bone fractures or fusions of the bones in the foot and ankle to eliminate chronic pain from trauma or arthritis), and potentially sports injury and spine applications. Our current product candidates are designed to target a broad range of clinical indications in bone, ligament, tendon and cartilage repair.

Our product candidates have been the subject of numerous orthopedic clinical studies that have been completed or are on-going which seek to demonstrate the safety, clinical utility and/or efficacy of the product candidates in our pipeline, including our lead orthopedic product candidate Augment, a fully synthetic and off-the-shelf bone growth factor product for the treatment of bone defects and injuries. Augment is the subject of our North American pivotal (Phase III) randomized controlled trial, which compares Augment to autograft for use in hindfoot and ankle fusion surgery. This trial will be the primary data set used to support regulatory approval in the United States, the European Union (''EU'') and Australia. In addition, we have pre-clinical programs focused on the development of treatments for bone defects in the spine and various sports injury applications, including those requiring ligament, tendon and cartilage repair.

In the second quarter of 2009, we submitted to the U.S. Food and Drug Administration (''FDA'') both the pre-clinical pharmacology/toxicology and quality/manufacturing modules of a modular pre-market approval (''PMA'') application for the marketing of Augment in the United States. A modular submission breaks the PMA document into three sections or ''modules'' filed at different times that together become a complete application. The modular approach allows the applicant to potentially resolve any concerns noted by the FDA earlier in the review process than would occur with a traditional PMA application, and may ultimately shorten the review and approval timeline. In October 2009, we reported positive top-line results from our North American Augment pivotal trial. The primary study goal of this clinical study was to establish non-inferiority of Augment compared to autograft. Autograft is the current standard of care but is limited in that it must be obtained and transplanted from another bone in the patient's body, often requiring a second surgical procedure. The positive top-line results of the study indicate that, with the use of Augment, patients can expect a comparable treatment outcome while being spared the pain and potential morbidity associated with autograft bone harvesting and transplantation. In February 2010, we submitted to the FDA the third PMA module, which contains the 24-week data from the North American Augment pivotal trial, and completes our PMA seeking FDA approval of Augment in the United States.

In November 2009, we received approval from Health Canada of our Device License Application (''DLA'') in Canada for Augment. The product is approved for use as an alternative to autologous bone graft in the surgical treatment of foot and ankle fusions in Canada. Based upon this approval, we initiated the commercial marketing of Augment in Canada in the beginning of 2010 through our exclusive distribution partner, Joint Solutions Alliance Corporation (''Joint Solutions''). During the first quarter of 2010, our commercial activities in Canada have focused on the support of Joint Solutions' efforts to get Augment onto the list of approved products at the key hospitals throughout Canada. Every new product must be reviewed by individual hospital ''product evaluation committees,'' which act as the gatekeepers at the hospital purchasing level. These committees look at the potential impact of a new product on patient care and on the budget in the specific therapeutic category related to that product. This process can take several months. We are currently

working with Joint Solutions to progress Augment through the appropriate committees at the key accounts that we believe present the best opportunities for the product.

Our numerous clinical studies, including our Augment studies, suggest that our platform technology may be effective in our target applications. If successful, we expect these clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, the EU and Australia. If approved by the appropriate regulatory authorities, we believe that our product candidates may offer new, effective and less invasive treatment options in orthopedic, spine and sports related injuries to improve the quality of life for millions of patients suffering injuries or deterioration of bones, ligaments, tendons and cartilage.

In February 2010, we filed an application of Conformity Assessment with the Australian Therapeutic Goods Administration (''TGA'') for Augment. This application seeks approval to market Augment in Australia as an alternative to autograft in the treatment of foot and ankle fusions. The filing utilized the technical and clinical data that were provided to Health Canada in the recent DLA and to the FDA in the recent filing of the PMA for Augment in the United States. The TGA review is expected to take 12 to 18 months to complete, however, the timing of regulatory review can be uncertain and as a result we may be unable to obtain Australian approval of Augment in a timely manner, if at all. Looking forward to the successful completion of Augment marketing approval, the Company has established a relationship with an orthopedic distributor, Surgical Specialties Pty Ltd (''Surgical Specialties''), in Sydney, Australia. Surgical Specialties will be the exclusive distributor of Augment and Augment Injectable in Australia and New Zealand.

According to the National Bureau of Economic Research, the U.S. economy entered into a recession in December 2007. Although the U.S. Commerce Department has reported economic growth in the third and fourth quarters of 2009 and many economists now believe that the recession has ended, the continuing economic uncertainty and the ensuing market instability have continued to impact our general business strategy, which may be adversely affected if the current economic conditions do not continue to improve. For example, the economy may impact the demand for elective medical procedures that we are targeting with our product candidates, or may impact the pricing that we may set for our products, if approved. However, since our anticipated product launch in the United States for our lead product candidate may be a year or more away, the impact of the economy on commercial opportunities for that product remains uncertain.

We have responded to the current economic conditions by investing our cash and cash equivalents and our investments conservatively, and by employing cost control measures to conserve cash and manage expenses, such as scaling back growth in staff, eliminating unnecessary expenditures and postponing certain program activities where appropriate. In addition, to the extent possible given contractual commitments, in order to postpone major expenses we have postponed certain major equipment purchases and delivery and validation efforts for manufacturing equipment intended for our new manufacturing facility which we have leased in the same complex as our headquarters in Franklin, Tennessee. If the economy continues to improve and as we near regulatory approval of Augment in the United States, we anticipate that we will reassess certain of these measures and resume growth in staffing and certain program activities.

Product Candidates

Currently, there are limited biological therapies to stimulate the healing and regeneration of tissues, such as bone, cartilage, ligaments and tendons. As a result, many of these injuries may result in permanent impairment and chronic pain. As baby boomers age, the incidence of musculoskeletal injuries and ailments are expected to be far more prevalent. We believe that our technology is well positioned to address many of these issues. We also believe that the fundamental mode of action of our platform technology in promoting tissue regeneration suggests that it may be effective in a broad array of musculoskeletal applications. Consequently, our technology may prove to address unmet medical needs in bone fractures and fusions, spinal fractures and fusions, and sports injuries.

Our most advanced product candidates are targeted to be used in the open surgical treatment of fractures and fusions (using Augment) and the closed non-surgical or minimally invasive treatment of fractures (using Augment™ Injectable Bone Graft (''Augment Injectable'')). Our product candidates use recombinant human Platelet-Derived Growth Factor (''rhPDGF-BB''), which is one of the principal naturally occurring wound healing stimulators, to kick start the tissue regeneration process in the body. We believe that rhPDGF-BB is well suited for various applications due to its stimulation of a broad spectrum of cellular events critical for the

initiation and progression of tissue healing. rhPDGF-BB acts like a magnet to attract cells necessary for tissue healing through a process known as chemotaxis, while also stimulating an increased number of healing cells through a process known as mitogenesis, thereby expanding the population of cells involved in the repair process. Additionally, data suggests rhPDGF-BB enhances new blood vessel formation, in a process called ''angiogenesis,'' which is also critical for healing.

We believe the combination of the growth factor rhPDGF-BB and an appropriate synthetic matrix is key to the overall effectiveness of our product candidates. For example, the synthetic matrix used in Augment is beta-tricalcium phosphate (''ß-TCP''), which is a bone matrix. The growth factor rhPDGF-BB jump starts the healing process by providing the biological stimulus for tissue repair, while the ß-TCP synthetic bone matrix provides the framework or scaffold for tissue regeneration, or new bone growth, to occur. Moreover, these two components, which are also included in Augment Injectable, have been authorized by the FDA for use in other applications and are being marketed to treat other diseases and injuries. The ß-TCP is used in orthopedic applications as a resorbable bone void filler and rhPDGF is used for stimulating healing of chronic ulcers in the lower extremities of diabetic patients. In addition, the combination of rhPDGF-BB and ß-TCP is used in treating periodontal bone defects and gingival recession. By combining already marketed components to make a novel and proprietary product, we believe that we will be able to streamline the development process and accelerate the ultimate commercialization of our product candidates.

We believe that our product candidates are unique and novel, and that our product development strategy, which uses regenerative protein therapeutic-device combination products, has demonstrated success. Other companies have applied a similar strategy in the development of such combination products for the treatment of cardiovascular disease. Such ''convergent devices'' have revolutionized the way that cardiovascular disease is treated and have proven to be both a clinical and commercial success. We believe the orthopedic industry is in the early stages of a similar transformation from the use of traditional, passive, highly invasive metallic devices to more advanced, bio-active devices.

This strategy was proven to be effective in the development of our first periodontal product, *GEM 21S,* which was approved by the FDA in November 2005 for the treatment of periodontal bone defects and gum tissue recession associated with periodontal disease. This strategy was effective in that we were able to obtain product approval in less than five years. *GEM 21S* was approved for marketing in the United States and Canada based on data from a 180 patient randomized controlled pivotal clinical trial which demonstrated that it significantly and safely improved bone regeneration in the jaws. It is the first totally synthetic product combining a purified recombinant growth factor with a synthetic bone matrix to be approved by the FDA for human application. Our strategy was also proven to be effective in Canada for the development of our first orthopedic product candidate, Augment, which was approved by Health Canada in November 2009 for the treatment of foot and ankle fusions in Canada. Augment was approved for marketing in Canada based on data from a 60 patient study, together with data on *GEM 21S* and pilot data on Augment in the United States and Sweden.

Building on the successful approval of *GEM 21S*, and the approval of Augment in Canada, we are applying a similar strategy in the development of our pipeline of regenerative protein therapeutic-device combination product candidates for a broad range of orthopedic indications. We are optimistic that we are well positioned to capitalize on the orthopedic industry's transformation to more advanced bio-active devices as we are seeking FDA approval for marketing and commercialization of Augment in the United States.

We have established strong clinical contacts, manufacturing facilities and a regulatory pathway to product development. These resources, coupled with the well characterized biology and history of safe use of rhPDGF-BB and the clinically proven efficacy of our platform technology, all position us to become a leader in the development and commercialization of biologically-active devices that will capitalize on the growing market for these products in orthopedic, spine and sports injury applications. While the results of our studies have been positive to date, we may not be successful in developing, obtaining regulatory approval for, or commercializing our current pipeline of product candidates or we may not do so in a timely fashion.

The following clinical studies regarding our orthopedic product candidates have previously been completed or are currently ongoing:

Type	Product	Location	Clinical Indication	Status
Pilot	Augment	United States	Foot and Ankle Fusions	Completed
Pivotal	Augment	United States and Canada	Foot and Ankle Fusions	Enrollment Completed
Registration	Augment	Canada	Foot and Ankle Fusions	Completed
Registration	Augment	Europe	Foot and Ankle Fusions	Enrollment Completed
Pilot	Augment	Europe	Wrist Fractures	Completed
Pilot	Augment Injectable	Canada	Foot and Ankle Fusions	Completed
Pilot	Augment Injectable	Europe	Wrist Fractures	Completed
Pivotal	Augment Injectable	United States and Canada	Foot and Ankle Fusions	Initiated Canadian Enrollment

We believe that rhPDGF is well suited for use in multiple product candidates due to its stimulation of a broad spectrum of cellular events critical for the initiation and progression of orthopedic tissue repair and regeneration. The diversity and importance of the biological activities stimulated by rhPDGF were key elements in our selection of this growth factor as the primary biological ingredient in our initial product and product candidates. Although human studies to demonstrate rhPDGF's cellular stimulatory property in our product candidates have not been performed, published animal and *in vitro* studies report that many kinds of cells important to orthopedic tissue repair respond to rhPDGF, including bone forming cells, cartilage forming cells, bone and cartilage-lineage forming cells and tendon and ligament forming cells. The observation that rhPDGF is naturally contained in platelets and released specifically at injury sites during blood clotting to initiate events critical to healing has led to rhPDGF being termed nature's ''wound healing protein.'' The rhPDGF-BB used in our product candidates is a synthetic version of this naturally occurring substance produced using recombinant DNA techniques.

Based on the efficacy demonstrated in our Augment clinical studies, the *GEM 21S* pivotal clinical study, and the demonstrated ability of rhPDGF to stimulate tissue healing, we believe that our pipeline of orthopedic product candidates has the potential to positively impact patient care and to influence a new generation of orthopedic therapies. We believe our management expertise in the development of regenerative protein therapeutic-device combination products, combined with our intellectual property position, and the proven biology and safety of rhPDGF, all position us to become a leader in the development and commercialization of novel therapeutics for the treatment of orthopedic injuries.

BioMimetic Therapeutics Highlights

Large market opportunities

- Targeting orthopedic, spine and sports injury markets. We believe that orthobiologic opportunities represent a multi-billion dollar market driven by an aging population and demand for better therapies.
- Relatively few current therapies with potent bio-stimulatory activity are on the market.
- Relatively low market penetration may generate substantial revenues.

Proven rhPDGF technology	• FDA and Canadian approval of GEM 21S for periodontal bone regeneration and Canadian approval of Augment for treatment of foot and ankle fusions suggests potential for efficacy in other bone and musculoskeletal applications. • FDA approval of Regranex® (formerly a product of Johnson & Johnson, currently a product of Systagenix Wound Management, Inc.) for healing of diabetic ulcers suggests potential for broad wound healing applications of rhPDGF. • Clinical and pre-clinical data for Augment and Augment Injectable suggest potential for improved fracture healing and fusions.
Multiple applications	• rhPDGF represents a platform technology that may have multiple applications in musculoskeletal repair. • rhPDGF is a key stimulator of the body's natural wound healing process. It has a well-established mechanism of action that leads to stimulation of certain cell types, including those important to bone, cartilage, tendon and ligament healing. • Potential applications include fracture and fusion procedures in the axial (spine) and appendicular (long bone) skeleton as well as the extremities (hand and foot).
Familiar regulatory path	• FDA is regulating our regenerative protein therapeutic-device combination product candidates Augment and Augment Injectable as medical devices. • We believe data supporting GEM 21S FDA approval and Augment Canadian approval should provide support for the approval of future rhPDGF products. • Commercial manufacturing and production previously accomplished for GEM 21S. Good Manufacturing Practices compliance found acceptable and International Organization for Standardization (''ISO'') certification obtained. • Safety profile and bioactivity of rhPDGF clearly established.
Industry trend towards regenerative protein therapeutic-device combination products	• rhPDGF provides the bio-active drug component to stimulate healing and the device component (matrix) provides tissue specific guide for regeneration. • Strategy follows successful precedent in regenerative protein therapeutic-device combination products in cardiovascular (drug coated stents) and periodontal (*GEM 21S*) therapies. • Strategy addresses clinical preference for bio-active implants. • Market potential for orthobiologics already indicated by sales of INFUSE® Bone Graft (Medtronic, Inc.).

Market Trends

According to industry data, the worldwide orthopedic market was estimated at $25 billion in 2007. This includes joint replacement, fracture repair, sports injury and spinal procedures. Strong growth in the worldwide orthopedic market is expected, driven by aging baby boomers, the desire for active lifestyles well into retirement and the growth in the incidence of osteoporosis, osteoarthritis, obesity, diabetes and other diseases that cause injury to orthopedic tissues and/or impair the ability of the body to heal injuries.

In addition to its growth, the orthopedic markets are undergoing a transition. The orthopedic and sports injury markets have recently experienced increased demand for the adoption of biologically active treatments, which seek to stimulate the body's own capabilities for regeneration of tissue at injury sites. We believe the orthopedic and sports injury industry is in the early stages of a transition from the use of traditional, passive, highly invasive metallic devices to more advanced, bio-active devices. Evidence of this trend is the fact that osteobiologics, in particular bone grafting related products, is one of the fastest growing segments in the orthopedics market. According to 2008 market research reports, the global orthobiologics market was estimated to be worth $4.2 billion in 2007, and with a growth rate of 17%, it is projected to almost double by 2012.

The impressive market performance of the Medtronic, Inc. (''Medtronic'') product INFUSE® Bone Graft for treatment of certain spinal fusions and bone fractures demonstrates market receptivity and acceptance for protein osteobiologics. Industry data indicate that sales of INFUSE were approximately $840 million in 2009. Sales reported for INFUSE for Medtronic's fourth fiscal quarter of 2009 were flat as compared to the same period in 2008. We believe sales for INFUSE have slowed as a result of reported complications associated with off-label use of the product in cervical spinal fusions, as well as ongoing governmental investigations into possible promotion of off-label use of INFUSE by Medtronic.

The advancement of medical technology in the treatment of orthopedic injuries also is driving an increase in the number of procedures performed annually. Treatments that are minimally invasive and offer pain relief and a return to the activities of daily living have resulted in more people seeing their doctors to resolve long standing orthopedic problems.

Current Therapies for Bone Disorders and Injuries

Physicians treating orthopedic injuries must first determine whether conservative, non-surgical treatment or more aggressive surgical treatment is required. This choice is generally dictated by the seriousness of the injury, the degree of tissue disruption or loss and the patient's general health. For closed, non-surgical treatment, the primary therapies available that are designed to assist the natural healing process of the injured bone and adjacent soft tissue are electrical and ultrasonic bone stimulation. When surgical treatment is indicated, physicians will often use bone or soft tissue grafts in addition to fixation with internal and/or external mechanical devices that stabilize the injury site. Currently available therapies or procedures to stimulate the healing process in the presence of these devices include autograft, allograft or xenograft, synthetic bone or tissue graft products, platelet-rich plasma systems and bone morphogenic proteins.

Autograft, a graft using a patient's own tissues, is the leading procedure for replacing or supplementing lost bone matter. Using bone tissue may stimulate bone growth and provides a scaffold or matrix onto which new bone tissue can grow. However, to procure or harvest bone from another site of the patient to perform the autograph procedure, an additional surgical procedure is most often required, often from the hip. This additional surgical procedure may be more painful than the patient's primary surgical procedure to treat the injury and may lead to complications, including increased blood loss, and chronic pain or infection, which may result in an extended hospital stay. Also, there is a limited supply of available donor bone per patient. Furthermore, autograft may not be a suitable treatment for elderly patients or patients with osteoporosis, since the additional surgical procedure to harvest bone may further weaken already frail bones and the quality of the harvested bone may not be sufficient to enhance the bone healing process.

In order to eliminate the need for additional painful surgery, physicians also use allograft or xenograft. Allograft and xenograft use bone tissue harvested from a human cadaver or animal, respectively. These materials come in various forms, including chips, blocks and particulate, which allows physicians flexibility in using them to treat injured or defective bone. Allograft and xenograft bone is of varying quality depending on the donor, the process and techniques used to prepare the bone tissue and the facility at which it is processed. Using cadaver or animal bone may pose some risk of transmitting infectious diseases to the patient and although this risk is currently thought to be very low, it remains a concern among some patients. Finally, the bio-activity level of allograft bone can vary substantially and may be insufficient to assist the healing process.

Given the limitations associated with autografts, allografts and xenografts, synthetic bone grafts have become popular in recent years. Physicians use synthetic bone or tissue graft products, like calcium sulfate and tricalcium phosphate, as filler or scaffold material that can be packed into voids or gaps resulting from defects or fractures. Like allografts, synthetic bone grafts also are available in various forms. Synthetic bone grafts provide a physical mesh-work or scaffold that helps guide tissue repair, but do not contain bio-active molecules that stimulate the healing process. Lacking bio-active molecules, these materials can provide only a passive, physical matrix or template for tissue growth without providing any direct biological stimulus to accelerate healing.

Recent studies have demonstrated the benefits of using orthobiologicals to treat orthopedic injuries and defects. Clinicians have focused on therapies that are osteostimulatory, meaning that they lead to or induce bone regeneration. For example, platelet-rich plasma systems (''PRPs'') involve taking blood from a patient, concentrating the platelet cells from the blood and activating the cells to release growth factors, including PDGF. Because PRPs contain growth factors, they stimulate tissue regeneration. While PRPs do not involve the painful graft harvesting associated with autografts, the production process of the platelet/blood concentrate is time-consuming and requires specialized equipment. Furthermore, the results are unpredictable because the concentrations of growth factors present in the platelet preparations vary from patient to patient.

A recent advance in the therapy for spine and orthopedic repair is the use of bone morphogenetic proteins (''BMPs''). BMPs have the ability to stimulate new bone formation by causing the differentiation of stem cells into osteoblasts, which initiate bone formation. The use of BMPs does not involve the painful graft harvesting associated with autograft. BMPs have provided tremendous value to the spinal repair industry as they help speed recovery time and improve medical outcomes. Surgeons have proven to be fast adopters of these technologies, generating sales of BMPs estimated to exceed $900 million in 2009 according to analysts' reports. Despite these benefits, BMPs have a number of disadvantages, including their high cost (approximately $4,500 per spine fusion level), their limited approved indications for use and their potential for inappropriate bone formation. In particular, unwanted bone growth has been observed near nerves or in other areas outside the targeted sites. Theses adverse reactions have led to additional corrective surgeries. In addition, complications associated with swelling of neck and throat tissue have occurred with BMP products, which resulted in compression of the airway and/or neurological structures of the neck. In some cases these complications resulted in difficulty swallowing, breathing or speaking. Because the mechanism of action of PDGF is very different from that of BMP, we do not believe that these types of complications will occur with our product candidates, and none of these types of complications have been observed during any of our orthopedic clinical studies or with *GEM 21S*. There is only one BMP available in the United States which has been granted FDA pre-market approval for use, but in limited indications including spinal fusions, tibial fractures, sinus augmentations and localized jaw augmentations for defects associated with tooth extraction. A second BMP (OP-1, Stryker Corporation) has been allowed in the U.S. market by the FDA under a humanitarian device exemption. However, in March 2009, an FDA advisory panel voted six to one against recommending full market approval of OP-1. The panel cited numerous reasons for its decision, including Stryker Corporation's use of a post-hoc analysis of the data, which did not prove efficacy within the study design, and unanswered questions regarding the BMP protein's effect on the patient's immune system.

While some current therapies for bone defects, such as BMPs, have yielded favorable results in specific indications, most have exhibited only modest success. Many of the currently available therapies do not stimulate the healing process and therefore do not address the needs of patients with impaired or delayed healing such as smokers, people with osteoporosis or diabetes and the elderly. Because of these limitations, clinicians continue to seek more cost-effective and predictable regenerative therapies that are easy to use and lead to faster or more predictable tissue regeneration in a greater number of indications.

The following table summarizes some of the advantages and disadvantages of current therapies for bone disorders and injuries, including our product candidates discussed above in "— Product Candidates."

Therapy	Advantages	Disadvantages
Autograft	Provides scaffold. Stimulates bone growth. High chance of incorporation.	Additional surgery required. Pain at harvest site. Risk of infection. Longer recovery time. Limited supply per patient.
Allograft/Xenograft	Provides scaffold. Does not require painful graft harvesting. May stimulate bone growth. Available in various forms.	Inconsistent quality and sourcing leading to variable growth stimulation. Potential contamination / disease transmission. Potential for immune response.
Synthetics	Abundant supply. Provides scaffold. Does not require painful graft harvesting. Available in various forms.	Longer healing time versus autograft. Limited growth stimulation. Lacks bio-active proteins.
PRP systems	Stimulates bone growth. Concentrates natural bio-active proteins. Does not require painful graft harvesting.	Increased procedure time. Requires specialized equipment. Variable quality. Requires scaffold. Technique dependent.
BMPs	Stimulates bone growth. Bio-active osteoinductive proteins. Does not require painful graft harvesting.	Limited indications approved. High cost. Limited or no effect on soft tissue healing. Potential for inappropriate bone formation and other serious complications. Neutralizing antibodies seen, indicating a potential immune system response.
Augment and other BMTI product candidates	Stimulates bone growth. Bio-active osteo-stimulatory protein. Broad wound healing activity. Does not require painful graft harvesting. Provides scaffold. No inappropriate bone formation. No neutralizing antibodies seen, indicating no lasting immune system response.	Higher cost than currently available synthetics. Limited early data in orthopedic clinical trials. Limited initial indications for *GEM 21S*.

Current Therapies for Cartilage, Tendon and Ligament Injuries

Cartilage

Cartilage is the soft tissue in the joints of the body that acts as a shock absorber and lubricant during motion of the joint. The knee contains two types of cartilage: meniscus and articular cartilage. Unlike other tissues in the body, cartilage does not naturally repair itself. In 2003, over 3.4 million patients were diagnosed with injuries to the cartilage and meniscus in the knee. Many patients had experienced previous surgeries for the same or a related condition, demonstrating the need for more reliable and predictive treatments.

The standard of care for treating cartilage is generally considered to be microfracture, which is a procedure wherein the damaged cartilage is removed and bleeding is induced in the underlying bone in order to encourage cartilage repair. Transplants, both autologous (from the same patient) and allograft (from a cadaver) are also utilized, although at increased costs in terms of pain, morbidity and operating room time (in the case of autograft) and for the cost of the donated tissue (in the case of allograft). Newer techniques, such as autologous chondrocyte implantation (''ACI'') that attempt to repair small defects to cartilage have shown promise in small studies. ACI requires two surgeries over a period of eight weeks and requires the cultivation of the patient's own cartilage cells in a laboratory, resulting in a very high treatment cost. Procedures such as visco-supplementation, the injection of a hyaluronan (a molecule in the matrix of many connective tissues) based liquid into the knee joint, provide temporary pain relief but have limited ability to heal the tissue.

Tendon and Ligament

Tendons and ligaments are the soft tissue structures that connect ''muscle to bone'' and ''bone to bone,'' respectively. These structures may become injured either through chronic overuse (such as tendinosis), or a traumatic event (such as tendon rupture yielding a tendon-tendon injury such as an achilles tear or a tendon-bone injury such as a rotator cuff tear).

Chronic tendon injuries can often be treated conservatively, relying on the structures to scar down sufficiently to be stable. However, certain populations of patients may continue to suffer from chronic pain and/or loss of function. These patients may be treated with more aggressive surgical repair. Numerous first line therapies exist, although none are completely satisfactory for all patients. First line therapies for chronic tendon injuries include physical therapy, bracing, extracorporeal shockwave therapy and injection of corticosteroids. Platelet Rich Plasma (''PRP'') and blood concentrates have also been injected with variable documented success.

Acute tendon injuries, injuries resulting from a traumatic event, are generally ''wired'' together using orthopedic sutures. Collagen-based overlay materials have been occasionally utilized to enhance repairs of tendon to tendon injuries.

Tendon and ligament injuries related to attachment to bone (e.g. anterior cruciate ligament (''ACL'') or rotator cuff injuries) may lead to decreased strength and range of motion. The treatment of these injuries is currently limited to reattachment, or mechanical fixation, of the structures using orthopedic suture and anchors, either with or without the addition of autograft or allograft tissues.

The BioMimetic Advantage

We believe we are positioned to improve upon a variety of existing therapies through the addition of a biologically active growth factor that will stimulate tissue regeneration and repair, thereby providing faster and more predictable healing. Further, we believe that we will be in a position to open new orthopedic product segments that address underserved or unmet clinical needs, particularly in advancing the treatment of injuries to bone, cartilage, ligaments and tendons.

We believe our product candidates are positioned to achieve widespread market acceptance and strong market penetration by providing significant advantages compared to existing therapies. Augment, our lead product candidate, and our other product candidates are based on the FDA-approved component rhPDGF that is combined with synthetic or natural scaffold materials, such as ß-TCP, which have a history of demonstrated safety and efficacy in previous uses. We believe that our lead product candidates provide the following advantages:

- *Applications across multiple musculoskeletal indications.* We believe that our product candidates have applications to treat multiple orthopedic and musculoskeletal injuries and defects, including those of bone, cartilage, ligaments and tendons. This broad spectrum of activity is due to our use of rhPDGF, which has been shown to stimulate multiple cellular and biochemical processes important for the repair of these tissues.

- *Key stimulator of wound healing.* Our product candidates all incorporate rhPDGF, a bio-active protein that is a key mediator of wound healing and tissue regeneration. Naturally occurring PDGF, released by platelets at sites of tissue injury, stimulates a series of cellular and biochemical events that are critical for tissue repair to occur. Bio-active proteins, such as rhPDGF, are absent from synthetic bone void fillers and are present in only limited amounts in allografts and xenografts.
- *Combined benefits of both the medical device and drug components.* Our product candidates are regenerative protein therapeutic-device combination products, which combine the benefits of existing devices, such as β-TCP, that provide a physical framework or scaffold that facilitates and guides tissue growth, with the stimulatory action of the bio-active protein, rhPDGF.
- *Lower potential for adverse side effects than allograft and less pain and shorter surgical procedure time than autograft.* Because Augment does not rely on human tissue, the perceived risk of transmitting infectious disease from the human source, which is present for allograft, is eliminated. Additionally, unlike the procurement of autograft from the patient, Augment does not require painful graft harvesting, thereby avoiding an additional surgical procedure that increases post-operative pain, procedure time and risk of infection for the patient.
- *Proven safety profile.* β-TCP and rhPDGF are both FDA cleared and approved for marketing in other applications and have extensive safety histories. β-TCP is a purified, porous form of calcium phosphate similar to natural bone mineral and has been used in orthopedics for over 20 years. Both β-TCP and rhPDGF are the primary components of our previously developed products. This includes *GEM 21S*, which has been approved and marketed in the United States and Canada for use in periodontal indications since November 2005 and June 2006, respectively, and Augment, which was approved in November 2009 by Health Canada for marketing and use as an alternative to autologous bone graft in the surgical treatment of foot and ankle fusions in Canada, acknowledging the safety and effectiveness of the product as an alternative to autograft in foot and ankle fusion surgeries.
- *Reliable, scalable manufacturing process.* We have a manufacturing supply agreement covering the active ingredient rhPDGF included in our product candidates. We source rhPDGF from Novartis Vaccines and Diagnostics, Inc., a division of the Novartis Group (''Novartis''). Novartis is also the sole supplier of the rhPDGF used in Regranex®. Novartis manufactures rhPDGF in yeast cells, thereby providing an increased safety profile over competing products derived from human or animal tissues. This manufacturing process provides a consistent product and scalable production, unlike the variability in quality of allografts, xenografts and PRP. Additionally, we have multiple business relationships that cover the different matrices that we combine with rhPDGF as part of our regenerative protein therapeutic-device combination product candidates.
- *Potential to address substantial unmet clinical needs.* We are focused on the development of products that treat unmet clinical needs in large market opportunities. To date there are limited therapeutic treatments that directly and reproducibly stimulate healing processes in the areas in which we are focusing. This is particularly true for repair of certain types of bone fractures and in the treatment of sports injuries.

Strategy

Our objective is to be a leader in the development and commercialization of novel, biologically active regenerative protein therapeutic-device combination products to treat musculoskeletal injuries and conditions affecting bones, tendons, ligaments and cartilage in the orthopedic, spine and sports injury markets.

The key elements of our strategy are to:

- *Develop and commercialize regenerative protein therapeutic-device combination products that are superior to current medical devices for the treatment of injuries and defects of the musculoskeletal system.* We intend to use our proprietary technologies and know-how in both recombinant protein therapeutics and orthopedic devices to address unmet medical needs in orthopedics and sports injury indications.

- *Focus on products with a rapid and cost-effective time to market that utilize well characterized components.* We were able to develop *GEM 21S* from inception to U.S. marketing approval in less than five years. We have a track record of efficient product development that relies upon components used in products previously authorized for marketing by the FDA, and accessing those components through existing manufacturers. For *GEM 21S*, we referenced existing safety histories on the component products in our own regulatory filings and thus believe we were able to further shorten the product development cycle. We will seek to repeat this process of using FDA-cleared or approved components in our subsequent product candidates. This strategy, however, may not result in the acceleration of the regulatory approval process for our product candidates, or we may not obtain such approval.

- *Mitigate risks by leveraging our GEM 21S data and experience to accelerate development of our orthopedic product candidates.* We believe the ability of *GEM 21S* to safely stimulate bone healing in chronically inflamed bone defects in the jaw resulting from periodontal diseases indicates the potential of Augment and certain other product candidates, which, like *GEM 21S*, are based on rhPDGF and β-TCP to stimulate bone growth in orthopedic indications. Much of the data and experience generated as part of the *GEM 21S* clinical development process, including product manufacturing procedures and records, stability test results, analytical test methodology, pre-clinical and human safety test results and efficacy information, facilitated our ability to gain approval of Augment in Canada in 2009. We believe that such data will also facilitate both the approval of Augment in other countries, and the approval of our other product candidates in markets around the world.

- *Maximize the value of our orthopedic and sports injury product candidates through control of distribution channels.* We have retained all marketing and commercialization rights to our orthopedic and sports injury product candidates. In the United States, we plan to build a sales force utilizing independent representatives managed by an in-house sales management team and supported by employee product specialists. This will allow us to have an immediate impact in the market by leveraging existing surgeon relationships. Over time, we will transition through a hybrid independent-direct structure, ultimately evolving to a direct sales model. Outside the United States, we may work with a large distribution partner, or alternatively, we may utilize distributor relationships to enable product introduction and adoption in local markets.

- *Monetization of our orofacial therapeutic business to obtain additional funding for the development of our orthopedic and sports medicine product candidates.* In January 2008, we completed a transaction with Luitpold Pharmaceuticals, Inc. (''Luitpold'') to sell them our remaining orofacial therapeutic business, including the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. As a result of this transaction, in 2008 we received $30.0 million in cash, plus approximately $3.4 million in cash from the sale of existing *GEM 21S* inventory during 2008. Also, in 2009, we received an additional $10.0 million in time-based payments under terms of the sale agreement, as well as additional revenue from ongoing royalty payments based on net sales of *GEM 21S*. This transaction has enabled us to focus our expertise and future development efforts on our orthopedic and sports medicine product candidates, and has provided additional capital allowing us to aggressively advance our pipeline of orthopedic product candidates through clinical development and into commercialization.

- *Capitalize on the broad healing activity of rhPDGF.* *GEM 21S* and all our initial regenerative protein therapeutic-device combination product candidates utilize rhPDGF to enhance the activity of the device component, such as β-TCP. rhPDGF stimulates cells responsible for the healing of bone, and also has been shown in animal and in vitro studies to stimulate cells responsible for the healing of cartilage, ligaments and tendons. By initially focusing our efforts on this single bio-active protein, we believe that we can efficiently leverage our expertise in this molecule to address multiple clinical indications with large market opportunities.

Product Candidates and Target Indications

The table below summarizes our current product candidates and the target indications for the product candidates that we are pursuing:

Market Segment	Product Candidate	Target Indication
Orthopedic	Augment Bone Graft	Open (surgical) fracture and fusion treatment
	Augment Injectable Bone Graft	Closed (non-surgical) fracture treatment Minimally invasive fracture/fusion treatment
Spine	TBD — under development	Spine fusion
Sports Injury	Augment C	Cartilage repair
	Augment RC	Rotator cuff tendon to bone repair
	Augment AT	Treatment of acute tendon injuries
	Augment CT	Treatment of chronic tendon injuries

The following summary sets forth certain key market opportunities for us and the corresponding product candidates. Ultimately, however, our goal is to achieve approval of our product candidates for a broad range of bone grafting indications. As detailed in the product development section below, we have advanced product candidates to clinical development for certain of these opportunities, and for others we are in pre-clinical development.

Augment Bone Graft for Orthopedic and Spine Indications

Open (surgical) Treatment of Fractures/Fusions. In recent years, there have been more than one million procedures performed annually in the United States involving fusions and corrective surgeries of the foot and ankle. Many of these procedures utilize a bone graft material to stimulate the healing of the bone following surgery. Open, surgical treatment of fractures of the long bones (femur, tibia, fibula, humerus, radius, ulna) accounts for approximately 800,000 additional surgical procedures in the United States annually. Surgeons frequently use bone graft in these procedures to fill voids and stimulate the wound healing process. Of these graft procedures, an estimated 10% to 20% have impaired or delayed healing or non-union.

We are evaluating Augment in several open clinical applications, including foot and ankle fusions and distal radius fractures. Augment is similar to *GEM 21S* in that it combines a particulate ß-TCP with rhPDGF. We have received FDA clearance under the trade name OsteoMimetic for a proprietary ß-TCP, which is a component of our Augment product candidate, for orthopedic applications as a bone void filler when the void or gap is not intrinsic to the stability of the bone. Although we currently do not plan on marketing OsteoMimetic as a stand-alone product, we believe FDA clearance may support the regulatory review process for Augment.

Closed (non-surgical) Treatment of Fractures. Approximately 11 million fractures per year in the United States of the radius, humerus, tibia, fibula and femur occur where the treatment relies upon closed, non-surgical treatment. Of these fractures that were treated, an estimated 5% to 10% have impaired or delayed healing due to patient specific factors such as smoking, diabetes and osteoporosis.

We developed Augment Injectable for the minimally invasive, surgical treatment of fractures as well as the treatment of fractures not requiring surgery. Augment Injectable combines rhPDGF with an injectable bone matrix consisting of ß-TCP and collagen. The product candidate can be injected through the skin into the fracture site, locally delivering rhPDGF to accelerate fracture repair. Closed fracture reduction procedures comprise the largest number of orthopedic procedures today. According to hospital and outpatient procedural data, 2.8 million closed fracture procedures are performed per year. While a significant number of these fractures are treated with casts, we believe that a large number of patients who require longer healing times would benefit from our Augment Injectable product candidate. We have completed a pilot study in Sweden that further demonstrated the safety of the product for the treatment of distal radius fractures.

Spine Fusions. There are more than 500,000 spine fusion procedures performed in the United States each year for the treatment of degenerative disc disease (''DDD'') and other debilitating conditions of the spine. Virtually all of these procedures utilize autograft or a bone graft substitute to assist in the achievement of the fusion. BMPs, predominantly INFUSE, have been widely used in this application and have proven to be effective in the treatment of thoraco-lumbar fusions. However, BMPs were the subject of a July 1, 2008, FDA Public Health Notification ''Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion.'' The FDA Notification states that the FDA has received ''at least 38 reports of complications during the last four years with the use of rhBMP in cervical spine fusion. These complications were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures of the neck.'' Cervical spine is a segment which represents nearly half of all spine fusions performed. We believe that there is an opportunity for one of our product candidates to fill this clinical need.

Revision Total Joint Arthroplasty. Total joint arthroplasty is the definitive treatment for end stage arthritis in the hip and knee. In 2009, close to one million joint replacement procedures were performed in the United States. Of these procedures, an estimated 80,000 were revision surgeries resulting from a failure or wearing out of the primary prosthesis. Revision hip and knee arthroplasty is often characterized by diminished bone and soft tissue structures supporting the implant. Surgeons frequently use some type of bone graft as a void filler and a stimulus for the regeneration of bone. Even when the primary procedure used cement, the majority of revision procedures are performed using a porous prosthesis, with the goal being to gain a biological interlock between the bone and the implant. We believe that a synthetic void filler that can help stimulate the biological interlock with the prosthesis could improve outcomes in these procedures.

Product Candidates for Sports Injuries

Cartilage, ligament and tendon repair and regeneration represent significant unmet clinical needs. It is estimated that there are over 2.3 million orthopedic soft tissue injuries each year in the United States, most of which are treated conservatively with rehabilitation techniques. Because of the lack of therapies that can stimulate healing and regenerate these tissues, many of these injuries result in a degree of permanent impairment and chronic pain.

We are using our platform technology to develop product candidates which address unmet medical needs in sports injury applications by targeting cartilage, ligament and tendon repair and regeneration. rhPDGF has been documented as a potent mitogen for cell types impacted by these injuries (e.g. tenocytes and chondrocytes) and, when delivered appropriately, rhPDGF can induce rapid increases in vascularity (i.e. angiogenesis), cell proliferation (i.e. mitogenesis) and cell recruitment (i.e. chemotaxis).

Cartilage Injuries. Cartilage is the soft tissue in the joints of the body that acts as a shock absorber and lubricant during motion of the joint. Because damaged cartilage does not heal by itself and slowly breaks down over time, the result can lead to a complete wearing away of cartilage, leading to osteoarthritis. Currently, there are limited therapies to regenerate cartilage, although a number of therapeutic and surgical methods are used to minimize the pain and disability from cartilage injuries. In 2009, an estimated 1.3 million knee procedures were performed in the United States to repair or regenerate cartilage and meniscus defects. In addition, in 2009, approximately 3.1 million injections of viscosupplementation were administered in the United States to treat cartilage and meniscus defects. While these injections may reduce the pain associated with osteoarthritis for a limited time period, they do not stimulate the healing of the damaged cartilage.

Tendon and Ligament Injuries. Tendons are the tissue structures that connect muscles to bone, and ligaments are the tissue structures that connect bone to bone. Both of these structures are crucial to the biomechanical functions of the body. Injuries to tendons and ligaments are very common. An estimated 30% to 50% of all sports related injuries are tendon disorders and approximately 25% to 45% of patients eventually require surgery following ineffective, conservative treatment. Currently, there are limited therapeutic products that stimulate the healing and regeneration of ligament and tendon tissues.

Tendon to bone injuries are a frequent source of visits to orthopedic surgeons. It has been estimated that in 2009, over 400,000 rotator cuff tendon injuries will have led to surgical intervention in the United States. As many as 94% of these surgical repairs were estimated to be non-healing or develop re-injury.

Ligament tears, or specifically, tears of the anterior cruciate ligament (''ACL''), are most commonly associated with traumatic sports injuries. Minor tears are eligible for conservative treatment, but each year more than 400,000 knee ligament reconstruction procedures are performed. The poor healing ability of the ACL contributes to the frequency of these surgeries which often require additional surgical sites for harvesting donor tissue, resulting in increased patient pain, morbidity and operating room procedure time.

Tendon to tendon injuries, such as an acute rupture of the achilles tendon or a traumatic flexor tendon injury, often result in surgery and lead to large rehabilitation times and time lost from work or other activity.

Chronic tendon injuries due to overuse are also very common and frequently cited as a main contributor to worker's compensation claims. For example, lateral epicondylitis (i.e. tennis elbow) has been estimated to occur in 1% to 3% of the U.S. population. Current options to treat chronic tendon injuries are limited to conservative therapies which further contribute to time lost from work. Failure of conservative therapy may still result in costly surgery which yields a cessation of pain, however often with a negative impact on strength and function.

Product Development Programs

In developing the indications discussed above for our product candidates, we have implemented a variety of pre-clinical and clinical development programs. We believe these development programs will ultimately support the regulatory approval of our product candidates for certain of our target indications discussed above.

Product Development Programs for Orthopedic Indications

We currently have several clinical trials for orthopedic clinical development indications that have been completed or that are ongoing, which seek to establish the safety, clinical utility and/or effectiveness of Augment and our other product candidates in certain of our target indications discussed above. In particular, the following studies have been completed or are currently in progress:

Augment™ Bone Graft

(1) North American Augment Pilot Trial — Foot and Ankle Fusions. In February 2006, we initiated a feasibility clinical trial with Augment for the treatment of foot and ankle fusions. The protocol for this study included 20 patients at three centers with nine months follow-up. The study was designed to compare the use of Augment to the use of autograft, which is bone harvested from another location within the patient's own body, to facilitate fusion in a foot and ankle procedure. We completed enrollment of 20 patients in July 2006. In December 2006, we announced interim results for this study, and we updated those results in July 2007. The reported data indicated that the Augment treatment appears comparable to autograft for the stimulation of bone healing (fusion), without the pain and morbidity associated with the harvesting of the autograft.

(2) North American Augment Pivotal Study — Foot and Ankle Fusions. In June 2007, we received unconditional FDA approval for a North American pivotal clinical trial evaluating the safety and effectiveness of Augment to stimulate bone healing in foot and ankle fusions (''Augment pivotal study''). This clinical trial is a randomized, controlled study comparing Augment to autograft, the current gold standard for bone grafting in this type of surgery. The study goal was to establish non-inferiority of Augment compared to autograft, which has the limitation that it must be obtained and transplanted from another bone in the patient's body, often requiring a second surgical procedure. The trial was designed to enroll 396 patients; however, enrollment continued through December 31, 2008 to accommodate those additional patients who had already consented into the study and were scheduled for surgery. A total of 434 patients were enrolled in this study.

In October 2009, we announced positive top-line results from our Augment pivotal study. The primary endpoint of the study is the percentage of patients achieving fusion at 24 weeks, with fusion defined as 50% or greater bone bridging on CT scans, as evaluated by an independent musculoskeletal radiologist. For the pre-specified primary endpoint, patients treated with Augment experienced a similar fusion rate compared with those receiving autograft, and the data met statistical non-inferiority. Since many patients had multiple joints treated, analysis was also performed on a per joint basis, and that data also established non-inferiority. Clinical healing status at the patient level for patients treated with Augment was comparable to patients treated with autograft. These positive top-line results indicate that, with the use of Augment, patients can expect a treatment outcome comparable to autograft while being spared the pain and potential morbidity associated with traditional autograft bone harvesting and transplantation.

In March 2010, we announced additional data from our Augment pivotal study at the annual meeting of the American Academy of Orthopedic Surgeons (''AAOS''). The lead investigator of the Augment North American pivotal study, Dr. Christopher DiGiovanni, presented additional data regarding the 24 week results of the study. These data are based on the ''modified intent-to-treat'' (''mITT'') patient population, which is the pre-specified primary study population. The results are shown for the full complement of joints in which all treated joints within a patient must meet the success criteria as well as on an individual basis in which each treated joint is scored separately.

Highlights of the previously reported top-line results from our Augment pivotal study, as well as the secondary clinical endpoints not previously reported, have been summarized and presented in table form below. For the purposes of the table, we determined statistical significance based on a widely used, conventional statistical method that establishes a measure known as the p-value of clinical results. Using this method, a p-value of 0.05 or less represents statistical significance, meaning that there is a less than one-in-twenty likelihood that the observed results occurred by chance. For all these outcomes the number of patients evaluated (n) is 397.

Parameter / Subjects (n=397)	Augment-Treated Patients	Autograft-Treated Patients	Statistical Significance for Non-Inferiority? (p<0.05)
CT fusion rates:			
Full complement of joints *	61.2%	62.0%	p=0.038 (yes)
All joints (assessed individually) *	66.5%	62.6%	p<0.001 (yes)
Clinical healing (physician evaluation):			
Patient level *	83.1%	83.9%	p=0.010 (yes)
Full complement of joints	82.3%	83.2%	p=0.011 (yes)
All joints (assessed individually)	83.5%	83.3%	p<0.001 (yes)
Non-union / delayed union *	8.8%	10.2%	p=0.008 (yes)
Plain film radiographic union rates (3 aspects):			
Full complement of joints	30.8%	32.8%	p=0.054 (no)
All joints (assessed individually)	38.3%	37.9%	p=0.007 (yes)
Plain film radiographic union rates (2 aspects):			
Full complement of joints	60.8%	66.4%	p=0.194 (no)
All joints (assessed individually)	67.5%	70.9%	p=0.049 (yes)
Clinical healing (aggregate measures):			
Composite success rate (a pre-specified combination of radiographic, clinical and functional measures)	66.9%	66.4%	p=0.017 (yes)
Clinical success rate (defined as improvement in pain from baseline with no need for revision surgery)	74.6%	78.1%	p=0.071 (no)
Therapeutic failure rate (defined as non-union or delayed union at 24 weeks, or required secondary therapeutic intervention for non-union or delayed union)	9.2%	10.9%	p<0.001 (yes)
Functional / quality-of-life:			
SF-12 mean physical component score (''PCS'')	39.9%	41.4%	p<0.001 (yes)
Foot function index (''FFI'') mean total score	27.4%	22.3%	p=0.012 (yes)
American Orthopedic Foot and Ankle Society (''AOFAS'') mean total score	73.9%	75.9%	p<0.001 (yes)
Pain:			
Fusion site pain	18.9%	16.5%	p=0.001 (yes)
Weight-bearing pain	23.5%	19.3%	p=0.016 (yes)
Graft harvest site pain	n/a	8.1%	p<0.001 (yes)

* - Indicates data previously reported in October 2009.

For purposes of the preceding table, we also used two validated and widely accepted instruments for evaluating patient function prior to and following a surgical procedure in the foot and ankle. These are the AOFAS Hindfoot questionnaire and the Foot Function Index, both of which evaluate the patient's ability to stand, walk and perform normal activities of daily living. The SF-12 is a widely used quality-of-life instrument that assesses the patient's overall well being. These functional and quality-of-life outcomes met statistical non-inferiority for these standard instruments. Similarly, key pain outcomes were judged to be similar between the two groups and statistical significance for non-inferiority was met for both the fusion site pain and for pain on weight-bearing. Regarding pain at the graft harvest site, the Augment group was determined to be superior to the autograft group, since the Augment patients did not have any autologous bone harvested in the study.

We also reported new data relating to the safety of Augment compared to the autograft control. The Augment group exhibited a lower rate of serious treatment emergent adverse events, a lower rate of overall and surgery-related complications, a lower rate of serious complications, fewer surgery-related complications and a lower rate of infection when compared with the autograft group. A summary of the key safety results for all treated patients is presented below. A p-value of greater than 0.05 indicates that the treatments are not statistically different.

Safety Outcome	Augment-Treated Patients	Autograft-Treated Patients	Not Statistically Different? (p>0.05)
Pre-treatment signs and symptoms	3.7%	2.8%	p=0.779 (yes)
Treatment emergent adverse events	72.4%	70.4%	p=0.730 (yes)
Serious treatment emergent adverse events	7.7%	14.1%	p=0.055 (yes)
Overall complications	33.5%	38.0%	p=0.386 (yes)
Complications associated with surgical procedure	23.5%	29.6%	p=0.193 (yes)
Serious complications	4.4%	6.3%	p=0.480 (yes)
Serious surgical complications	4.0%	6.3%	p=0.337 (yes)
Infections (previously reported)	7.7%	9.9%	p=0.462 (yes)

The data that remains to be reported in our Augment pivotal study includes the 36 week CT scan and 52 week data that represents the study completion for all patients. We anticipate releasing this data around the middle of 2010.

In the second quarter of 2009, we submitted both the pre-clinical pharmacology/toxicology and quality/manufacturing modules of a modular pre-market approval ("PMA") application for marketing of Augment in the United States. In February 2010, we submitted the third PMA module, which contains the data from the clinical trial. This final module, which contains a comprehensive review of the clinical data related to Augment, completes the PMA application to the FDA. Our PMA application is currently being reviewed by the FDA. We expect that, in the second half of 2010, an FDA advisory committee, which is typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, Augment should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. We anticipate that approval of Augment in the United States will occur within six months after the panel meeting if the panel recommends approval and if the FDA finds the PMA information satisfactory.

(3) Canadian Augment Pilot and Registration Trial — Foot and Ankle Fusions. In January 2006, we initiated a 20 patient open-label pilot study at three clinical centers to demonstrate the safety and clinical utility of Augment to stimulate bone regeneration in the treatment of foot and ankle fusions. The trial protocol called for a nine month patient follow-up. We successfully completed enrollment in this study in April 2006, and based on the preliminary data, in May 2006, we received authorization from Health Canada to expand the study from the original 20 patients, up to 60 patients. We completed enrollment of the additional patients, and in September 2007, we completed a nine month follow-up of these patients. All patients in the study received Augment in lieu of autograft to assist the fusion procedure. Study results were measured against previous fusion studies from the literature where autograft was used to augment fusion. In December 2007, we announced a summary of the results from this study. The data demonstrate a rate of fusion which appears to

be comparable to autograft as measured by CT scans and radiographs, without the pain and morbidity associated with the harvesting of the autograft.

Using these results, together with data on *GEM 21S* and pilot data on Augment in the United States and Sweden, in the second quarter of 2008, we filed a Device License Application ("DLA") with Health Canada. The DLA submission is required in Canada for approval of the commercialization of Augment as a medical device for use in the treatment of foot and ankle fusions.

In November 2009, we announced that we received approval from Health Canada to begin marketing Augment in Canada as an alternative to the use of autograft in foot and ankle fusion indications. Joint Solutions is the exclusive distributor of our Augment product in Canada. We also deployed clinical specialists in the Canadian market, which is approximately 5% the size of the U.S. market, to work collaboratively with the Joint Solutions team. The product was made available to customers in Canada in January 2010. We are working with distributor personnel to gain product approval at individual institutions through review by the hospitals' new product evaluation committees, a process that can take several months to complete.

(4) EU Augment Trial — Foot and Ankle Fusions. In May 2007, we initiated a clinical study in Europe to evaluate Augment for the treatment of foot and ankle fusions. In November 2008, we completed the enrollment with a total of 108 patients. This study is an open label trial, and will be used to support the safety of Augment. We expect that the data from the study should be available around mid-year 2010. We expect to use the data in conjunction with data from the North American pivotal trial and other trials to apply for product registration approval in the EU.

(5) EU Augment Pilot Trial — Distal Radius (Wrist) Fractures. We have completed patient enrollment in a pilot clinical trial in the EU (Sweden) for the evaluation of Augment for the treatment of distal radius fractures requiring surgical treatment. This pilot trial includes 19 patients at one center with six months follow-up, and is designed as a randomized controlled trial evaluating distal radius fractures treated with external fixation combined with Augment versus external fixation alone. In January 2007, we announced interim results of this study that suggest that Augment accelerated bone regeneration as measured by CT scans. The preliminary results demonstrate accelerated bone regeneration at earlier time points in patients treated with Augment combined with external fixation compared to patients treated with external fixation alone.

Augment™ Injectable Bone Graft

(6) Canadian Augment Injectable Pilot Trial — Foot and Ankle Fusions. We completed enrollment in a pilot study in December 2007 for the use of Augment Injectable for the treatment of foot and ankle fusions. Although Augment Injectable is designed as an injectable for use in closed treatment, this study utilizes essentially the same protocol as our Augment foot and ankle study in Canada, with Augment Injectable being used in an open procedure. The trial is an open-label study with seven of the 10 patients considered to be high risk for poor healing as a result of co-morbidities. The results of the study demonstrated that all 10 patients achieved complete clinical success within six months after surgery. In addition, analysis of CT scans at three to four months after surgery showed that 90% of the patients had achieved radiographic fusion.

(7) EU Augment Injectable Pilot Trial — Distal Radius Fractures. In January 2007, we initiated a pilot clinical study in Sweden to investigate the use of Augment Injectable in patients being treated for fractures of the distal radius (wrist). We have enrolled total of 21 patients in the study, consisting of 11 patients treated with Augment Injectable combined with external fixation and 10 patients treated with external fixation alone. Enrollment in the study was completed in December 2007. The results of data analysis shows patients treated with Augment Injectable demonstrated earlier bone formation at three and six weeks as measured by CT scans. The six month evaluation of "complete bone fill," defined as more than 75% fill of the fracture gap, was 100% for Augment Injectable patients, as compared to 82% for the patients treated with external fixation alone. The product candidate was demonstrated to be safe, with no reported adverse events related to the study devices.

(8) North American Augment Injectable Pivotal Study — Foot and Ankle Fusions. The results from the Canadian Augment Injectable Pilot Trial and the EU Augment Injectable Pilot Trial noted above provided us with sufficient evidence of Augment Injectable's safety and clinical utility to allow us to progress Augment Injectable forward in the development process.

Accordingly, in 2009 we filed an Investigational Testing Authorization ("Augment Injectable ITA") application with Health Canada and an Investigational Device Exemptions ("Augment Injectable IDE") application with the FDA. Health Canada approved the Augment Injectable ITA, and in October 2009, we initiated patient enrollment in a North American pivotal study to assess the safety and efficacy of Augment Injectable as a substitute for autograft in foot and ankle fusion procedures ("Augment Injectable study"). This randomized, controlled study is intended to support the registration of Augment Injectable in Canada and the United States. The Augment Injectable study is designed to incorporate approximately 300 patients, some of whom will be autograft patients that were enrolled in our North American Augment pivotal study. The Augment Injectable study protocol in Canada is similar to the Augment pivotal study protocol so certain control (i.e. autograft) patients enrolled in the Augment pivotal study can be used to supplement the control group in the new study. Up to 20 clinical centers in North America will be involved, with five sites that have already begun enrolling patients in Canada.

We are finalizing the details of the protocol and the statistical plan of the Augment Injectable study with the FDA and will not commence patient enrollment in the study in the United States until the details of the protocol and the statistical plan are complete. We cannot be certain, however, whether the FDA will approve the Augment Injectable IDE or, if approved, that the approved protocol will permit the pooling of the study's patients with the patients that we are currently enrolling under the Canadian Augment Injectable ITA or with the control patients included in our Augment pivotal study. We expect to receive a final decision on our IDE around mid-year 2010, and would anticipate initiating patient enrollment in the United States shortly thereafter, and completing patient enrollment within six months of commencing U.S. enrollment.

With the studies outlined above, we now have clinical data for three anatomic sites (the foot and ankle, the distal radius, and the jaw) which suggest that our platform technology stimulates bone regeneration. In addition, to date there have been no product related Serious Adverse Events ("SAE") attributed to Augment or Augment Injectable related to any of the clinical studies outlined above.

We believe that the results from our Augment and Augment Injectable studies, along with the ability of *GEM 21S* to stimulate bone formation in jaw bone defects, suggest the potential for our product candidates to be effective in stimulating new bone growth in a variety of orthopedic applications, including our target indications that are outlined above.

Product Development Programs for Sports Medicine Indications

Based upon the demonstrated biology from both *in vivo* and *in vitro* studies which indicate that rhPDGF can stimulate the various structural cell types that make up cartilage, ligaments and tendons, we believe that rhPDGF has the potential to be an effective therapy for the repair of these tissue types. Cartilage, ligament and tendon tissues are composed of cells of mesenchymal origin. rhPDGF has been shown to stimulate the recruitment and proliferation of both the mature structural cell types of these tissues as well as the recruitment and proliferation of undifferentiated mesenchymal stem cells, causing a localized increase in the number of these cells at a site of injury. Once present, the stem cells can be differentiated into the appropriate cell type for the tissue undergoing repair. These can include differentiation into chondrocytes for cartilage repair, or tenocytes and fibroblasts for tendon and ligament repair.

Considering the demonstrated ability of rhPDGF to stimulate tissue repair in the periodontal space, where the regeneration of both bone and ligament tissues are required for the restoration of normal tissue structure, we believe that rhPDGF is a candidate for development in the sports medicine area where these types of tissues are similarly involved. We have started pre-clinical studies to evaluate matrix materials that can be combined with rhPDGF for tendon, ligament and cartilage repair applications. The matrix materials under evaluation are being selected to specifically target the tissue type to be treated. Various animal studies are in process to demonstrate the safety and effectiveness of rhPDGF alone or in combination with matrix materials.

At the Orthopedic Research Society meeting in March 2010, we presented results of two pre-clinical studies demonstrating that rhPDGF-BB, in combination with tissue specific matrix materials, promotes healing in Achilles and rotator cuff injuries in sheep models. In addition, we also presented *in vitro* data supporting rhPDGF-BB's ability to influence tenocytes. Based on these positive results, we intend to initiate a pilot clinical trial in sports medicine by the end of 2010. In light of the present phase of development, however, we cannot provide any assurance that we will be successful in developing, obtaining regulatory approval for or commercializing our sports medicine product candidates.

Scientific Background

PDGF Family of Growth Factors

Platelet-derived Growth Factor (''PDGF'') is a family of growth factors which contains five different members that are found naturally in the body. Our platform technology is based on a synthetic version of the BB form of PDGF (''PDGF-BB'') which is a homodimer of two separate B-chains that are covalently linked together through disulfide bonds. The PDGF-BB that is used in our product candidates is manufactured using recombinant DNA technology in a yeast expression system. The gene that codes for the human sequence of the PDGF B-chain is inserted into yeast cells. The gene is then activated to cause the production of the PDGF B-chain protein. The protein is secreted from the yeast cell into its culture media, and the protein purified from the media to homogeneity.

There are two PDGF receptors that are present on the surface of target cells. Depending upon the number and ratio of the receptors present on a cell, the cell will be more or less responsive to the different PDGF family members. Recombinant human Platelet-derived Growth Factor (''rhPDGF-BB'') has the ability to bind with high affinity to both receptors, providing it with unique properties within the PDGF family. Depending on the location of an injury, different cell types that respond to rhPDGF-BB are stimulated.

Role of PDGF in Tissue Repair

Tissue repair at injury sites occurs as a result of a complex series of events. For successful tissue repair to take place, the appropriate cell types must be recruited to the injured site in a coordinated fashion. PDGF is one of the proteins that are critical for orchestrating this process as it is at the top of the wound healing cascade. PDGF is responsible for stimulating a variety of cellular events critical for the initiation and progression of tissue repair. These include attracting cells into a wound site and stimulating their replication. Depending upon the location of the injury, different cell types respond to PDGF. Animal and *in vitro* studies have demonstrated that cell types that are stimulated include bone forming cells, cartilage forming cells, MSCs which are bone and cartilage-lineage forming cells, and fibroblasts which are tendon and ligament forming cells. Published animal and *in vitro* studies demonstrate that PDGF may also work together with other growth factors to enhance the formation of new blood vessels by stimulating vascular smooth muscle cells, a cell type critical for the formation of blood vessels. Additionally, PDGF promotes the release of other growth factors and signaling molecules that accelerate the natural healing process. As a result of its ability to stimulate a multi-faceted set of activities, we believe PDGF plays an integral role in initiating the tissue repair process in the different clinical indications that we are pursuing.

To support the stimulatory properties of rhPDGF, as part of our platform technology we combine the protein with resorbable three-dimensional scaffolds that are specifically tailored for the tissue being treated. This approach provides both the matrix critical to support the in-growth of the appropriate cell types, while providing for the release of rhPDGF in a localized manner under controlled delivery conditions. The scaffold or matrix component also combines the benefits of delivering a stimulatory growth factor with the structural requirements of a synthetic scaffold to support cell migration and tissue regeneration at the wound site.

Approvals of Augment in Canada and GEM 21S in the United States and Canada Validates our Platform Technology

We have validated our platform technology, which combines rhPDGF with resorbable scaffold materials, through the successful development of *GEM 21S* for use in periodontal bone and tissue regeneration and the successful development of Augment for use in foot and ankle fusion indications in Canada. We believe that the approval by the FDA and Health Canada of *GEM 21S* and the approval by Health Canada of Augment provide proof of concept and suggests that our platform technology promotes tissue regeneration and will apply to a broad array of musculoskeletal applications, such as orthopedic, spine and sports injury applications.

The details of our clinical development program for Augment in Canada are discussed above in the section entitled ''Product Development Programs for Orthopedic Indications.'' With regard to *GEM21S*, we began our human clinical development program by testing the use of rhPDGF with allograft to stimulate tissue healing. Nine months after placing the test material around teeth in patients with severe periodontal disease, the teeth and adjacent jawbone were excised and we analyzed the teeth and accompanying tissue for new bone formation. The data demonstrated that treatment with rhPDGF resulted in significant new bone formation adjacent to the tooth root.

Based on these data, we conducted a 180 patient double-blind, randomized controlled trial to evaluate the safety and efficacy of *GEM 21S* for the regeneration of bone and adjacent tissues in the treatment of periodontal defects. The study contained three groups: two groups were given different doses of rhPDGF used in combination with ß-TCP and the third group, the active control, was given ß-TCP plus a buffer (i.e., no rhPDGF). We included only subjects with advanced bone defects requiring surgical treatment in the study. The patients received standard periodontal surgery followed by the placement of the test compound.

The results of the clinical study demonstrate that *GEM 21S* treatment led to a significant increase in healing of the bone defect in the periodontal lesion. Additionally, *GEM 21S* treatment expedited soft tissue attachment gain at three months following surgery (CAL gain) and decreased gum tissue recession, further demonstrating the efficacy of *GEM 21S*.

The results of the clinical study further demonstrated that *GEM 21S* treatment led to statistically significant benefits in bone growth and healing of the periodontal bone defects compared to the active control group that received the ß-TCP, without the addition of rhPDGF. There were no serious adverse events during the study that were directly attributed to the use of *GEM 21S* and no statistically significant difference in the incidence of adverse events between the treatment and control groups. In summary, the results of the pivotal clinical study demonstrated that *GEM 21S* is a safe and effective treatment, leading to acceleration of healing and the stimulation of new bone formation.

Divestiture of Orofacial Therapeutic Business

In January 2008, we completed the sale of our orofacial therapeutic business to Luitpold. Under this transaction, we terminated certain 2003 agreements with Luitpold relating to our manufacturing and supplying of *GEM 21S* and Luitpold's distribution and marketing of *GEM21S*, and we amended and restated certain other 2003 agreements relating to intellectual property.

In addition, under the 2008 transaction, Luitpold acquired: (1) the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S;* (2) all rights to the *GEM* trademark family; (3) certain rights to adapt our future orthopedic and sports medicine products to dental applications; and (4) certain rights to negotiate on other growth factors and product improvements that we license from third parties. Through our existing commercial supply agreement with Novartis, we remain the sole source supplier of bulk rhPDGF-BB to Luitpold. In addition, our U.S. and Canadian regulatory approvals, including the *GEM 21S* PMA, have been or will be transferred to Luitpold, and with the exception of the EU regulatory filing for *GEM 21S*, Luitpold now has responsibility for all future filings. The rights to the *GEM 21S* (now known as *GEMESIS*™ in Europe) EU regulatory approval will be transferred once approval is obtained, if at all. We have agreed not to compete with Luitpold in the orofacial therapeutic business for a specified period of time. Also, as part of this transaction, each party agreed to indemnify the other party for certain losses.

Orthopedic Scientific Advisory Board

Our orthopedic scientific advisory board brings expertise in orthopedics, as well as FDA experience. During 2009, there was one meeting of the orthopedic scientific advisory board. We consult individual members of our scientific advisory board separately approximately once each quarter on clinical and pre-clinical study design, product and product candidate formulation, clinical indications and on all applications of tissue engineering, focusing on orthopedic indications.

We pay consulting fees, including stock option grants, to members of our scientific advisory board for the services they provide to us, in addition to reimbursing them for incurred expenses. The amounts vary depending on the nature of the services. We paid to or on behalf of the current members of our scientific advisory boards aggregate consulting fees and reimbursements of $29,944, $52,664 and $424,290 in 2009, 2008 and 2007, respectively. In addition, we granted options to purchase an aggregate of 5,000, 5,000 and 12,500 shares of our common stock to current members of our scientific advisory boards in 2009, 2008 and 2007, respectively.

The current members of our orthopedic scientific advisory board are:

Name	Professional Affiliation
Gary Friedlaender, M.D.	Director of BioMimetic; Chairman of BioMimetic's Orthopedic Scientific Advisory Board; Wayne O. Southwick Professor of Orthopaedics and Professor of Pathology, Chair of Orthopedics and Rehabilitation, Department of Orthopaedics and Rehabilitation, Yale University School of Medicine
Edward Akelman, M.D.	Professor and Vice Chairman, Warren Alpert Medical School of Brown University, Department of Orthopedics; Chief, Division of Hand, Upper Extremity and Microvascular Surgery, Rhode Island Hospital
Arnold Caplan, Ph.D.	Director of Skeletal Research Center and Professor of Biology, Case Western Reserve University
Michael Ehrlich, M.D.	Vincent Zecchino Professor and Chairman, Department of Orthopaedics, the Warren Alpert Medical School of Brown University; Surgeon-in-Chief, Rhode Island and Miriam Hospital
Jeffrey Hollinger, D.D.S., Ph.D.	Professor of Biological Sciences and Biomedical Engineering and Director, Bone Tissue Engineering Center, Carnegie Mellon University
Joseph Lane, M.D.	Professor of Orthopedic Surgery, Assistant Dean, Medical Students, Weill Cornell Medical College; Chief, Metabolic Bone Disease Service, Hospital for Special Surgery; Attending, Orthopedics, New York-Presbyterian Hospital
John Mathis, M.D., M.Sc.	Medical Director, The Centers for Advanced Imaging, Roanoke, Virginia
Stuart Goodman, M.D.	Robert L. and Mary Ellenburg Professor of Surgery, Professor, Department of Orthopedic Surgery, Stanford University
Sheldon Lin, M.D.	Associate Professor of Orthopedic Surgery, New Jersey Medical School

Sales, Marketing and Distribution

We expect that the first approved indication for the use of Augment in both the United States and Europe will be the treatment of foot and ankle fusions. As a consequence, our marketing strategy revolves around outreach and educational programs directed at orthopedic and podiatric surgeons who specialize in surgeries of the foot. In anticipation of product commercialization, we have taken steps proactively to engage with the professional societies for these groups, specifically the American Orthopedic Foot and Ankle Society (''AOFAS'') for orthopedic surgeons and the American College of Foot and Ankle Surgeons (''ACFAS'') for

podiatric surgeons. By attending society sponsored meetings as a technical exhibitor and sponsor, we are establishing an awareness of our company with these influential groups and facilitating access for our sales force once the product is approved, if at all.

With an established group of key opinion leaders who have been involved with our clinical studies, the thrust of our marketing programs will be the facilitation of ''peer-to-peer'' information exchange regarding Augment and the results of the clinical trials. Activities such as Grand Rounds presentations, visiting professor sessions, and sponsored workshops at educational meetings will enable us to get our key opinion leaders in front of their peers to discuss their personal experience in the use of Augment in the foot and ankle. As the product is used by foot and ankle surgeons, we expect that there will be interest from their colleagues in trauma and reconstructive surgery for the use of Augment in other bone regeneration applications. After identifying surgeon driven applications, we will initiate extension studies in pursuit of additional label claims for Augment that will have the potential to expand the scope of use for the product beyond the foot and ankle.

In anticipation of the approval of Augment or our other product candidates in the United States, we expect to develop a commercial organization consisting of a sales management team, independent sales agents and company employee sales representatives and product specialists who will market the product to orthopedic surgeons and podiatric surgeons. These representatives will be selected based on their experience in selling orthopedic products used in the operating room, along with their familiarity with foot and ankle and bone grafting surgeries. The agency network will be managed by a company sales management team and will be supported by company employed product specialists, who will train the sales force and provide product education for the surgeon customers. We expect that by the end of the first year of sales in the United States, we may have a 100 person sales force representing Augment in the market.

For commercialization outside of the United States, we are considering two alternative sales channels. We may choose to partner with a third party with an established sales force in key European and Asian markets that will enable broad market coverage. Alternatively, we may choose to assemble a network of distributors to market Augment in selected high potential markets. In Canada, based upon Health Canada's approval of Augment in November 2009, we initiated the commercial marketing of Augment in the beginning of 2010 through our Canadian distributor, Joint Solutions, a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada. We also deployed clinical specialists in the Canadian market to work collaboratively with the Joint Solutions team. The product was made available to customers in Canada in January 2010.

Manufacturing

We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantity of our product candidates through the development and clinical testing phases.

In December 2009, we entered into an amended and restated manufacturing and supply agreement with Novartis covering the bioactive component of our product candidates, rhPDGF. See ''Business — Purchase and Supply Obligations — Novartis/Chiron.'' Novartis's rhPDGF is used as a component in two FDA approved or cleared products (*GEM 21S* and *Regranex*) and is, therefore, manufactured in accordance with all applicable regulatory quality standards. We also have signed an agreement with Kensey Nash Corporation (''Kensey Nash'') for development and supply of specific scaffolds for use in orthopedic and, potentially, sports medicine applications. These agreements provide us with the key constituents of our lead product candidates. Based on a similar supply chain strategy we used successfully for the *GEM 21S* product, we use contract facilities to complete the manufacturing, packaging and final product testing for our clinical orthopedic product candidate kits. Pyramid Laboratories, Inc. performs the aseptic vial filling of the rhPDGF component. Penn Pharmaceutical Services, Ltd. produces the filled ß-TCP cup and produces the final kit assembly. Isotron plc sterilizes the cups. We and AAI Development, Inc. perform the final product testing.

Our current facility, located in Franklin, Tennessee, is leased and consists of approximately 32,000 square feet, provides office, research and development and quality control space. See ''Business — Lease Obligations'' for details regarding the lease agreements. We also lease approximately 30,000 square feet of space in a new building. We intend to utilize the new space as a good manufacturing practices (''GMP'') manufacturing facility and expect to move certain of our manufacturing operations to the new space. This new facility will provide space to meet our current and projected needs for certain aspects of our manufacturing and product

release testing for our orthopedic and sports medicine product candidates. In addition, it will provide for future expansion of office, laboratory, or manufacturing space and capabilities for other product candidates that we are developing. Once the facility is operational, we may continue to utilize third party suppliers for certain aspects of our manufacturing operation, including bulk ß-TCP and rhPDGF production, ß-TCP cup filling, component and final kit sterilization and distribution. The building shell was completed in late 2009, and we expect the build out will begin in 2010 or 2011. In order to qualify the facility as a GMP manufacturing facility, the build out must be complete, the utility systems, process and testing equipment must be installed and qualified, regulatory filings must be assembled and filed, and regulatory agency inspections must be passed prior to receiving approval. We anticipate that the facility will be approved for commercial operations within two years of our starting the build out. We cannot be certain, however, whether the FDA will approve the manufacturing facility.

Lease Obligations

In May 2007, we entered into a lease agreement effective January 1, 2007 with Noblegene Development LLC (''Noblegene''), replacing in its entirety our previous lease with Noblegene dated April 2004, as amended in July 2005. This lease agreement extends the lease term and includes additional office space of approximately 9,000 square feet, bringing the total space to approximately 32,000 square feet at our headquarters in Franklin, Tennessee. Under the terms of the lease, in 2009 we paid Noblegene monthly rent of $50,017 to $51,517, as adjusted, plus additional proportionate operating and insurance costs associated with the building and the business campus. The lease agreement also contains annual scheduled rate increases equivalent to a minimum of three percent. Under the original lease terms, we had been provided with a rent credit of $106,831 to be used toward improvements. In connection with the lease agreement and related to the additional space, we were provided with an additional rent credit resulting in a total rent credit of $5 per usable square foot (or $160,000 total). This rent credit was used toward leasehold improvements in 2007. The initial term of the lease continues until December 31, 2016, and we have the option to extend the lease for two additional five-year terms.

In August 2007, we entered into a lease agreement with Noblegene for approximately 30,000 square feet of space in a new building located in the same complex as our headquarters in Franklin, Tennessee. We intend to move certain of our manufacturing operations to the new space. The lease provides for a tenant improvement allowance of $2.5 million to reimburse us for construction costs associated with building out the leased space. We expect to receive the tenant improvement allowance within 30 days of the earlier of: (a) two years after the date we obtain a Certificate of Occupancy for the new space; or (b) upon Noblegene obtaining a permanent mortgage on the new building. The initial term of the lease continues 10 years from the October 2009 commencement date. We have the option to extend the term of the lease for two additional five-year terms. Under the terms of the lease, we agree to indemnify Noblegene under specific circumstances.

In January 2008, we entered into an amendment to our two existing lease agreements described above with Noblegene. The amendment added certain additional exclusions to the definition of ''operating costs'' in both of the lease agreements. The amendment also provided for us to pay $56,686 to Noblegene as a final payment of 2007 operating costs under one of the lease agreements.

In January 2009, we amended our August 2007 lease agreement with Noblegene. The amendment increased the base rent by $1.00 to $26.00 per rentable square foot (or, $65,000 per month) and provided for a one-time payment of $200,000 from us to Noblegene. We agreed to the increase in rent, and the one-time payment, to compensate Noblegene for increased construction costs due to the Company's requested changes in the building design. Our lease rate will be reduced at various intervals if the building's occupancy increases. In all other respects, the lease agreement remains the same.

In December 2009, we entered into new lease agreements for certain office equipment and copiers under agreements classified as capital leases. The leased assets serve as security for these liabilities.

Our Company's President and Chief Executive Officer is a former partner in Noblegene but maintained an ownership interest at the time we entered into both lease agreements. In March 2008, our CEO sold his ownership interest back to Noblegene. Since the owner of Noblegene is a brother-in-law of our CEO's wife, Noblegene continues to be a related party.

Purchase and Supply Obligations

Our ability to manufacture our product candidates depends on a limited number of specialty suppliers of raw materials. We have manufacturing and supply agreements with our specialty suppliers. As part of these agreements, we are required to make payments to the licensors and comply with other obligations as we progress through product development and commercialization. We have developed a network of suppliers, manufacturers, and contract service providers to provide sufficient quantity of raw materials for our product candidates through the development, clinical testing and commercialization phases. We have contractual obligations for supply agreements with Novartis, Kensey Nash and Cam Bioceramics BV (''Cam Bioceramics'') as follows:

Novartis/Chiron

In July 2004, we entered into a commercial supply agreement with Chiron Corporation (''Chiron'') that permitted us to obtain bulk supply of rhPDGF for use in manufacturing products for commercial sale. Subsequently, Novartis acquired Chiron and assumed the rights and responsibilities under the original agreement.

In December 2009, we amended and restated the manufacturing and supply agreement with Novartis to better define our respective obligations. Under the terms of the amended and restated agreement, Novartis agrees to continue to exclusively supply us with our requirements of rhPDGF-BB for use in periodontal and orthopedic applications. In addition, we remain obligated to purchase modified minimum specified quantities of rhPDGF with the product pricing varying depending on the quantity of rhPDGF that we order. The amended and restated agreement has an initial term of three years, and provides for automatic successive three-year renewal terms thereafter. During any renewal term the agreement may be terminated by either party upon six months' notice. Novartis agreed to manufacture rhPDGF-BB exclusively for us, and supply rhPDGF-BB exclusively to us, for use in the following fields: (1) treatment of periodontal and dental diseases; (2) cranio-maxillofacial applications; and (3) other skeletal applications including the healing of bone, cartilage, tendon and ligaments of the skeletal system. We agreed to purchase our requirements of rhPDGF-BB within these fields exclusively from Novartis.

If the Novartis amended and restated agreement is terminated by us due to (1) Novartis' material breach, (2) Novartis' bankruptcy, insolvency or similar condition or (3) Novartis' failure to deliver agreed upon quantities of rhPDGF-BB, or if Novartis terminates the Agreement for any reason other than a material breach by us or our bankruptcy, insolvency or similar condition, then Novartis is required, at our option, to provide to us a minimum quantity of rhPDGF-BB and use commercially reasonable efforts to assist us to indentify a new supplier and provide the new supplier, or third party manufacturer, with all necessary Novartis technology and supporting documentation required to produce rhPDGF-BB for us.

Kensey Nash

In June 2005, we entered into a Development, Manufacturing and Supply Agreement with Kensey Nash to develop commercial products using specific scaffolds manufactured and supplied by Kensey Nash for use in orthopedic and sports medicine applications. Under the agreement, Kensey Nash will exclusively manufacture and supply the scaffold materials for us and we will be responsible for final formulation, fill and finish activities. We are responsible for obtaining U.S. and foreign regulatory approvals for any resulting products. We are required to commercialize any resulting products in the United States within 12 months of receipt of FDA approval. We have the exclusive right to distribute and sell the resulting products worldwide. In addition, we agreed to pay royalties to Kensey Nash based on net sales of commercial products worldwide for the term of the agreement.

The agreement covers a 10-year term following the commercialization of a product, with two automatic two-year extensions, unless either party provides notice not to extend. If Kensey Nash elects not to extend the agreement, it is obligated to continue to supply us with predefined amounts of products for a limited time beyond the agreement's expiration. The agreement terminates if we do not make our first commercial sale of a product developed under the agreement within seven years. We paid Kensey Nash an initial payment on the effective date of the agreement. We made a second payment after we agreed to continue the agreement beyond a feasibility period.

In December 2006, we amended the agreement with Kensey Nash to accelerate certain milestone payments associated with the development of a matrix for sports medicine applications. In particular, we made a payment to Kensey Nash upon executing the amendment as compensation for development that had been completed relating to a matrix for sports medicine applications, and we agreed to make certain quarterly payments to Kensey Nash during 2007 and 2008. To offset these payments, the milestone payments in the original agreement relating to the first commercial sale of product were reduced by an amount equal to the quarterly payments and the payment made upon signing the amendment.

In August 2008, we terminated the then current development project relating to a product for tendon and ligament injury treatment being developed under the agreement. This termination was effective in September 2008, at which time we stopped making the quarterly payments to Kensey Nash. We are still required to make subsequent payments to Kensey Nash based on the achievement of certain regulatory and commercial milestones of other orthopedic products developed under the agreement.

In April 2008, we amended the agreement with Kensey Nash to provide for new payments from us to Kensey Nash for the accomplishment of certain development milestones for potential new product candidates.

Cam Bioceramics.

In August 2009, we entered into a master services agreement with Cam Bioceramics that permitted us to obtain bulk supply of beta-tricalcium phosphate (''ß-TCP''), which is a synthetic bone matrix used in our product candidate Augment and other product candidates. Under the terms of the agreement, Cam Bioceramics supplies us with ß-TCP for use in certain orthopedic applications. We are obligated to purchase minimum specified quantities of ß-TCP based on binding 12-month forecasts of quantities of ß-TCP that we require.

Equipment

We have executed agreements with various equipment suppliers for the manufacture of equipment that will be used in the new manufacturing facility described in ''Manufacturing'' above. As of December 31, 2009, we have paid a total of $4.2 million for the equipment which has been finished but not yet placed in service. In addition, under these agreements, we have estimated remaining purchase commitments of $0.6 million remaining to be paid through the year 2012.

Certain of our suppliers has the ability to curtail manufacturing of the products at their discretion with the only requirements being that each must provide a minimum level of future product prior to ending production and each must transfer the technology to another manufacturer.

Milestone, Asset Purchase and Royalty Payments

Various milestone and asset purchase payments are required under our agreements with Luitpold, Kensey Nash and Novartis, discussed above, as well as our intellectual property license agreements with ZymoGenetics, Inc. (''ZymoGenetics'') and Harvard University (''Harvard'') as discussed in ''Intellectual Property'' below. Luitpold is required to make certain milestone and asset purchase payments to us, and we are required to make certain milestone payments to ZymoGenetics, Harvard, Kensey Nash and Novartis, based on the occurrence of certain events. These milestones and asset purchase payments relate to the achievement of certain transfers of assets, clinical developments, regulatory filings and approvals and sales levels for Augment and *GEM 21S* and our product candidates. Under our 2003 agreements with Luitpold, upon receipt of FDA approval of *GEM 21S*, we received a $15.0 million milestone payment from Luitpold and an additional $5.0 million milestone payment from Luitpold on the second anniversary of our FDA approval. Under our 2007 asset purchase agreement with Luitpold, we received $15.0 million from Luitpold upon closing the transaction in January 2008, an additional $15.0 million 60 days following the closing, and an additional $10.0 million in time-based payments in 2009. We were required to make milestone payments to ZymoGenetics in connection with the initiation of pivotal clinical trials of *GEM 21S*, certain regulatory filings and approvals for *GEM 21S*, the receipt of FDA approval of *GEM 21S*, the filing of the Augment IDE, and the initiation of the Augment Canadian registration study. We were required to make milestone payments to Harvard in connection with the receipt of FDA approval of *GEM 21S*, the initiation of pivotal clinical trials of *GEM 21S*, our execution of a manufacturing and supply agreement with Novartis and our acquisition of certain patents from the Institute of Molecular Biology. We are required to make milestone payments to Kensey Nash in connection with certain time frames, the initiation of clinical trials, certain regulatory filings, product approvals, and/or commercial launch of Augment Injectable.

Under our 2008 agreements with Luitpold, upon approval of *GEM 21S* (now known as *GEMESIS*™ in Europe) in the EU, we are entitled to receive a $10.0 million milestone payment from Luitpold, who now owns the *GEM 21S* and *GEMESIS* products. The European Medicines Agency (''EMA'') previously determined that *GEMESIS* would be reviewed as a medicinal (i.e., a drug) combination product, and not as a medical device product which is how the product was reviewed in the United States and Canada. Accordingly, we filed a Marketing Authorization Application (''MAA'') for *GEMESIS*, but the EMA rejected our application, due in part to the different clinical and quality requirements of a drug product in the EU compared to a medical device product in the United States. We appealed that decision, but our appeal has been denied. We are currently re-evaluating our regulatory strategy for *GEMESIS* in the EU, and are considering seeking reclassification of *GEMESIS* from a medicinal to a medical device based on recent changes in the Medical Device Directives (''MDD''). Because of uncertainties in the review process, we have excluded this milestone payment from our financial guidance for 2010.

Many of the events triggering a milestone or asset purchase payment requirement remain contingent and have not yet occurred, or may occur following the expiration of an agreement. The only remaining payment to us under these agreements is the $10.0 million milestone payment that Luitpold would be obligated to pay to us when, and if, we obtain EU regulatory approval of *GEMESIS*. As previously noted, the timing of that payment remains uncertain. Excluding this Luitpold payment, and assuming that all future contingencies are met before the relevant agreements expire and all payments are made, we anticipate that the milestone payments that we are required to make in the near term, during 2010 and 2011, will result in a net payment by us of approximately $3.1 million. We anticipate that milestone payments by us from 2012 to 2014 will result in a net payment by us of approximately $7.1 million, resulting in an overall net payment by us of $10.2 million through 2014.

We are required to make minimum royalty payments to ZymoGenetics, however that obligation has now expired for periodontal products. For orthopedic products, the minimum royalty payments to ZymoGenetics consist of $1.0 million in the first full year following the first commercial sale, and $1.5 million and $2.5 million in the second and third years, respectively.

Other than the specific milestone payments listed above, we believe that a substantial portion of future milestone payments are not material to our business or prospects because we anticipate that they will occur well in the future, or they are conditioned upon achieving product sales targets which also are well in the future or represent sales targets which are substantially in excess of the current or foreseeable sales targets, the achievement of which, if attained, would be in the future.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our products, product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing upon our proprietary rights. We seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business.

We derive our patent rights from four sources: (1) ownership rights derived from technology we developed; (2) ownership rights purchased from the Institute of Molecular Biology; (3) licensing rights acquired from Harvard; and (4) licensing rights acquired from ZymoGenetics. We believe that our owned and licensed patents provide freedom to operate under patents that cover the composition and use of tissue growth factors.

Currently, the most important among these patent rights are three U.S. patents, each of which covers our current orthopedic product candidates (Augment and Augment Injectable) and *GEM 21S*. In addition, these patents may provide protection for additional product candidates under development depending on the final formulations for those products. One of these patents was recently issued in January 2009. This patent is based on technology that we developed internally, and covers product formulations that include a defined PDGF dosage range combined with a TCP or a TCP/collagen matrix having certain defined particle size and porosity characteristics. This patent will provide protection until at least June 2025. The second of these patents is a method patent that we co-own and exclusively license from Harvard. This patent covers the use of PDGF to promote the growth of damaged bone, periodontium or ligament, and its original term expired in June 2009. The U.S. Patent Office, however, has granted us a patent term extension for this patent as a result

of the FDA's regulatory review of *GEM 21S*. Under the term extension, this patent will now expire in March 2012 with respect to products covered by the patent that are used in the same indications for which *GEM 21S* has been approved. The third of these patents is exclusively licensed from ZymoGenetics in the dental and orthopedic fields. This patent is a composition patent that covers the isolated form of rhPDGF included in our current orthopedic product candidates and *GEM 21S*, and as a result of a term extension will expire in October 2010.

Outside of the United States, Augment, Augment Injectable and *GEM 21S* are protected in Australia and South Africa by issued patents that are counterparts to our US patent noted above that issued in January 2009. Similar patent applications have been approved in Europe and in Mexico, and the issuance of those patents is pending. Counterparts to these patents are also pending in a numerous additional countries around the world including Canada and Japan. Like the U.S. patent, the Australian and South African patents will expire in 2025, and we expect that the approved European and Mexican patents, as well as any of the other pending patent applications, if approved, will also expire 2025. Although the U.S., Australian and Mexican patents were granted, we cannot be certain that the remaining pending counterpart foreign patent applications will ultimately be granted, or if granted that the scope of the claims would be broad enough to provide protection for Augment, Augment Injectable, *GEM 21S* or our other product candidates. In addition to these patents, Augment Injectable and *GEM 21S* are protected in the EU and Canada by licensed patents that are counterparts to the ZymoGenetics U.S. patent noted above. The EU patent expires in October 2010, and the Canadian patent expires in 2015.

In total we now own or co-own 12 U.S. patents, about 80 foreign patents, and 68 pending U.S. and foreign patent applications. Furthermore, we have exclusively licensed 19 U.S. patents and over 50 foreign patents. The following is a summary of all our patent rights.

Rights Owned Based on Internally Developed Technology

With regard to technology that we developed internally we now own three issued patents in the United States, Australia and South Africa, and numerous pending U.S. utility patent applications, U.S. provisional patent applications, international utility patent applications, and national phase foreign applications. The issued patents cover Augment, Augment Injectable, and *GEM 21S*. The pending patent applications seek to cover specific dosages of PDGF or specific medical applications of PDGF that we have developed. Our patent applications are pending review by the U.S. Patent and Trademark Office and by various foreign patent offices. We are unable to predict what protection will be afforded by these applications or if any protection will be ultimately granted.

Rights Purchased from IMB, Including Rights Co-Owned and Exclusively Licensed from Harvard

We own an additional 11 U.S. patents and numerous foreign counterpart patents, which were purchased from the Institute of Molecular Biology (''IMB''). Nine of the patents purchased from IMB are co-owned with Harvard. As discussed further below, Harvard has exclusively licensed its rights in these patents to us. Several of these patents cover compositions of various growth factors, including PDGF, either alone or in combination with one another. Others of these patents cover methods of using such compositions to heal wounds or to promote the growth of bone, ligaments, or nerves. Of these 11 owned U.S. patents, four remain unexpired, one of which remains in force only as a result of a patent term extension based on the regulatory review period of *GEM21S*. The next of these patents to expire will occur in March 2012, and the last of these patents will expire in January 2020. The seven patents that have expired did not cover our current orthopedic product candidates or *GEM 21S*. With regard to the one patent that remains in force as result of the patent term extension, its natural term expired in 2009, and as result that patent no longer provides protection for our orthopedic product candidates and only provides protection for *GEM21S*.

We entered into a license agreement with Harvard that provides us with an exclusive worldwide license to the patents we co-own with Harvard, and which are directed towards the use of rhPDGF and other growth factors for the healing and restoration of bone and other tissue defects. The agreement term extends to the date of the last to expire licensed patent. Under the agreement we are obligated to make certain royalty and milestone payments to Harvard. Harvard may terminate the agreement if we fail to make such payments, maintain certain insurance requirements, or fail to pursue commercialization of the licensed technology. In addition, Harvard may terminate the agreement if we are convicted of certain criminal acts, become insolvent,

or breach an obligation under the agreement and fail to cure the breach within 120 days of notice. We may terminate the agreement by giving Harvard 120 day's written notice of our intent to do so.

Rights Licensed from ZymoGenetics

We have licensed 19 U.S. patents and their foreign counterparts from ZymoGenetics covering various formulations of PDGF or manufacturing processes for PDGF. Of the six of these licensed U.S. patents that remain unexpired under their original patent terms, the first patent will expire in December 2012 and the last of these patents will expire in May 2016. An additional ZymoGenetics licensed patent remains in force as a result of a patent term extension. The term extension will expire in October 2010.

We entered into two license agreements with ZymoGenetics that give us the exclusive rights within certain fields of use under the ZymoGenetics patents. The first agreement, entered into in March 2001, provides us with rights to develop rhPDGF in the periodontal and cranio-maxillofacial applications. Under this agreement, we acquired a license under patent rights and know-how controlled by ZymoGenetics, to develop, make, import, sell and commercialize products for the treatment of periodontal disease and bone defects of the head and face. We paid ZymoGenetics an initial license fee and agreed to meet certain due diligence milestones, including working to register one or more of the licensed products for commercial sale. In addition, we agreed to pay royalties to ZymoGenetics based on net sales of licensed products on a country-by-country basis for the term of the agreement. We also are responsible for payments based upon the achievement of certain milestones as well as a sales bonus payment if total sales by us, our affiliates and sublicensees exceed an agreed upon threshold. In addition, we were required to pay ZymoGenetics a sublicense fee as a result of the sublicense to the ZymoGenetics' patents that we granted to Luitpold. Virtually all of our rights under this agreement have been sublicensed to Luitpold, initially in a December 2003 exclusive sublicense agreement and later in a 2008 amended and restated sublicense agreement as part of our sale of our dental business to Luitpold.

The second ZymoGenetics license agreement, entered into in January 2003, expands the field of use for the development of rhPDGF to include bone, cartilage, tendon and ligament applications. We paid ZymoGenetics an initial license fee in shares of our common stock, and agreed to meet certain similar due diligence milestones as under the 2001 license described above. We also agreed to pay royalties to ZymoGenetics based on net sales of licensed products on a country-by-country basis for the term of the agreement. In addition, during the term of the agreement, we are responsible for payments based upon the achievement of certain milestones as well as a sales bonus payment if total sales by us, our affiliates and sublicensees exceed an agreed upon threshold.

Both ZymoGenetics agreements expire on a country-by-country basis upon the expiration of the last to expire patent in each country. Either party may terminate these agreements upon the insolvency of the other party, or if the other party breaches a material provision and fails to cure such breach within 60 days of notice.

Potential Intellectual Property Issues

Some of our competitors and others manufacture and sell products containing some of the components of *GEM 21S* and Augment, namely rhPDGF-BB and ß-TCP. Certain intellectual property covering our use of rhPDGF-BB is owned and licensed to us by ZymoGenetics. ZymoGenetics has licensed rhPDGF-BB to other third parties for technical uses and indications that differ from ours. ß-TCP has been used in various products for over 20 years, and we are not aware of any intellectual property covering ß-TCP that our products would infringe.

Although we believe that the patents and patent applications, including those that we license, provide a competitive advantage, the patent positions of biopharmaceutical and device companies are highly complex and uncertain. The combination product and medical device industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Furthermore, as the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. Although we have not received notice of any claims, and are not aware that our product candidates infringe other parties' patents and proprietary rights, our product candidates and methods may be covered by U.S. patents held by our competitors. Any claim relating to infringement of patents that is asserted against us

may be costly and time-consuming to defend, would divert the attention of our management and key personnel, and may require us to pay substantial damages. If a successful infringement claims is asserted against us, we may be unable to commercialize some of our product candidates unless we are able to obtain a license, or may have to cease some of our business operations, which could severely harm our business. Consequently, our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors, as well as our ability to enforce our patent rights.

We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position. We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors who we expect to work on our product and product candidates to agree to disclose and assign to us all inventions conceived during the work day, developed using our property or which relate to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our product and product candidates or to obtain and use information that we regard as proprietary.

In the future, we may collaborate with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, licensors and consultants. In addition, other parties may circumvent any proprietary protection that we do have. As a result, we may not be able to maintain our proprietary position.

Trademarks

Augment™ and *OsteoMimetic*™ are our only trademarks. *GEM 21S*®, *GEM 21A*™, and *GEM*® were transferred to Luitpold in connection with our divestiture of our orofacial therapeutic business. As part of that transaction, we abandoned applications for registration of *GEM OS*, *GEM C,* and *GEM LT* in the United States and abroad.

Competition

The market for new orthobiologic products is highly competitive. The market is characterized by extensive research efforts and rapid technological change. We face intense competition worldwide from medical device, biomedical technology and medical products and combination products companies, including major pharmaceutical companies. We may be unable to respond to technological advances through the development and introduction of new products. Many of our existing and potential competitors have substantially greater financial, marketing, sales, distribution, manufacturing and technological resources than us. These competitors also may be in the process of seeking FDA or other regulatory approvals, or patent protection, for new products. Our competitors may commercialize new products in advance of our products. Our products also face competition from numerous products and procedures, which currently are considered part of the standard of care. In order to compete effectively, our products will have to achieve widespread market acceptance.

Augment

Our Augment product candidates will compete with an array of synthetic bone graft materials, ranging from resorbable pure phase ß-TCP granules to calcium sulfate pre-formed pellets. In addition, more than 20 allograft base tissue and demineralized bone matrix options are available to orthopedic surgeons. If we elect to pursue spinal fusion, tibial factures or non-union fractures, we will also compete with bone morphogenetic proteins, including INFUSE (BMP-2,Medtronic) and OP-1 (BMP-7, Stryker Corporation). INFUSE and OP-1 may be under review for additional indications which could compete with our products.

Some of the largest orthopedic companies in the United States include Stryker, DePuy Orthopaedics, Inc. (a subsidiary of Johnson & Johnson), Zimmer Holdings, Inc., Medtronic, Synthes, Inc., Biomet, Inc., Smith & Nephew Group plc and Wright Medical Group, Inc. These companies distribute allograft and synthetic bone graft materials. In addition, some of the nation's largest tissue processors and procurement agencies (including Osteotech, Inc., the Musculoskeletal Transplant Foundation (''MTF'') Regeneration Technologies, Inc., LifeCell Corporation and CryoLife, Inc.) and numerous tissue banks also distribute allograft tissue. Osteotech distributes its products directly and through agreements with DePuy, Smith & Nephew, MTF and the American Red Cross. MTF also processes allograft into a proprietary demineralized bone matrix, which is distributed by Synthes, while Regeneration Technologies' allograft tissue is used in a variety of graft materials distributed by Exactech, Inc., Medtronic and Stryker.

Biomet, DePuy and Medtronic also sell PRP systems, while Wright Medical's Ignite system and Orthovita's Imbibe syringe cater to surgeons who prefer to use bone marrow aspirate (''BMA'').

Cartilage, Ligament and Tendon

We expect our cartilage, ligament and tendon product candidates to compete against currently approved therapies, including: viscosupplementation, the articular cartilage implantation product, Carticel® (distributed by Genzyme Tissue Repair), tendon repair overlays as well as the commercially available PRP and BMA systems discussed above.

Regulatory Matters

FDA Regulation

Each of our products must be cleared or approved by the FDA before it is marketed in the United States. Before and after approval or clearance in the United States, our product candidates are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and/or the Public Health Service Act, as well as by other regulatory bodies. FDA regulations govern, among other things, the following activities in which we and our contract manufacturers, contract testing laboratories and suppliers are involved:

- product development;
- product testing;
- product manufacturing;
- product labeling;
- product safety;
- product storage;
- product market clearance or approval;
- product advertising and promotion;
- product import and export; and
- product sales and distribution.

Failure to comply with the law could result in, among other things, warning letters, civil penalties, delays in approving or refusal to approve a product candidate, product recall, product seizure, interruption of production, operating restrictions, suspension on withdrawal of product approval, injunctions, or criminal prosecution.

The FDA has determined that Augment and Augment Injectable are combination products because they consist of a combination of a device (ß-TCP) and a biologic drug (rhPDGF). For a combination product, the FDA determines what center or centers within the FDA will review the product and its indication for use, and also determines under what legal authority the product will be reviewed. For the current indications, Augment and Augment Injectable are being reviewed by the Center for Devices and Radiological Health (''CDRH''), with participation by the Center for Drug Evaluation and Research (''CDER''), under the medical device regulations. With respect to certain of our other product candidates, the FDA may determine that they should be regulated as drugs with CDER as the lead Center and CDRH as the consulting Center, in which case the governmental review requirements would vary in some respects. If a product candidate were reviewed under the drug or biologic regulations by a different FDA Center (the CDER, for example), then the regulatory requirements could change and additional and/or different data may be required.

FDA Approval or Clearance of Medical Devices

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and efficacy:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: general controls, pre-market notification (510(k)), and specific controls such as performance standards, patient registries, and post-market surveillance; and
- Class III: general controls and approval of a pre-market approval (''PMA'') application.

All of our product candidates are in Class II or Class III, and require FDA authorization prior to marketing, by means of either a 510(k) clearance or a PMA approval. The FDA has determined that Augment and Augment Injectable are class III devices requiring a PMA. Our product candidates containing a grafting material alone should be eligible for clearance via the 510(k) route. For example, we obtained clearance for a 510(k) application for clearance of ß-TCP grafting material as ''bone void filler.''

To request marketing authorization by means of a 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to another legally marketed medical device; that is, it has the same intended use, and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than does a legally marketed device. 510(k) submissions generally include, among other things, a description of the device and its manufacturing, device labeling, medical devices to which the device is substantially equivalent, safety and biocompatibility information, and the results of performance testing. In some cases, a 510(k) submission must include data from human clinical studies. Marketing may commence only when the FDA issues a clearance letter finding substantial equivalence. After a device receives 510(k) clearance, any product modification that could significantly affect the safety or effectiveness of the product, or that would constitute a significant change in intended use, requires a new 510(k) clearance or, if the device would no longer be substantially equivalent, would require a PMA. If the FDA determines that the product does not qualify for 510(k) clearance, then the company must submit and the FDA must approve a PMA before marketing can begin.

A PMA application must provide a demonstration of safety and effectiveness, which generally requires extensive pre-clinical and clinical trial data. Information about the device and its components, device design, manufacturing and labeling, among other information, must also be included in the PMA. As part of the PMA review, the FDA will inspect the manufacturer's facilities for compliance with Quality System Regulation, or QSR, requirements, which govern testing, control, documentation and other aspects of quality assurance with respect to manufacturing. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. If the FDA finds the information satisfactory, it will approve the PMA. The PMA approval can include post-approval conditions including, among other things, restrictions on labeling, promotion, sale and distribution, or requirements to do additional clinical studies post-approval. Even after approval of a PMA, a new PMA or PMA supplement is required to authorize certain modifications to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA. During the review of either a 510(k) or PMA, the FDA may request more information or additional studies and may decide that the indications for which we seek approval or clearance should be limited. We cannot be sure that our product candidates will be cleared or approved in a timely fashion or at all. The review of combination products is often more complex and more time consuming than the review of a product under the jurisdiction of only one center within the FDA. In addition, laws and regulations and the interpretation of those laws and regulations by the FDA may change in the future. We cannot foresee what effect, if any, such changes may have on us.

Clinical Trials of Medical Devices

One or more clinical trials are required in most cases to support a PMA application and are sometimes required to support a 510(k) submission. Clinical studies of unapproved or uncleared medical devices or devices being studied for uses for which they are not approved or cleared (investigational devices) must be conducted in compliance with FDA requirements. If an investigational device could pose a significant risk to patients, the sponsor company must submit an IDE application to the FDA prior to initiation of the clinical study. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. Clinical studies of investigational devices may not begin until an institutional review board, or IRB, has approved the study.

During the study, the sponsor must comply with the FDA's IDE requirements. These requirements include investigator selection, trial monitoring, adverse event reporting, and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. We, the FDA, or the IRB at each institution at which a clinical trial is being conducted may suspend a clinical trial at any time for various reasons, including a belief that the subjects are being exposed to an unacceptable risk. During the approval or clearance process, the FDA typically inspects the records relating to the conduct of one or more investigational sites participating in the study supporting the application.

Post-market Regulation of Medical Devices

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- the QSR regulation, which governs, among other things, how manufacturers design, test, manufacture, exercise quality control over, and document manufacturing of their products;
- labeling and claims regulations, which prohibit the promotion of products for unapproved or ''off-label'' uses and impose other restrictions on labeling; and
- the Medical Device Reporting regulation, which requires reporting to the FDA certain adverse experiences associated with use of the product.

We continue to be subject to inspection by the FDA to determine our compliance with regulatory requirements, as do our suppliers, contract manufacturers, and contract testing laboratories.

International sales of medical devices manufactured in the United States that are not approved or cleared by the FDA are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported.

FDA Approval of Drug Products

The steps required before a drug may be approved by the FDA and marketed in the United States include:

- pre-clinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an investigational new drug exemption (''IND'') for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of a new drug application (''NDA'');
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices (''cGMP''); and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluations of the drug's chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND does not necessarily result in the FDA allowing clinical trials to commence.

Clinical Trials of Drug Products

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring subject safety, and the effectiveness criteria, or endpoints, to be evaluated. Each protocol must be submitted to the FDA as part of the IND and the FDA may or may not allow that trial to proceed.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Each trial must be reviewed and approved by an independent Institutional Review Board before it can begin. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its safety, dosage tolerance, pharmacodynamics, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate preliminarily the efficacy of the drug for specific indications.

Phase III trials usually further evaluate clinical efficacy and test further for safety by administering the drug in its final form in an expanded patient population. We cannot guarantee that Phase I, Phase II or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more indications. Before approving an application, the FDA usually will inspect the facility or the facilities at which the drug is manufactured, and will not approve the drug unless cGMP compliance is satisfactory. If the FDA determines the application or manufacturing facilities are not acceptable, the FDA may outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. During the review period, an FDA advisory committee, typically a panel of clinicians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions the drug should be approved. After approval, certain changes to the approved drug, such as adding new indications, manufacturing changes, or additional labeling claims, are subject to further FDA review and approval before the changes can be implemented. The testing and approval process requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis, if at all. As a condition of approval of an application, the FDA may require postmarket testing and surveillance to monitor the drug's safety or efficacy.

Post-Market Regulation of Drug Products

After the FDA approves a drug product, we and our contract manufacturers must comply with a number of post-approval requirements. For example, holders of an approved NDA are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their drug products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects

manufacturing facilities to assess compliance with cGMP. Accordingly, we and our contract manufacturers must continue to expend time, money, and effort to maintain compliance with cGMP and other aspects of regulatory compliance.

We use and will continue to use third-party manufacturers to produce our products and product candidates in clinical and commercial quantities, and we cannot be sure that future FDA inspections will not identify compliance issues 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 product candidate may result in restrictions on a product, product candidate, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market or suspension of a clinical trial involving a product candidate.

International Regulation

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- product standards;
- packaging requirements;
- labeling requirements;
- import and export restrictions; and
- tariff regulations, duties and tax requirements.

The time required to obtain clearances or approvals by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The primary regulatory body in Canada is Health Canada. In addition to needing appropriate data to obtain market licensing in Canada, we must have ISO 13485:2003 certification. We currently have this certification and will need to maintain it in order to maintain our approval of Augment in Canada and to have the potential to gain approval of additional product candidates in Canada.

The primary regulatory environment in Europe is that of the EU, which consists of 25 member states and 42 competent authorities encompassing most of the major countries in Europe. In the EU, the EMA and the EU Commission have determined that *GEMESIS* will be regulated as medicinal products.

We formed a wholly owned subsidiary in the United Kingdom, BioMimetic Therapeutics Limited, in October 2005 to facilitate our EU regulatory filings. We cannot be sure that additional clinical trials will not be required to obtain EU regulatory approval for *GEMESIS*, or that such approval will be granted in a timely fashion, or at all.

U.S. Anti-kickback and False Claims Laws

In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of combination products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other potential purchasers of such products. Other provisions of state and federal law provide civil and criminal penalties for presenting, or causing to be presented, to third-party payers for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. Although we plan to structure our future business relationships with purchasers of our products to comply with these and other applicable laws, it is possible that some of our business practices in the future could be subject to scrutiny and challenge by federal or state enforcement officials under these laws. This type of challenge could have a material adverse effect on our business, financial condition and results of operations.

Third-party Reimbursement

We anticipate that sales volumes and prices of Augment and any other products we commercialize will depend in large part on the availability of reimbursement from third party payers. Third party payers include governmental programs such as Medicare and Medicaid, private insurance plans, and workers' compensation plans. These third party payers may deny reimbursement for a product or therapy if they determine that the product or therapy was not medically appropriate or necessary. The third party payers also may place limitations on the types of physicians that can perform specific types of procedures. Also, third party payers are increasingly challenging the prices charged for medical products and services. Some third party payers must also approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution, we may find limited demand for the device until reimbursement approval has been obtained from governmental and private third party payers.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third party payers, that an adequate level of reimbursement will be available or that the third party payers' reimbursement policies will not adversely affect our ability to sell our products profitably.

A key component in the reimbursement decision by most private insurers and the Centers for Medicare & Medicaid Services, which administers Medicare, is the assignment of an ICD-9 code, covering inpatient surgical procedures or a Current Procedural Terminology (''CPT'') code, which covers outpatient, ambulatory surgical center procedures. These codes are used in the submission of claims to insurers for reimbursement for medical services. While there are no specific ICD-9 or CPT codes for our product candidates, the target procedures such as ankle fusions and open fracture treatment do have specific procedure codes which provide a global payment for all products and services related to the surgical procedure. Consequently, we are confident that procedural coding will not be an issue. The challenge that we will face in the reimbursement arena is convincing third party payers to cover the use of our products, when reported under the existing surgical codes. We intend to provide clinical evidence and economic arguments to payers to detail how the use of our products provide equivalent clinical outcomes to autologous bone graft, but avoid the additional time, patient discomfort and potential morbidity related to the harvesting of the autologous bone graft. For certain other indications of our orthopedic product candidates (e.g., closed fractures), a new reimbursement code will likely be required, and we will seek a new code prior to commercializing such product candidates.

In the United States, some insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs are paying their providers on a per capita basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month, and consequently, may limit the willingness of these providers to use our products.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third party payers will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third party payer coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

Subsidiaries

In October 2005, we formed a wholly owned subsidiary in the United Kingdom, BioMimetic Therapeutics Limited, for the purpose of effecting our EU regulatory filings. In October 2006, we formed a wholly owned subsidiary, BioMimetic Therapeutics Pty Ltd., for the purpose of effecting our Australian regulatory filings.

Employees

As of December 31, 2009, we employed 89 people, of which 39 were employed in research and development, 21 in regulatory and quality assurance, six in operations and 23 in general and administrative. One employee holds both D.M.D and D.M.Sc. degrees, one employee holds a Danish M.Sc., and nine additional employees hold Ph.D. degrees. None of our employees are represented by a labor union, and we believe our employee relations are good.

Corporate and Investor Information

Our company was incorporated in Tennessee in April 1999 under the name BioMimetic Pharmaceuticals, Inc. In June 2001, we reincorporated in Delaware, and in July 2005, we changed our corporate name to BioMimetic Therapeutics, Inc. We make available on our website (*www.biomimetics.com*), free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to the Exchange Act as soon as reasonably practicable after we electronically file such material with, or otherwise furnish it to, the Securities and Exchange Commission (''SEC'').

Item 1A. RISK FACTORS

Risks Relating to Our Business

Current economic conditions could adversely affect our operations.

According to the National Bureau of Economic Research, the U.S. economy entered into a recession in December 2007. Although the U.S. Commerce Department has reported economic growth in the third and fourth quarters of 2009 and many economists now believe that the recession has ended, the continuing economic uncertainty and the ensuing market instability have made the business more volatile and more costly. Consequently, our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets do not continue to improve, or if they deteriorate further, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. We believe our existing cash and investments, which includes $25.0 million in gross proceeds from stock offerings in 2009 and $10.0 million in time-based payments received from Luitpold in 2009, will be sufficient to meet our anticipated cash requirements at least through the middle of 2011. However, a more radical economic downturn or increase in our expenses could require us to seek additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price, and could require us to delay or abandon product development plans or plans to acquire additional technology.

There is a risk that one or more of our suppliers, clinical investigators, consultants and other partners may encounter difficulties during these challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

The current conditions may also adversely affect our potential customers, including patients, medical professionals and their practices, hospitals and other health care providers. These conditions may also impact the overall amount spent on healthcare generally. This could result in a decrease in the demand for our products, longer sales cycles, slower adoption of our new technology and increased price competition.

Our product candidates are in various stages of development and may not be developed or commercialized successfully.

Our product candidates are based on technologies that have not been used previously in the manner and combination we propose and must compete with more established treatments currently accepted as the standards of care. Market acceptance of our products will largely depend on our ability to demonstrate their relative safety, efficacy, cost-effectiveness and ease of use.

We are subject to the risk that:

- the FDA or a foreign regulatory authority finds some or all of our product candidates ineffective or unsafe;
- we do not receive necessary regulatory approvals;
- we are unable to get some or all of our product candidates to market in a timely manner;
- we are not able to produce our product or product candidates in commercial quantities at reasonable costs;
- our products undergo post-market evaluations resulting in marketing restrictions or withdrawal of regulatory approval of our products; and
- the patient and physician community does not accept our product or product candidates.

In addition, our product development programs may be curtailed, redirected, eliminated or delayed at any time for many reasons, including:

- adverse or ambiguous results;
- undesirable side effects that delay or extend the trials;

- inability to locate, recruit, qualify and retain a sufficient number of clinical investigators or patients for our trials;
- regulatory delays or other regulatory actions;
- failure to satisfy one or more requirements or restrictions imposed by the FDA as a basis for approving the initiation of a clinical study;
- difficulties in obtaining sufficient quantities of the particular product candidate or any other components needed for our pre-clinical testing or clinical trials;
- difficulties in obtaining the necessary regulatory support from our raw materials suppliers to enable us to obtain or maintain regulatory approval to market our product or product candidates; or
- re-evaluation of our clinical development strategy.

We cannot predict whether the commercialization of Augment in Canada will be successful or whether we will successfully develop and commercialize any of our product candidates. If we fail to do so, we will not be able to generate substantial revenue, which would have a material, adverse effect on our business, financial condition and results of operations.

Our current product candidates are all based on the same protein, rhPDGF-BB. If one of our product candidates, or one of another company's products or product candidates containing rhPDGF-BB or a similar growth factor, reveals safety or fundamental efficacy issues in clinical use or in clinical trials, then the development path for all our other current product candidates may be adversely impacted.

The development of each of our product candidates is based on our understanding of how the protein rhPDGF-BB contributes to the repair of bone and soft tissue. Soft tissue includes muscles, tendons and ligaments that connect, support or surround the bones and organs of the body. While there are important differences in each of our product candidates in terms of its purpose, each product candidate focuses on accelerating the repair of musculoskeletal tissue and relies on the ability of rhPDGF-BB to stimulate the body's natural healing processes.

Since we are developing our product candidates in parallel, if one product candidate experiences negative clinical trial results or is shown to be ineffective, it may impact the development path or future development of the other product candidates. If we find that one product candidate is unsafe, there may be an adverse effect on the development of our other product candidates.

If a product or product candidate developed by another company contains the same protein rhPDGF-BB, or a similar growth factor, as our product candidates, and if its product or product candidate reveal safety or fundamental efficacy issues, then the development of our product candidates may be impacted as well. Likewise, investor perception concerning a potentially adverse impact on our product candidates may cause our stock price to decline or may result in stock price volatility.

If we fail to meet our obligations under our existing license agreements or fail to enter into new license agreements, our business may be materially adversely impacted.

Our rights to the development, use and marketing of our product candidates are governed by a series of licensing agreements, including those with Harvard and ZymoGenetics. These license agreements provide us with rights to certain intellectual property created by the licensor, which allow us to develop and commercialize our product and product candidates.

As part of these agreements, during the term of the agreements we are required to make payments to the licensors and comply with other obligations as we progress through product development and commercialization. If we fail to make these payments or satisfy other obligations for any reason, these licenses could be terminated by the licensors, thereby possibly limiting our ability to market our product or limiting our ability to maintain exclusivity with respect to our product or product candidates. Furthermore, if a dispute arises regarding our obligations under these agreements, our business may be materially adversely impacted.

Our licensors or others may dispute the scope of our rights under any of these licenses. Additionally, the licensors under these licenses might breach the terms of their respective agreements or fail to prevent infringement of the licensed patents by third parties. Loss of any of these licenses for any reason could materially harm our financial condition and operating results.

We may need additional licenses to intellectual property owned by third parties in order to commercialize new products. If we cannot obtain these additional licenses, we may not be able to develop or commercialize these future products.

Our rights to use technologies licensed to us by third parties are not entirely within our control, and we may not be able to produce our product and product candidates without these technologies.

We depend upon a limited number of specialty suppliers of raw materials.

Our ability to manufacture our product candidates depends on a limited number of specialty suppliers of raw materials. In particular, we depend upon Novartis to supply us with sufficient quantities of rhPDGF for commercial production and clinical development activities and to meet the commercial demand for our product. We are obligated to purchase minimum specified quantities of rhPDGF. Our agreement with Novartis may be terminated under certain circumstances.

We have established certain relationships with ß-TCP suppliers and are continuing to evaluate ß-TCP products and other matrices from these potential suppliers for use in orthopedic applications. There is a risk that we will not be able to secure adequate sources of rhPDGF or ß-TCP to meet our clinical and commercial needs for our orthopedic applications.

The failure of a supplier to continue to provide us with these materials at a price or quality acceptable to us, or at all, would impede our ability to manufacture Augment for the Canadian market and our product candidates. Moreover, our failure to maintain strategic reserve supplies of each significant single-sourced material used to manufacture Augment and the product candidates that we develop may negatively impact our development and commercialization activities. If our specialty suppliers cannot perform as agreed, we may not be able to replace them in a timely manner or on terms that are acceptable to us and the production of our product candidates would be interrupted, resulting in delays in clinical trials and additional costs. We will be required to obtain regulatory clearance from the FDA or foreign regulatory authorities before we can use different suppliers or components. If we have to switch to replacement suppliers, we may face additional regulatory delays and the manufacture and delivery of Augment in Canada and our product candidates could be interrupted for an extended period of time, which may delay completion of our clinical trials, regulatory approval of our product candidates or commercialization of any approved products.

We and our suppliers are subject to numerous federal, state and local laws relating to matters, including safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. In addition, advertising and promotional materials relating to medical devices are subject to regulation by the Federal Trade Commission in specific instances. We and our suppliers may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements, our failure or the failure of our manufacturers to comply with these requirements, or the adoption of new requirements could delay the development of our product candidates or regulatory approval of our product candidates or successful commercialization of any approved products, resulting in additional losses to us.

We may be unable to establish or enter into the necessary business relationships and agreements with other companies who provide a component critical to the development and commercialization of our product candidates.

We rely heavily upon arrangements with third-parties for intellectual property, raw materials, manufacturing assistance, regulatory assistance and other assistance necessary to develop and market Augment in Canada and our other product candidates. Our strategy includes continuing to develop business relationships with other biotechnology companies to assist in the commercialization efforts for our product candidates. We face significant competition in seeking appropriate business relationships, which may be complex and time-consuming to negotiate, document and implement. We may not be able to enter into any such business

relationships or agreements on terms that are acceptable to us, or at all. If that were to happen, we may have to curtail the development or delay the commercialization of our product candidates.

We currently do not have an alternative source of rhPDGF. If we are not able to obtain rhPDGF from Novartis, we may not be able to meet our supply obligations to Luitpold for rhPDGF after our current inventory is depleted. Based on our current forecasts for our rhPDGF needs, our planned clinical study programs for our product candidates and our anticipated pre-clinical studies, and sales forecasts of Augment, which was recently approved for use in Canada, the rhPDGF in our inventory, in addition to our minimum purchase commitments of rhPDGF in 2010, should meet our needs for approximately the next 18 months. Under the terms of our supply agreement, Novartis is required to support our efforts to establish our continued production of rhPDGF should it terminate the agreement; however, establishing a manufacturing process to replace Novartis' may take multiple years and a significant financial investment to complete, if at all, and there is no assurance we would be successful in that effort. We also may not be able to manufacture any product candidates that contain rhPDGF, including our lead product candidate, Augment, after our current inventory is depleted.

We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We are moving forward with plans to occupy a new manufacturing facility in the same complex as our headquarters in Franklin, Tennessee. We intend to move certain steps of the later stages of the manufacturing process of our orthopedic and sports medicine product and product candidates into that facility, including final formulation, filling the vials that will be packaged in the finished kits, and assembling the kits. The building shell was completed in late 2009, and we expect the build out will begin in 2010 or 2011. In order to qualify the facility as a GMP manufacturing facility, the build out must be complete, the utility systems, process and testing equipment must be installed and qualified, regulatory filings must be assembled and filed, and regulatory agency inspections must be passed prior to receiving approval. We anticipate that the facility will be approved for commercial operations within two years of our starting the build out. We cannot be certain, however, whether the FDA will approve the manufacturing facility.

Currently we are utilizing at least four contract facilities to complete the manufacturing, packaging and final product testing for Augment (for our Canadian commercial product and for our clinical study kits), and we are using at least three contract facilities to complete the manufacturing, packaging and final product testing for our Augment Injectable clinical study kits. If there were a disruption to the new manufacturing facility or those of our contract manufacturers, we would have no other means of manufacturing our product and product candidates until we were able to restore the manufacturing capability at the new facility or develop alternative manufacturing facilities. If we are unable to produce sufficient quantities of our product for meeting sales targets in Canada or of our product candidates for use in our current and planned clinical trials, or if our manufacturing process yields substandard products, then our product development efforts could be delayed and/or our sales and commercialization efforts could be adversely impacted.

We have limited resources, facilities and experience to commercially manufacture our product and product candidates. In order to produce our product and product candidates in the quantities that we anticipate will be required to meet future market demand, we will need to complete qualification of the commercial scale production process at our contract facilities and at our in-house facility. There are technical challenges to developing and qualifying commercial-scale manufacturing operations. Further, building a new facility will require the investment of substantial additional funds as well as hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete the process qualification activities in a timely manner. This could strain our existing managerial, operational, financial and other resources. Furthermore, if we fail to manage our growth effectively we may not be able to produce our product and product candidates in sufficient quantities to meet the future requirements of the products. If we are unable to manufacture a sufficient supply of Augment or any product candidate, our revenues, business and financial prospects would be adversely affected. In addition, if the in-house production process is not efficient or produces products that do not meet quality and other standards, our future gross margins may decline.

If we are unable to establish adequate sales and marketing capabilities, we may not be able to generate significant revenue and may not become profitable.

We do not have a dedicated sales force and have limited experience in the sales, marketing and distribution of regenerative protein therapeutic-device combination products or drug products. In order to commercialize our product candidates, we must develop our sales, marketing and distribution capabilities or make arrangements with a third party to perform these functions. If we are unable to establish adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable.

As a result of any arrangements we may enter into with third parties to perform sales, marketing and distribution services, our product revenues could be lower than if we directly marketed and sold Augment in Canada or any other product candidate that we may develop. Furthermore, as a result of our Canadian distribution agreement with Joint Solutions, our Australian distribution agreement with Surgical Specialties, or other marketing and sales arrangements we may enter into with other companies, any revenues received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of our future distributors may have products or product candidates that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. If our relationships with Joint Solutions, Surgical Specialties or future distributors do not progress as anticipated, or if their sales and marketing strategies fail to generate sales of our products in the future, our business, financial condition and results of operations would be harmed.

The orthopedic product industries are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer and more effective than any products that we may develop, our commercial opportunity will be reduced or eliminated.

Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of biologics. We face competition from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions in the United States and abroad. Many of our principal competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with, or mergers with or acquisitions by, large and established companies or through the development of novel products and technologies.

Our competitors may:

- develop and patent processes or products earlier than us;
- obtain regulatory approvals for competing products more rapidly than us; or
- develop more effective or less expensive products or technologies that render our technology or product and product candidates obsolete or non-competitive.

The industry in which we operate has undergone, and we expect it to continue to undergo, rapid and significant technological change, and we expect competition to intensify as technological advances are made. Our competitors may develop and commercialize medical devices, regenerative protein therapeutic-device combination products, biologic products or pharmaceutical products that are safer or more effective, have fewer side effects or are less expensive than any products that we may develop. For example, we are aware of companies that are developing various other technologies for treating orthopedic injuries and disease, which could make our product candidates obsolete. We also compete with our competitors in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

If our product and product candidates do not gain market acceptance among physicians, patients and the medical community, we may be unable to generate significant revenue, if any.

Even if we obtain regulatory approval for our product candidates, they may not, and Augment in Canada may not, gain market acceptance among physicians, healthcare payers, patients and the medical community. Market acceptance will depend on our ability to demonstrate the benefits of our approved products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. In addition, we believe market acceptance depends on the effectiveness of our marketing strategy, the pricing of our approved products and the reimbursement policies of government and third party payers. Physicians may not prescribe our approved products for a variety of reasons and patients may determine for any reason that our product is not useful to them. If any of our approved products fail to achieve market acceptance, our ability to generate revenue will be limited.

In Canada, market acceptance is also dependent upon the acceptance of our product by individual hospital ''product evaluation committees,'' which act as the gatekeepers at the hospital purchasing level. These committees look at the potential impact of a new product on patient care and on the budget in the specific therapeutic category related to that product. This process can take several months. We are currently involved with our Canadian distributor in progressing Augment through the appropriate committees at the key accounts that we believe present the best opportunities for the product. We cannot be certain that the various Canadian product evaluation committees will approve Augment in a timely manner, if at all. If product evaluation committees refuse to approve the use of Augment at their hospital, we may be unable to meet projected Augment sales targets for Canada, and our ability to generate revenue from Canadian sales will be limited.

The loss of our key management and scientific personnel may hinder our ability to execute our business plan.

As a small company with 89 employees as of December 31, 2009, our success depends on the continuing contributions of our management team and scientific personnel and on maintaining relationships with the network of medical and academic centers that conduct our clinical trials. We depend on the services of our key scientific employees and the principal members of our management staff. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts from other pharmaceutical and biotechnology companies, as well as from universities and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. The loss of one or more of these individuals, or our inability to attract additional qualified personnel, could substantially impair our ability to implement our business plan.

We face an inherent risk of liability in the event that the use or misuse of Augment in Canada or our product candidates results in personal injury or death.

The use of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims which could result in financial losses. Our clinical and commercial product liability insurance coverage may not be sufficient to cover claims that may be made against us. In addition, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely impact or eliminate the prospects for commercialization of the product candidate, or sale of the product, which is the subject of any such claim. Off-label use of our product may occur. While we do not promote any off-label use, off-label uses of products are common and the FDA does not regulate a physician's choice of treatment. Off-label use or misuse of any product for which we obtain approval may subject us to additional liability which may have a material adverse effect on our business, financial condition and results of operations.

If we are sued in a product liability action, we could be forced to pay substantial damages and the attention of our management team may be diverted from operating our business.

We currently manufacture investigational regenerative protein therapeutic-device combination product candidates and an approved Canadian commercial regenerative protein therapeutic-device combination product. These product candidates and the commercial product are implanted in patients during surgery or injected

into patients at the treatment site. In addition, we are developing additional similar products for additional surgical indications, and a drug product candidate for administering to patients. As a result, we may be subject to a product liability lawsuit. In particular, the market for spine products has a history of product liability litigation. Under past agreements with our former distributor for *GEM 21S* and agreements with certain suppliers and distributors, we indemnify these parties from certain product liability claims. Any product liability claim brought against us and/or a party that we have indemnified, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, we would have to pay any amount awarded by a court in excess of policy limits. We maintain product liability insurance in the annual aggregate amount of up to $20 million, although our insurance policies have various exclusions. Thus, we may be subject to a product liability claim for which we have no insurance coverage, in which case we may be liable for the entire amount of any award. Even in the absence of a claim, our insurance rates may rise in the future to a point where we may decide not to carry this insurance. A meritless or unsuccessful product liability claim would be time-consuming and expensive to defend and could result in the diversion of management's attention from our core business. A successful product liability claim or series of claims brought against us in excess of our coverage could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Intellectual Property

If we cannot protect our intellectual property, our ability to market Augment in Canada and our ability to develop and commercialize our product candidates may be severely limited.

Our success will depend in part on our ability, and on the ability of Harvard and ZymoGenetics, to maintain and enforce patent protection for the therapeutic uses of rhPDGF. Without patent protection, other companies could offer substantially identical products for sale without incurring the sizable discovery, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of approved products would then be diminished.

We rely on our intellectual property, as well as the intellectual property of ZymoGenetics and the intellectual property we co-own with Harvard, to provide freedom to operate and to exclude others from developing rhPDGF for the treatment of general bone defects and bone defects associated with advanced periodontal disease, fractures and other indications. We currently own or exclusively license three unexpired U.S. patents covering certain unique aspects of our product and product candidates. Other patents that covered our product candidates have expired. We do not believe, however that such patent expirations have significantly affected our intellectual property position.

Our license agreements with Harvard and ZymoGenetics provide exclusivity with respect to certain designated patents. The exclusivity under our ZymoGenetics licenses is limited to the periodontal, orthopedic and sports medicine fields. However, if any patent or other right which we own or exclusively license from ZymoGenetics or Harvard is challenged, a court may determine that the patent or right is invalid or unenforceable. Even if the validity or enforceability of a patent is upheld by a court, the court may not prevent alleged infringement on the grounds that the activity is not covered by the patent claims. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third-party rights, would be costly and time consuming, and may distract management from other important tasks.

Neither we nor our licensors may be able to obtain additional issued patents relating to our technology. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. In addition, our patent applications, patents and our licensors' patents may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions typically are not published until 18 months after filing, or in some cases ever, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

We also rely on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of non-disclosure and confidentiality agreements with employees, consultants, advisors and others. These agreements may be breached and we may not have adequate remedies for a breach. In addition, these agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information or prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to the information, which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements, or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies.

Our success also depends on our ability to operate and commercialize our product and product candidates without infringing the patents or proprietary rights of others.

Third parties may claim that we or our licensors or suppliers are infringing their patents or are misappropriating their proprietary information. If there is a successful claim against us or our licensors or suppliers for infringement of the patents or proprietary rights of others, we may be required to, among other things:

- pay substantial damages;
- stop using our technologies;
- stop certain research and development efforts;
- develop non-infringing products or methods; or
- obtain one or more licenses from third parties.

A license required under any such patents or proprietary rights may not be available to us, or may not be available on acceptable terms. If we or our licensors or suppliers are sued for infringement, we could encounter substantial delays in, or be prohibited from, developing, manufacturing and commercializing our product candidates or prohibited from continuing the commercialization of Augment in Canada.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas that are similar to those areas in which they were involved at their former employers, we may be subject to claims that these employees may have used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against these claims, which could result in substantial costs and be a distraction to management and may have a material adverse effect on us, even if we are successful in defending these claims.

Delays encountered during the FDA approval process could shorten the patent protection period during which we have the exclusive right to commercialize technologies or could allow others to come to market with similar technologies before us.

Regulatory Risks

We are subject to extensive governmental regulation including the requirement of FDA approval or clearance before our product candidates may be marketed.

Both before and after approval or clearance of our product candidates, we, our product candidates, our suppliers, our contract manufacturers and our contract testing laboratories are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;

- delays in the FDA's approving or clearing or the FDA's refusing to approve or clear a product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

Our product candidates require FDA authorization by means of an approval or clearance prior to marketing. Some of our product candidates, including Augment and Augment Injectable, are regulated as combination products. For a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. For the current orthopedic indications, Augment is being reviewed by medical device authorities at the Center for Devices and Radiological Health, with participation by the Center for Drug Evaluation and Research. Augment requires an approved PMA before it can be marketed in the United States. Certain of our other product candidates may be reviewed by the FDA as drug products, which would require an approved NDA before they can be marketed. The process of obtaining FDA approval of a PMA or NDA is lengthy, expensive, and uncertain, and we cannot be sure that our regenerative protein therapeutic-device combination product candidates regulated by the FDA as medical devices, or any other product candidates, will be approved in a timely fashion, or at all. If the FDA does not approve or clear our product candidates in a timely fashion, or at all, our business and financial condition may be adversely affected. The FDA may select a different center and/or different legal authority for our other product candidates, in which case the path to regulatory approval would be different and could be more lengthy and costly. The review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA.

In addition to the approval and clearance requirements, other numerous and pervasive regulatory requirements apply, both before and after approval or clearance, to us, our product and product candidates, and our suppliers, contract manufacturers, and contract laboratories. These include requirements related to:

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;
- export;
- reporting to the FDA certain adverse experiences associated with use of the product; and
- obtaining additional approvals or clearances for certain modifications to the products or their labeling or claims.

We also are subject to inspection by the FDA to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories, and we cannot be sure that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct.

The FDA's requirements may change and additional government regulations may be promulgated that could affect us, our product candidates, and our suppliers, contract manufacturers and contract laboratories. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action. We may be required to incur significant costs to comply with such laws and regulations in the future and such laws or regulations may have a material adverse effect upon our business.

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

International sales of our product and any of our product candidates that we commercialize are subject to the regulatory requirements of each country in which the products are sold. Accordingly, the introduction of our product candidates in markets outside the United States will be subject to regulatory approvals in those jurisdictions. The regulatory review process varies from country to country and differs from the U.S. requirements. Many countries also impose product standards, packaging and labeling requirements and import restrictions on medical devices. We may also be required to perform additional pre-clinical or clinical studies even if the FDA approval has been obtained. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by foreign government authorities is unpredictable and uncertain and can be expensive. Our ability to market our approved products could be substantially limited due to delays in receipt of, or failure to receive, the necessary approvals or clearances.

In Canada, the manufacture, distribution and use of medical devices, drugs and equipment is regulated by a variety of industry-specific statutes and regulations. Medical products sold in Canada are regulated by the Canadian Food and Drugs Act. Even though a drug or device may be approved for use in another jurisdiction, it may not be sold in Canada until approved by the national regulatory agency, Health Canada. Although in May 2006 we received marketing approval from Health Canada to market *GEM 21S* in Canada, and in November 2009 we announced that we received approval from Health Canada to market Augment in Canada, we will need to present data from additional clinical trials to obtain approval for our other product candidates. In 2009 we filed an Investigational Testing Authorization (''Augment Injectable ITA'') application with Health Canada and an Investigational Device Exemptions (''Augment Injectable IDE'') application with the FDA seeking approval to initiate a North American pivotal study to assess the safety and efficacy of Augment Injectable as a substitute for autograft in foot and ankle fusion procedures. In October 2009, Health Canada approved the Augment Injectable ITA and we initiated patient enrollment in Canada. Although the Augment Injectable ITA was approved by Health Canada, we may need to revise our clinical trial or present additional data from other clinical trials to obtain approval for Augment Injectable in Canada. We ultimately may not obtain the approvals necessary to market our product candidates in Canada. In addition, we may not obtain approval from the FDA on our Augment Injectable IDE, or we may be required to revise our U.S. trial in a way that limits our ability to pool data from that trial with the ongoing Canadian Augment Injectable trial.

The European Medicines Agency (''EMA'') previously determined that *GEMESIS* would be reviewed as a medicinal (i.e., a drug) combination product, and not as a medical device product which is how the product was reviewed in the United States and Canada. Our lead product candidates, Augment and Augment Injectable, may be reviewed as medicinal combination products as well. Under EU regulatory systems, marketing authorization for medicinal products can be submitted under the centralized European Agency for the Evaluation of Medicinal Products or the decentralized mutual recognition process. It is our understanding that the centralized procedure is mandatory for biotechnology derived products regulated as medicinals such as *GEMESIS*, Augment and Augment Injectable. If a product is approved under the centralized procedure, it receives a single marketing authorization that is valid in all EU member states. The decentralized process provides for mutual recognition of national approved decisions which allows the holder of an approval from one EU member state to submit an application in other member states requesting that they recognize the approval already granted. We filed a Marketing Authorization Application (''MAA'') for *GEMESIS*, but the EMA rejected our application, due in part to the different clinical and quality requirements of a drug product in the EU compared to a medical device product in the United States. We appealed that decision, but our appeal has been denied. Further, as part of our agreement with Luitpold, we are entitled to receive a $10.0 million milestone payment from Luitpold upon EU regulatory approval of *GEMESIS*. Because of uncertainties in the review process, we have excluded this milestone payment from our financial guidance for 2010.

We are currently re-evaluating our regulatory strategy for *GEMESIS* in the EU, and are considering seeking reclassification of *GEMESIS* from a medicinal to a medical device based on recent changes in the Medical Device Directives ("MDD"). However, there can be no assurances that such a reclassification would be successful. Furthermore, even if the reclassification is successful, there is no assurance that this strategy would be sufficient to gain approval of *GEMESIS*. As a result, there is a risk that we may be unable to gain approval for *GEMESIS*, which would prevent us from receiving the $10 million milestone payment from Luitpold. In addition, our Augment family of product candidates may encounter similar issues, and there can be no assurances that we will obtain EU approval for our product candidates.

In Australia, the manufacture, distribution and use of medical devices, drugs and equipment is regulated by the Therapeutic Goods Act. Even though a drug or device may be approved for use in another jurisdiction, it may not be sold in Australia until approved by the national regulatory agency, the Therapeutic Goods Administration. In February 2010, we filed an application of Conformity Assessment with the Australian Therapeutic Goods Administration ("TGA") for Augment. This application seeks approval to market Augment in Australia as an alternative to autograft in the treatment of foot and ankle fusions. The filing utilized the technical and clinical data that were provided to Health Canada in the recent DLA and to the FDA in the recent filing of the PMA for Augment in the United States. Such data alone, however, may not be sufficient and we may need to conduct additional clinical trials in Australia to obtain approval for Augment or our other product candidates. We ultimately may not obtain the approvals necessary to market our products in Australia.

The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate will be safe and effective in advanced clinical trials involving larger numbers of patients, we will be unable to submit the PMA, NDA or other application necessary to receive regulatory approval to commercialize the product candidate. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. We face risks that:

- the product candidate may not prove to be safe or effective;
- the product candidate's benefits may not outweigh its risks;
- the results from more advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;
- the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than we interpret them; and
- the FDA or other regulatory agencies may require additional or expanded trials.

We have only limited experience in regulatory affairs, and some of our products may be based on new technologies. These factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals. Moreover, some of the products that are likely to result from our product development, licensing and acquisition programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of product candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop, license or acquire.

If we fail to obtain an adequate level of reimbursement for our approved products by third party payers, there may be no commercially viable markets for our approved products or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our approved products. The efficacy, safety, performance and cost-effectiveness of our product and product candidates and of any competing products will determine the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our approved products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our approved products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our future approved products currently under development and limit our ability to sell our approved products on a profitable basis. In addition, third party payers continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for any approved product is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of the approved products would be impaired and our future revenues, if any, would be adversely affected.

If we fail to comply with the U.S. Federal Anti-Kickback Statute and similar state laws, we could be subject to criminal and civil penalties and exclusion from the Medicare and Medicaid programs, which could have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by Medicare, Medicaid or any other federal health care program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states in which our approved products may be sold have adopted laws similar to the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by Federal health care program but, instead, apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in federal health care programs.

All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by the Federal Anti-Kickback Statute and similar state laws. We believe our operations are in compliance with the Federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute or similar state laws, it could have a material adverse effect on our business and results of operations.

Patients may discontinue their participation in our clinical trials, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged related to our product candidates under evaluation.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the availability of other treatments or marketed therapies (whether approved or experimental);
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

If a large number of patients in any one of our studies discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of our product candidates.

Product quality or performance issues may be discovered through ongoing regulation by the FDA and by comparable international agencies, as well as through our internal standard quality process.

The medical device industry is subject to substantial regulation by the FDA and by comparable international agencies. In addition to requiring clearance or approval to market new or improved devices, we are subject to ongoing regulation as a device manufacturer. Governmental regulations cover many aspects of our operations, including quality systems, marketing and device reporting. As a result, we continually collect and analyze information about product quality and product performance through field observations, customer feedback and other quality metrics. Any product quality or performance issues that are discovered during our information collection and analysis efforts in connection with our regulatory compliance may have a material adverse effect on our business, financial condition and results of operations.

The use of hazardous materials in our operations may subject us to environmental claims or liability.

We intend to conduct research and development and some future manufacturing operations in our Franklin, Tennessee facility. Our research and development processes will involve the controlled use of hazardous materials, chemicals and radioactive compounds. We will conduct experiments that are common in the biotechnology industry, in which we may use small quantities of chemical hazards, including those that are corrosive, toxic and flammable, and trace amounts of radioactive materials. The risk of accidental injury or contamination from these materials cannot be eliminated. We do not maintain a separate insurance policy for these types of risks. If there is an accident or environmental discharge or contamination, we may be held liable for any resulting damages, and any liability could exceed our resources. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant and may have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Our Financial Results and Need for Financing

We have a history of losses and we expect to continue to incur losses and may not achieve or maintain profitability.

We have invested and continue to invest a significant portion of our time and resources in developing and testing our product candidates. As a result of our significant research and development, clinical development, regulatory compliance and general and administrative expenses, we expect that our operating losses may continue for the next few years as we continue to incur significant expenses for clinical trials. As of December 31, 2009, we had an accumulated deficit of $93.5 million. We have ongoing pivotal clinical studies for the use of Augment for the treatment of foot and ankle fusions in the United States, Canada and the EU.

In January 2008, we sold to Luitpold our remaining orofacial therapeutic business, whereas Luitpold was granted the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. This transaction has enabled us to focus our expertise and our future development efforts on our orthopedic, spine and sports medicine product candidates. This transaction leaves us without an FDA approved product currently in commercialization.

Even if we succeed in developing and commercializing one or more of our product candidates, we may not be able to generate sufficient revenue and we may never achieve or maintain profitability.

Our ability to use our net operating loss carryforwards could be limited.

Our ability to use our net operating loss carryforwards could be limited. At December 31, 2009, we had federal net operating loss carryforwards totaling $63.3 million available to reduce our future federal income tax liabilities. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities may be subject to annual limitations. In connection with any future offering, we may realize a ''more than fifty percent change in ownership'' which could further limit our ability to use our net operating loss carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because U.S. tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss for federal income tax purposes. The inability to take advantage of all or part of our accumulated net operating loss may have a material adverse effect on our financial condition and results of operations.

We will need to raise additional capital in the future. If we are unable to successfully raise additional capital in the future, our product development could be limited and our long term viability may be threatened; however, if we do raise additional capital, your percentage ownership as a stockholder could decrease and constraints could be placed on the operation of our business.

We have experienced negative operating cash flows since our inception and have funded our operations primarily from proceeds received from sales of our stock and the licensing and sale of our orofacial therapeutic business. We believe that the December 31, 2009 balance of our cash and investments will be sufficient to meet our anticipated cash requirements at least through the middle of 2011.

We may seek to obtain additional funds at any time in the future through equity or debt financings, or strategic alliances with third parties, either alone or in combination with equity financings. We may seek such additional funds regardless of the extent to which funds are raised in a public offering as identified in our shelf registration statement described below.

We have filed a shelf registration statement on Form S-3 with the SEC which has been declared effective. Although we currently have no plans to do so, under the shelf registration statement, we may from time to time, in one or more series, separately or together, sell common stock, preferred stock, debt securities or warrants to purchase our common stock or any combination of such securities. The aggregate public offering price of the securities that we may offer pursuant to the registration statement is up to $150.0 million. There can be no assurances that we will successfully raise a sufficient amount of capital in any future public offerings to fund operations through profitability.

Potential financings may result in substantial dilution to the holders of our common stock or require contractual or other restrictions on our operations or on alternatives that may be available to us in considering strategic transactions, dividends or liquidation preferences, debt service and/or revenue sharing arrangements. If we raise additional funds by issuing debt securities, these debt securities will have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. Any such required financing may not be available in amounts or on terms acceptable to us and the failure to procure such required financing could have a material adverse effect on our business, financial condition and results of operations.

A variety of factors could impact our need to raise additional capital, the timing of any required financings and the amount of such financings.

Factors that may cause our future capital requirements to be greater than anticipated or could accelerate our need for funds include, without limitation:

- unforeseen developments during our pre-clinical activities and clinical trials;
- delays in the timing of receipt of required regulatory approvals;
- unanticipated expenditures in research and development or manufacturing activities;
- delayed market acceptance of our approved product;

- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of some of our product candidates;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using our approved product;
- inability to train a sufficient number of surgeons to create demand for our approved product;
- lack of financial resources to adequately support our operations;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- unforeseen problems with our third-party manufacturers and service providers or with our specialty suppliers of certain raw materials;
- unanticipated difficulties in operating in international markets;
- unanticipated financial resources needed to respond to technological changes and increased competition;
- unforeseen problems in attracting and retaining qualified personnel to market our approved product;
- enactment of new legislation or administrative regulations;
- the application to our business of new court decisions and regulatory interpretations;
- claims that might be brought in excess of our insurance coverage;
- the failure to comply with regulatory guidelines;
- unforeseen cost overruns associated with build out of our new manufacturing facility that we have leased; and
- the uncertainty in industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line through acquisitions or joint ventures. Any acquisition or joint venture would likely increase our capital requirements.

If adequate financing is not available, we may be required to delay, scale back or eliminate our operations, which would have a material adverse effect on our business, financial conditions and results of operations.

If we fail to maintain effective internal controls over financial reporting, our business, operating results and stock price could be materially adversely affected.

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to include a report by our management on our internal controls over financial reporting. This report, which is included in this annual report, contains an assessment by management of the effectiveness of our internal controls over financial reporting as of the end of our fiscal year and a statement as to whether or not our internal controls are effective. This annual report contains a statement that our independent auditors have issued an attestation report on the effectiveness of internal controls over financial reporting.

In 2007, we began to document and evaluate our internal controls over financial reporting. Our efforts to comply with Section 404 have resulted in, and are likely to continue to result in, significant costs, and the commitment of time and operational resources. If our management identifies one or more material weaknesses in our internal controls over financial reporting, we will be unable to assert that our internal controls over financial reporting are effective. If we are unable to assert that our internal controls over financial reporting are effective, or if our independent auditors are unable to express an unqualified opinion on the effectiveness of our internal controls over financial reporting, then the market perception of our financial condition and the trading price of our stock may be adversely affected and customer perception of our business may suffer.

Risks Relating to the Ownership of Our Common Stock

We expect that the price of our common stock will be highly volatile.

The current, active and liquid trading market for our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. Moreover, we cannot assure you that any securities analysts will initiate or maintain research coverage of our company and our common stock.

The trading prices of the securities of medical technology and biotechnology companies have been highly volatile. Accordingly, the trading price of our common stock is likely to be subject to wide fluctuations. Factors that could affect the trading price of our common stock include, among other things:

- whether we receive FDA approval to market any of our product candidates in the United States or similar regulatory approval in foreign jurisdictions;
- whether we successfully commercialize Augment in Canada or any other approved product in the future;
- developments relating to patents, proprietary rights and potential infringement;
- announcements by us or our competitors of technological innovations or new commercial products;
- reimbursement policies of various governmental and third party payers;
- public concern over the safety and efficacy of *GEM 21S*, Augment or any of our product candidates;
- changes in estimates of our revenue and operating results;
- variances in our revenue or operating results from forecasts or projections;
- recommendations of securities analysts regarding investment in our stock;
- our ability to maintain and/or raise sufficient capital to fund our operations until we are able to commercialize a product candidate and become profitable; and
- market conditions in our industry and the current economic downturn as a whole.

If our future quarterly or annual operating results are below the expectations of securities analysts or investors, the price of our common stock will likely decline. In addition, share price fluctuations may be exaggerated if the trading volume of our common stock is low.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals or milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we expect that we will publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the commercialization of our product and product candidates may be delayed.

Future sales of our common stock by existing stockholders could cause our stock price to decline.

The market price of our common stock may drop significantly if our existing stockholders sell a large number of shares of our common stock or are perceived by the market as intending to sell them. All of the shares sold in our May 2006 initial public offering, our February 2007 secondary offering and our June 2009 rights offering are freely tradable without restriction or further registration under the federal securities laws, except for shares purchased by our ‘‘affiliates’’ as that term is defined in Rule 144 under the Securities Act. We expect that we also will be required to register any securities sold in future private financings. In addition, all of our common stock issued prior to our initial public offering is freely tradable without restriction or further registration under the federal securities laws, unless owned by our affiliates. Furthermore, as of December 31, 2009, holders of approximately 2,816,309 shares of common stock may have piggyback registration rights with respect to their shares in connection with future offerings. Those registration rights will

expire upon the earlier of the transfer of those shares by the holder of the rights or the fifth anniversary of our initial public offering. Sales by stockholders of substantial amounts of our shares, including sales by Novo A/S or InterWest Partners, or the perception that these sales may occur in the future, could affect materially and adversely the market price of our common stock.

At December 31, 2009, there were options issued and outstanding to purchase 2,543,235 shares of our common stock with a weighted average exercise price of $9.45. Also at December 31, 2009, there were 629,977 options available for future for issuance of options under our stock option plans.

Our executive officers, directors and their affiliates maintain the ability to substantially influence all matters submitted to stockholders for approval.

As of December 31, 2009, our executive officers, directors and their affiliates beneficially owned shares representing approximately 34.4% of our capital stock. This total includes 1,830,253 shares (8.4% of our capital stock) owned by InterWest Partners, X, L.P. and its affiliates. Chris Ehrlich, one of our directors, is an affiliate of InterWest Partners. This total also includes 3,720,065 shares (17.0% of our capital stock) owned by Novo A/S. Thorkil K. Christensen, one of our directors, is the Chief Financial Officer of Novo A/S.

Accordingly, our current executive officers, directors and their affiliates have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions, as well as management and affairs. This concentration of ownership may delay or prevent a change of control of us at a premium price if these stockholders oppose it, even if it would benefit our other stockholders.

Provisions in our charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us.

Provisions of our corporate charter 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:

- a classified board of directors;
- 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.

In addition, Section 203 of the Delaware General Corporation Law 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

Our operations are headquartered in a leased facility in Franklin, Tennessee, consisting of approximately 32,000 square feet under a lease that expires on December 31, 2016, with an option to extend the lease.

In 2007, we entered into a new lease agreement for approximately 30,000 square feet of space in a new manufacturing facility recently built in the same complex as our headquarters in Franklin, Tennessee. The initial term of this new lease continues 10 years from the October 2009 commencement date, with an option to extend the lease. We are moving forward with plans to occupy the new manufacturing facility. We intend to move certain steps of the later stages of the manufacturing process of our orthopedic and sports medicine product candidates into that facility, including final formulation, filling the vials that will be packaged in the finished kits, and assembling the kits. The building shell was completed in late 2009, and the build out is expected to begin in 2010 or 2011. In order to qualify the facility as a GMP manufacturing facility, the build out must be complete, the utility systems, process and testing equipment must be installed and qualified, regulatory filings must be assembled and filed, and regulatory agency inspections must be passed prior to receiving approval. We anticipate that the facility will be approved for commercial operations within two years of our starting the build out. We cannot be certain, however, whether the FDA will approve the manufacturing facility.

Item 3. LEGAL PROCEEDINGS

In February 2009, we filed an arbitration claim with the Financial Industry Regulatory Authority, Inc. (“FINRA”) asserting various claims relating to investments in certain auction rate securities made on our behalf. In December 2009, we sold all of the remaining securities at issue in that arbitration proceeding. In addition, following receipt of a payment in the amount of $7.2 million from the respondent in the arbitration, we settled the arbitration claim and dismissed the case.

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

None.

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 May 15, 2006 under the symbol "BMTI." The following table sets forth, for the periods indicated, the high and low sales prices for our common stock, as reported on the NASDAQ Global Market, since our common stock commenced public trading:

	Price Range	
	High	Low
2009		
First Quarter	$10.14	$ 6.91
Second Quarter	$10.89	$ 6.52
Third Quarter	$13.56	$ 8.55
Fourth Quarter	$15.81	$10.40

	Price Range	
	High	Low
2008		
First Quarter	$18.18	$6.35
Second Quarter	$12.98	$7.71
Third Quarter	$14.09	$8.50
Fourth Quarter	$11.38	$4.69

Stockholders

As of March 8, 2010, there were 30 registered holders of record of shares of our common stock.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, capital requirements, covenants in our debt instruments (if any), and such other factors as our board of directors deems relevant.

Sales of Unregistered Securities

None.

Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth information about the securities issuable under our 2001 Long-Term Stock Incentive Plan and 2005 Employee Stock Purchase Plan at December 31, 2009. We have no equity compensation plans that were not approved by our security holders.

Plan Category	Number of Securities to Be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)
2001 Long-Term Stock Incentive Plan	2,543,235	$9.45	629,977
2005 Employee Stock Purchase Plan	N/A	N/A	131,857
Employee 401(k) Plan Company Match	N/A	N/A	59,659
Total	2,543,235	—	821,493

Unregistered Sales of Securities and Use of Proceeds

In April 2009, we sold to InterWest Partners X, L.P. 941,177 shares of common stock for an aggregate purchase price of $8.0 million, or $8.50 per share. The transaction was exempt from registration pursuant to section 4(2) of the Securities Act.

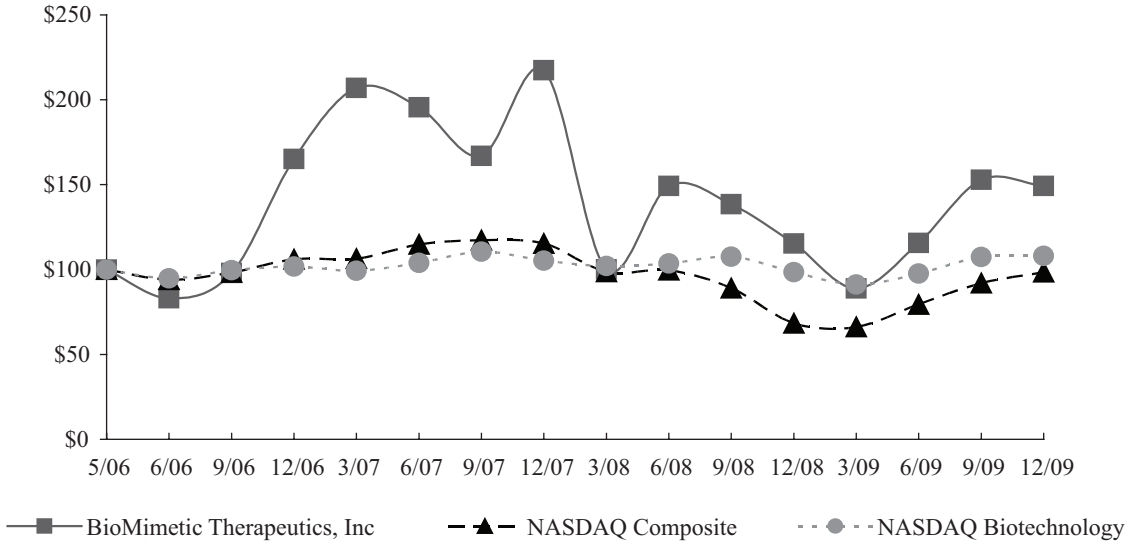
In June 2009, we sold to Novo A/S 343,406 shares of common stock for an aggregate purchase price of $2.9 million, or $8.50 per share, the subscription price for the registered rights offering we completed on the same day. The transaction was completed after the closing of the rights offering. The transaction was exempt from registration pursuant to section 4(2) of the Securities Act.

Performance Graph

The following graph compares the cumulative total stockholder return data for our common stock since May 15, 2006 (the first full day of trading after the initial public offering on May 12, 2006) to the cumulative return over such time period of (i) The Nasdaq Stock Market Composite Index, and (ii) The Nasdaq Biotechnology Index. The graph assumes that, on the date on which we completed the initial public offering of our common stock, $100 was invested in each of our common stock, the stocks comprising the Nasdaq Composite Index and the stocks comprising the Nasdaq Biotechnology Index, including dividend reinvestment.

Our Company has not declared or paid any cash dividends on our capital stock, and has not repurchased any shares of our capital stock. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

COMPARISON OF 43 MONTH CUMULATIVE TOTAL RETURN*
Among BioMimetic Therapeutic, Inc. The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



* $100 invested on 5/15/06 in stock or 4/30/06 in index, including reinvestment of dividends. Fiscal year ending December 31.

Item 6. SELECTED FINANCIAL DATA

The following table sets forth selected financial data that is qualified in its entirety by and should be read in conjunction with ''Management's Discussion and Analysis of Financial Condition and Results of Operations'' and our audited consolidated financial statements and related notes included elsewhere in this Annual Report.

The selected consolidated balance sheet data as of December 31, 2009 and 2008 and the selected consolidated statements of operations data for each of the three years in the period ended December 31, 2009 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The selected consolidated balance sheet data as of December 31, 2007, 2006 and 2005 and the selected consolidated statement of operations data for the each of the two years ended December 31, 2006 and 2005 have been derived from our audited consolidated financial statements which are not included in this Annual Report.

	Years Ended December 31,				
	2009	2008	2007	2006[2]	2005
	(In Thousands, Except Share and per Share Information)				
Revenues[1]:					
Product sales	$ 78	$ —	$ 5,040	$ 2,592	$ 60
Royalty income	522	2,144	1,213	569	31
Sublicense fee income	971	974	741	710	84
Collaborative research and development	—	—	—	224	4,335
Other revenue	—	30	36	39	7
Total revenues	1,571	3,148	7,030	4,134	4,517
Costs and expenses[1]:					
Cost of sales	6	—	3,939	2,212	70
Research and development	21,095	24,561	19,218	11,676	12,587
General and administrative	11,511	11,253	8,829	6,516	3,402
Depreciation and capital lease amortization	1,333	1,423	1,130	842	399
Patent license fee amortization	2,569	2,663	2,234	2,116	652
Total costs and expenses	36,514	39,900	35,350	23,362	17,110
Loss from operations	(34,943)	(36,752)	(28,320)	(19,228)	(12,593)
Interest (expense) income, net	(308)	247	1,710	2,165	921
Investment income (loss), net	6,864	(10,797)	1,952	—	—
Gain (loss) on disposal of equipment and other	11	5	2	(1)	(4)
Gain on arbitration settlement	7,219	—	—	—	—
Gain on disposal of orofacial therapeutic business	—	39,292	—	—	—
Income tax benefit	—	—	74	—	—
Preferred stock accretion	—	—	—	(132)	(366)
Net loss	$ (21,157)	$ (8,005)	$ (24,582)	$ (17,196)	$ (12,042)
Basic and diluted net loss per share	$ (1.03)	$ (0.43)	$ (1.37)	$ (1.62)	$ (7.59)
Weighted average shares used to compute basic and diluted net loss per share	20,510,132	18,529,068	17,951,147	10,589,969	1,587,219
Cash dividends declared	$ —	$ —	$ —	$ —	$ —

	As of December 31,				
	2009	2008	2007	2006[2]	2005
			(In Thousands)		
Balance Sheet Information:					
Cash and cash equivalents	$ 21,543	$ 17,535	$ 25,483	$ 47,065	$ 33,428
Investments – short term	47,002	33,218	—	—	—
Investments – long term	6,514	46,624	41,800	—	—
Total assets	88,912	125,120	89,618	65,395	52,642
Long-term capital lease obligations	175	35	53	49	—
Note payable	—	39,100	—	—	—
Total liabilities	21,861	66,066	27,166	20,394	23,281
Redeemable, convertible preferred stock	—	—	—	—	50,746
Accumulated deficit	(93,520)	(72,363)	(64,358)	(39,776)	(22,580)
Total stockholders' equity	67,052	59,054	62,452	45,001	(21,385)

(1) Prior to January 1, 2006, we primarily had been engaged in researching and developing our principal product, we were a development stage enterprise and we were recognizing collaborative research and development revenue pursuant to our research, development and marketing agreement with Luitpold. Effective January 1, 2006, we no longer consider ourselves to be a development stage enterprise because we believe that we have achieved our planned principal operations and have generated revenue from product sales.

(2) Effective January 1, 2006, we adopted ASC 505, *Equity-Based Payments to Non-Employees*, and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*). In accordance with the provisions of ASC 505 and ASC 718, we elected to adopt the standard using the modified prospective method of transition.

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

Overview

We are a biotechnology company which develops and commercializes innovative products to help stimulate the body's natural tissue regenerative process. We believe our protein therapeutic-device combination products have the potential to significantly improve the treatment of musculoskeletal injuries and conditions affecting bones, tendons, ligaments and cartilage. Our platform regenerative technology, which incorporates a potent version of one of the body's natural key stimulators of tissue repair, may offer physicians advanced biological solutions to actively stimulate tissue healing and regeneration.

We have already demonstrated that this technology is safe and effective in stimulating bone regeneration with the U.S. and Canadian regulatory approvals of our first periodontal product, *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), and with the Canadian regulatory approval of our first orthopedic product, Augment™ Bone Graft (''Augment''). We continue to focus on further developing this technology to stimulate tissue healing in orthopedic applications (such as certain types of bone fractures or fusions of the bones in the foot and ankle to eliminate chronic pain from trauma or arthritis), and potentially sports injury and spine applications. Our current product candidates are designed to target a broad range of clinical indications in bone, ligament, tendon and cartilage repair.

Our product candidates have been the subject of numerous orthopedic clinical studies that have been completed or are on-going which seek to demonstrate the safety, clinical utility and/or efficacy of the product candidates in our pipeline, including our lead orthopedic product candidate Augment, a fully synthetic and off-the-shelf bone growth factor product for the treatment of bone defects and injuries. Augment is the subject of our North American pivotal (Phase III) randomized controlled trial, which compares Augment to autograft for use in hindfoot and ankle fusion surgery. This trial will be the primary data set used to support regulatory approval in the United States, the European Union (''EU'') and Australia. In addition, we have pre-clinical programs focused on the development of treatments for bone defects in the spine and various sports injury applications, including those requiring ligament, tendon and cartilage repair.

In the second quarter of 2009, we submitted to the U.S. Food and Drug Administration (''FDA'') both the pre-clinical pharmacology/toxicology and quality/manufacturing modules of a modular pre-market approval (''PMA'') application for the marketing of Augment in the United States. A modular submission breaks the PMA document into three sections or ''modules'' filed at different times that together become a complete application. The modular approach allows the applicant to potentially resolve any concerns noted by the FDA earlier in the review process than would occur with a traditional PMA application, and may ultimately shorten the review and approval timeline. In October 2009, we reported positive top-line results from our North American Augment pivotal trial. The primary study goal of this clinical study was to establish non-inferiority of Augment compared to autograft. Autograft is the current standard of care but is limited in that it must be obtained and transplanted from another bone in the patient's body, often requiring a second surgical procedure. The positive top-line results of the study indicate that, with the use of Augment, patients can expect a comparable treatment outcome while being spared the pain and potential morbidity associated with autograft bone harvesting and transplantation. In February 2010, we submitted the third PMA module, which contains the 24-week data from the North American Augment pivotal trial, and completes our PMA seeking FDA approval of Augment in the United States.

In November 2009, we received approval from Health Canada of our Device License Application (''DLA'') in Canada for Augment. The product is approved for use as an alternative to autologous bone graft in the surgical treatment of foot and ankle fusions in Canada. Based upon this approval, we initiated the commercial marketing of Augment in Canada in the beginning of 2010 through our exclusive distribution partner, Joint Solutions Alliance Corporation (''Joint Solutions''). During the first quarter of 2010, our commercial activities in Canada have focused on the support of Joint Solutions' efforts to get Augment onto the list of approved products at the key hospitals throughout Canada. Every new product must be reviewed by individual hospital ''product evaluation committees,'' which act as the gatekeepers at the hospital purchasing level. These committees look at the potential impact of a new product on patient care and on the budget in the specific therapeutic category related to that product. This process can take several months. We are currently

working with Joint Solutions to progress Augment through the appropriate committees at the key accounts that we believe present the best opportunities for the product.

Our numerous clinical studies, including our Augment studies, suggest that our platform technology may be effective in our target applications. If successful, we expect these clinical studies should lead to regulatory approval of our regenerative product candidates in the United States, the EU and Australia. If approved by the appropriate regulatory authorities, we believe that our product candidates may offer new, effective and less invasive treatment options in orthopedic, spine and sports related injuries to improve the quality of life for millions of patients suffering injuries or deterioration of bones, ligaments, tendons and cartilage.

According to the National Bureau of Economic Research, the U.S. economy entered into a recession in December 2007. Although the U.S. Commerce Department has reported economic growth in the third and fourth quarters of 2009 and many economists now believe that the recession has ended, the continuing economic uncertainty and the ensuing market instability have continued to impact our general business strategy, which may be adversely affected if the current economic conditions do not continue to improve. For example, the economy may impact the demand for elective medical procedures that we are targeting with our product candidates, or may impact the pricing that we may set for our products, if approved. However, since our anticipated product launch in the United States for our lead product candidate may be a year or more away, the impact of the economy on commercial opportunities for that product remains uncertain.

We have responded to the current economic conditions by investing our cash and cash equivalents and our investments conservatively, and by employing cost control measures to conserve cash and manage expenses, such as scaling back growth in staff, eliminating unnecessary expenditures and postponing certain program activities where appropriate. In addition, to the extent possible given contractual commitments, in order to postpone major expenses we have postponed certain major equipment purchases and delivery and validation efforts for manufacturing equipment intended for our new manufacturing facility which we have leased in the same complex as our headquarters in Franklin, Tennessee. If the economy continues to improve and as we near regulatory approval of Augment in the United States, we anticipate that we will reassess certain of these measures and resume growth in staffing and certain program activities.

Recent Developments — Clinical Trials / Product Development Updates

Augment™ Bone Graft

North American Augment Pivotal Study — Foot and Ankle Fusions — In October 2009, we announced positive top-line results from our North American pivotal (Phase III) randomized, controlled trial comparing Augment to autograft for use in hindfoot and ankle fusion surgery (''Augment pivotal study''). The study goal was to establish non-inferiority of Augment compared to autograft, which has the limitation that it must be obtained and transplanted from another bone in the patient's body, often requiring a second surgical procedure. These positive top-line results indicate that, with the use of Augment, patients can expect a treatment outcome comparable to autograft while being spared the pain and potential morbidity associated with traditional autograft bone harvesting and transplantation.

In February 2010, we submitted to the FDA the third PMA module, which supplements the pre-clinical pharmacology/toxicology and quality/manufacturing modules submitted in the second quarter of 2009. This third PMA module contains the 24-week data from the North American Augment pivotal trial, and completes our PMA seeking FDA approval of Augment in the United States.

In March 2010, we announced additional data from our Augment pivotal study at the annual meeting of the American Academy of Orthopedic Surgeons (''AAOS''). The lead investigator of the Augment North American pivotal study, Dr. Christopher DiGiovanni, presented additional data regarding the 24 week results of the study. These data are based on the ''modified intent-to-treat'' (''mITT'') patient population, which is the pre-specified primary study population. Secondary clinical endpoints not previously reported included additional radiographic (Plain Film Union for two and three aspects), clinical (Clinical Healing by joint, Composite Success, Clinical Success, Therapeutic Failure), functional (SF-12, Foot Function Index, AOFAS scores) and patient indicated pain (Fusion Site, Weight-Bearing, Graft Harvest Site) evaluations. Out of a total of 15 additional secondary clinical endpoints, 12 met the test for non-inferiority compared to autograft at a statistically significant level. New data were also reported relating to the safety of Augment compared to the

autograft control. The Augment group exhibited a lower rate of serious treatment emergent adverse events, a lower rate of overall and surgery-related complications, a lower rate of serious complications, fewer surgery-related complications and a lower rate of infection when compared with the autograft group.

See "Business — Product Development Programs — Augment Bone Graft" for more information and a tabular presentation of these clinical data.

Our PMA application is currently under review by the FDA. We expect that, in the second half of 2010, an FDA advisory committee, which is typically a panel of clinicians and statisticians, is likely to be convened to review the application and recommend to the FDA whether, or upon what conditions, Augment should be approved. The FDA is not bound by the advisory panel decision, but the FDA often follows the panel's recommendation. We anticipate that approval of Augment in the United States will occur within six months after the panel meeting if the panel recommends approval and if the FDA finds the PMA information satisfactory.

EU Augment Trial — Foot and Ankle Fusions — In May 2007, we initiated a clinical study in the European Union ("EU"), to evaluate Augment for the treatment of foot and ankle fusions. In November 2008, we completed enrollment with a total enrollment of 108 patients. This study is an open label trial, and will be used to support the safety of Augment. We are compiling the data from the study and we anticipate that the data from the study should be available around mid-year 2010. We expect to submit the trial data, in conjunction with data from the North American pivotal trial, to the European Medicines Agency ("EMA") in the third quarter of 2010.

Canadian Augment Pilot and Registration Trial — Foot and Ankle Fusions — In November 2009, we announced that we received approval from Health Canada to begin the marketing of our lead orthopedic product, Augment, as an alternative to the use of autograft in foot and ankle fusion indications in Canada. Based upon Health Canada's approval, in December 2009 we shipped our first order of Augment to our Canadian distributor, Joint Solutions Alliance Corporation ("Joint Solutions"), a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada. Joint Solutions is the exclusive distributor of our Augment product in Canada, and we have deployed clinical specialists in the Canadian market, which is approximately 5% the size of the U.S. market, to work collaboratively with them. The Augment product was made available to customers in Canada in January 2010. We are working with distributor personnel to gain product approval at individual institutions through review by the hospitals' new product evaluation committees, a process that can take several months to complete.

Australian Therapeutic Goods Administration — In February 2010, we filed an application of Conformity Assessment with the Australian Therapeutic Goods Administration ("TGA") for Augment. This application seeks approval to market Augment in Australia as an alternative to autograft in the treatment of foot and ankle fusions. The filing utilized the technical and clinical data that were provided to Health Canada in the recent DLA and to the FDA in the recent filing of the PMA for Augment in the United States. The TGA review is expected to take 12 to18 months to complete, however, the timing of regulatory review can be uncertain and as a result we may be unable to obtain Australian approval of Augment in a timely manner, if at all. Looking forward to the successful completion of Augment marketing approval, the Company has established a relationship with an orthopedic distributor, Surgical Specialties Pty Ltd ("Surgical Specialties"), in Sydney, Australia. Surgical Specialties will be the exclusive distributor of Augment and Augment Injectable in Australia and New Zealand.

Augment™ Injectable Bone Graft

North American Augment Injectable Pivotal Study — Foot and Ankle Fusions. We previously announced results from both the Canadian Augment Injectable Pilot Trial and the EU Augment Injectable Pilot Trial, which provided us with sufficient evidence of Augment Injectable's safety and clinical utility to allow us to progress Augment Injectable forward in the development process.

Accordingly, in 2009 we filed an Investigational Testing Authorization ("Augment Injectable ITA") application with Health Canada and an Investigational Device Exemptions ("Augment Injectable IDE") application with the FDA. Health Canada approved the Augment Injectable ITA, and in October 2009, we initiated patient enrollment in a North American pivotal study to assess the safety and efficacy of Augment Injectable as a substitute for autograft in foot and ankle fusion procedures ("Augment Injectable study"). This

randomized, controlled study is intended to support the registration of Augment Injectable in Canada and the United States. The Augment Injectable study is designed to incorporate approximately 300 patients, some of whom will be autograft patients that were enrolled in our North American Augment pivotal study. The Augment Injectable study protocol in Canada is similar to the Augment pivotal study protocol so certain control (i.e. autograft) patients enrolled in the Augment pivotal study can be used to supplement the control group in the new study. Up to 20 clinical centers in North America will be involved, with five sites that have already begun enrolling patients in Canada.

We are finalizing the details of the protocol and the statistical plan of the Augment Injectable study with the FDA and will not commence patient enrollment in the study in the United States until the details of the protocol and the statistical plan are complete. We cannot be certain, however, whether the FDA will approve the Augment Injectable IDE or, if approved, that the approved protocol will permit the pooling of the study's patients with the patients that we are currently enrolling under the Canadian Augment Injectable ITA or with the control patients included in our Augment pivotal study. We expect to receive a final decision on our IDE around mid-year 2010, and would anticipate initiating patient enrollment in the United States shortly thereafter, and completing patient enrollment within six months of initial enrollment.

Sports Medicine

At the Orthopedic Research Society meeting in March 2010, we presented results of two pre-clinical studies demonstrating that rhPDGF-BB, in combination with tissue specific matrix materials, promotes healing in Achilles and rotator cuff injuries in sheep models. In addition, we also presented *in vitro* data supporting rhPDGF-BB's ability to influence tenocytes. Based on these positive results, we intend to initiate a pilot clinical trial in sports medicine by the end of 2010.

GEMESIS™ Bone Graft — European Medicines Agency Filing

The EMA previously determined that *GEMESIS*™ Bone Graft (''*GEMESIS*''), formerly *GEM 21S*, would be reviewed as a medicinal (i.e., a drug) combination product, and not as a medical device product which is how the product was reviewed in the United States and Canada. Accordingly, we filed a Marketing Authorization Application (''MAA'') for *GEMESIS*, but the EMA rejected our application, due in part to the different clinical and quality requirements of a drug product in the EU compared to a medical device product in the United States. We appealed that decision, but our appeal has been denied. We are currently re-evaluating our regulatory strategy for *GEMESIS* in the EU, and are considering seeking reclassification of *GEMESIS* from a medicinal to a medical device based on recent changes in the Medical Device Directives (''MDD''). Further, as part of our 2008 agreements with Luitpold, we are entitled to receive a $10.0 million milestone payment from Luitpold upon EU regulatory approval of *GEMESIS*. Because of uncertainties in the review process, we have excluded this milestone payment from our financial guidance for 2010.

Recent Developments — Other

Auction Rate Securities and Note Payable

In December 2009, we sold all of the remaining securities at issue in an arbitration proceeding which we had filed in February 2009 with the Financial Industry Regulatory Authority, Inc. (''FINRA'') asserting various claims relating to investments in certain auction rate securities made on our behalf. In addition, following receipt of a payment in the amount of $7.2 million from the respondent in the arbitration, we settled the arbitration claim and dismissed the case.

With the redemptions and sales of all our remaining ARS investments during 2009, we repaid in full the balance on our Time Promissory Note (''Note'') credit facility, under which we had borrowed $39.1 million in October 2008. The original promissory note has been returned to us marked ''paid in full.'' In addition, the issuer of the Note has released us from the Note, and has terminated our security and pledge agreement and securities account control agreement and terminated any UCC filings made with respect to the Note and security agreements.

Manufacturing and Supply Agreement

In December 2009, we amended and restated our manufacturing and supply agreement with Novartis Vaccines and Diagnostics, Inc. (''Novartis'') for the supply of bulk rhPDGF-BB. The agreement strengthens our mutual exclusivity whereby Novartis will manufacture rhPDGF-BB exclusively for us for therapeutic applications covering bone, cartilage, tendon and ligaments.

Patents

In January 2010, we announced that the European Patent Office (''EPO'') intends to grant patent application No. 05803356 titled ''Platelet-Derived Growth Factor Compositions and Methods of Use Thereof.'' The allowed claims will cover compositions of recombinant human Platelet-Derived Growth Factor (''rhPDGF'') combined with matrix materials having defined characteristics, which will cover our recombinant protein-device combination product candidates, including Augment and Augment Injectable, as well as *GEMESIS*, which we previously sold to Luitpold Pharmaceuticals, Inc. Once issued, the new patent will provide protection against the marketing of similar or generic versions of Augment, Augment Injectable, and *GEMESIS* in Europe until 2025.

Financial Overview

Since inception in 1999, we have funded our operations with proceeds from the sale of capital stock (including redeemable preferred stock, our initial public offering in May 2006, our secondary public offering in February 2007, a private placement in April 2009 and our rights offering in June 2009), from the licensing and sale of our orofacial therapeutic business in January 2008, and from research and development agreements, grants and product sales. The proceeds from these activities are reflected in the balance of cash and investments totaling $75.1 million as of December 31, 2009, which includes $21.6 million in cash and cash equivalents and $53.5 million in short-term and long-term investments in U.S. government sponsored enterprise (''GSE'') securities and U.S. Treasury Notes that are classified as available for sale.

During the year ended December 31, 2009, all of our investments in ARS were redeemed or sold for total proceeds of $52.4 million, including the December 2009 sale of our remaining ARS investments for $18.6 million. In 2008, we had determined that our ARS investments had experienced an ''other-than-temporary'' impairment in fair value and we had estimated the fair value to be $46.6 million, representing an impairment loss of $13.4 million, as of December 31, 2008. The redemptions and sales of our ARS investments during 2009 have resulted in a net realized gain of $5.8 million recorded to earnings in our consolidated statement of operations as of December 31, 2009. In addition, we received a $7.2 million payment from the settlement of an arbitration claim relating to the investments in ARS made on our behalf. As of December 31, 2009, we did not have any investments in ARS.

In October 2008, to address the liquidity issues experienced with these ARS investments in the short-term, we entered into a Time Promissory Note (''Note'') credit facility enabling us to borrow up to $39.1 million with certain of our ARS investments serving as collateral. With the redemptions and sales of all our remaining ARS investments during the year ended December 31, 2009, we have repaid in full the balance on the Note and the original promissory note has been returned to us marked ''paid in full.'' In addition, the issuer of the Note has released us from the Note, and has terminated our security and pledge agreement and securities account control agreement and terminated any UCC filings made with respect to the Note and security agreements.

We continue to incur research and development expenses due to the substantial expansion of our internal research capabilities and the numbers of patients we have enrolled and expect to enroll in the clinical trials of Augment, Augment Injectable and our other product candidates. We will make determinations as to which product candidates to advance and how much funding to direct to each on an ongoing basis in response to their scientific and clinical success. We expect that research and development expenses will continue to increase as a result of new and ongoing clinical trials and pre-clinical studies of our product candidates in the United States, Canada and the European Union (''EU''), as well as continuing expenses associated with regulatory filings.

The following table summarizes our research and development expenses for the five years ended December 31, 2009. Direct external costs represent significant expenses paid to third parties that specifically relate to the clinical development of Augment, such as payments to contract research organizations, clinical investigators, manufacture of clinical material, consultants, contract manufacturing start-up costs, manufacturing scale-up costs, milestone payments and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the manufacturing, regulatory affairs, clinical affairs, quality assurance, quality control and research and development are classified as research and development costs. Research and development spending for past periods is not indicative of spending in future periods.

	Years Ended December 31,				
Research & Development Costs	**2009**	**2008**	**2007**	**2006**	**2005**
Direct external:					
Periodontal	$ 251,306	$ 1,061,533	$ 1,789,290	$ 1,434,571	$ 7,763,299
Orthopedic	7,611,308	10,638,241	7,143,764	5,180,996	2,106,451
Sports medicine	984,969	491,825	716,125	325,170	40,650
	8,847,583	12,191,599	9,649,179	6,940,737	9,910,400
Internal:					
Periodontal	688,420	590,330	2,400,252	2,049,165	1,528,570
Orthopedic	9,595,711	9,999,420	5,878,196	2,438,251	1,141,659
Sports medicine	1,963,715	1,779,626	1,290,751	247,729	6,296
	12,247,846	12,369,376	9,569,199	4,735,145	2,676,525
Total	$21,095,429	$24,560,975	$19,218,378	$11,675,882	$12,586,925

We anticipate that our general and administrative expenses will continue to increase as we expand our operations, facilities and other administrative activities related to our efforts to bring our product candidates into commercialization.

Since inception, we have incurred losses from operations each year. As of December 31, 2009, we had an accumulated deficit of $93.5 million, which includes a $39.3 million net gain on the January 2008 sale of our orofacial therapeutic business. Although the size and timing of our future operating losses are subject to significant uncertainty, we expect that operating losses may continue over the next few years as we continue to fund our research and development activities and clinical trials and as we prepare for a future sales network to represent our products. In November 2009, we received approval of our DLA in Canada for use and marketing of Augment in Canada; however, we currently do not have an FDA approved product in commercialization in the United States.

The successful development of Augment and our other product candidates is highly uncertain. We cannot reasonably estimate the nature, timing and costs of the efforts necessary to complete the development and approval of, or the period in which material net cash flows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress and cost of our clinical trials;
- future clinical trial results;
- the cost and timing of regulatory approvals;
- the establishment of marketing, sales and distribution;
- the cost and timing associated with licensing, business relationships and similar arrangements;
- the cost and timing of establishing clinical and commercial supplies of Augment and our other product candidates;
- the timing and results of our pre-clinical research programs; and

- the effects of competing technologies and market developments; and
- the industry demand and patient wellness behavior as businesses and individuals suffer from the current economic downturn.

Any failure to complete the development of Augment or any of our other product candidates in a timely manner, or any failure to successfully market and commercialize Augment or any of our other product candidates, could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some of the consequences of failing to do so, are set forth under "Item 1A — Risk Factors."

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses, fair valuation of inventory, valuation of any losses on purchase commitments, fair valuation of stock related to stock-based compensation and income taxes. We base our estimates on authoritative literature and pronouncements, historical experience and on various other assumptions 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. Actual results may differ from these estimates under different assumptions or conditions. Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements. The results of our operations for any historical period are not necessarily indicative of the results of our operations for any other future period.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing at the end of this Annual Report, we believe that the following accounting policies relating to revenue recognition, research and development expense, inventory valuation, valuation of purchase commitments, accrued expenses and deferred liabilities, stock-based compensation, income taxes and investments in marketable securities are significant and, therefore, important to aid you in fully understanding and evaluating our reported financial results.

Revenue Recognition

We follow the revenue recognition criteria outlined in ASC 605, *Revenue Recognition* (includes former Staff Accounting Bulletin 101, *Revenue Recognition in Financial Statements*, as amended by SAB 104, *Revenue Recognition*, Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, and Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists*). Product sales revenue is recognized upon delivery of the product to the customer. Accordingly, upfront, non-refundable license fees under agreements where we have an ongoing research and development commitment are amortized, on a straight-line basis, over the performance period. Revenues from milestones are only recognized upon achievement of the milestone criteria. Milestone payments received for sublicense fees are deferred and recognized as revenue on a straight-line basis over the remaining term of the sublicense. Revenues received for ongoing research and development activities under collaborative agreements are recognized as these activities are performed pursuant to the terms of the related agreements. Royalty revenues are received from our sublicensor in arrears based on sales by the sublicensor. We recognize royalty income when we receive the sales information from Luitpold. Any amounts received in advance of performance are recorded as deferred revenue until earned.

Revenue related to grant awards is deferred and recognized as related research and development performance occurs.

Research and Development Costs

We expense costs associated with research and development activities as incurred. We evaluate payments made to suppliers and other vendors in accordance with ASC 830, *Research and Development* (Formerly SFAS No. 2, *Accounting for Research and Development Costs)*, and determine the appropriate accounting treatment based on the nature of the services provided, the contractual terms, and the timing of the obligation. Research and development costs include payments to third parties that specifically relate to Augment and our other product candidates in clinical development, such as payments to contract research organizations, clinical investigators, manufacture of clinical material, product related consultants, contract manufacturer start-up costs, manufacturing scale-up costs, milestone payments and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the manufacturing, regulatory affairs, clinical affairs, quality assurance, quality control, and research and development departments are classified as research and development costs. On January 1, 2008, we adopted Emerging Issues Task Force Issue 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (now included in ASC 830, *Research and Development),* and the adoption did not have a material impact on our financial position or results of operations as of and for the years ended December 31, 2009 and 2008.

Inventory Valuation

We value our inventory at the lower of our actual cost or the current estimated market value. We regularly review existing inventory quantities, expiration dates of existing inventory, and inventory purchase commitments with suppliers to evaluate a provision for excess, expired, obsolete and scrapped inventory based primarily on our historical usage and anticipated future usage. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated change in demand or technological developments could have a significant impact on the value of our inventory and our reported operating results.

Inventory is carried at the lower of cost (first-in, first-out) or net realizable value and consists primarily of the purchase of raw materials, shipping costs associated with the transportation of raw materials to the contract manufacturer, fees paid to contract manufacturers in connection with the production of filled periodontal cups and vials, kit packing fees, and quality control testing fees, less reserves for obsolescence, shrinkage, expired inventory and potential scrapping of product batches that may not be released for sale.

Valuation of Purchase Commitments

We have substantial firm purchase commitments with our suppliers related to our future inventory needs. As part of the process of preparing our consolidated financial statements, we assess the need for any provision for future losses associated with these future purchase commitments in accordance with ASC 330, *Inventory* and ASC 440, *Commitments* (Formerly Accounting Research Bulletin (''ARB'') No. 43, *Restatement and Revision of Accounting Research Bulletins)*. As of December 31, 2009, no reserves have been recorded associated with these future purchase commitments.

Accrued Expenses and Deferred Liabilities

As part of the process of preparing our consolidated financial statements, management is required to estimate expenses that we have incurred for which we have not been invoiced. This process involves identifying services that have been performed on our behalf and estimating the level of services performed by third parties and the associated cost incurred for such services where we have not been invoiced or otherwise notified of actual costs. Examples of expenses for which we accrue based on estimates include milestones payable, salaries and wages, unpaid vacation and sick pay, fees for services, such as those provided by clinical research and data management organizations, investigators and fees owed to contract manufacturers in conjunction with the manufacture of clinical trial materials. In connection with such service fees, these estimates are most affected by management's projections of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs that have begun to be incurred or we under-estimate or over-estimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which certain services commence, the

level of services performed on or before a given date, and the cost of such services are often subjective determinations. Management makes these estimates based upon the facts and circumstances known to it at the time and in accordance with U.S. generally accepted accounting principles.

Stock-based Compensation

During 2001, our board of directors approved the adoption of the 2001 Long-Term Stock Incentive Plan (the ''option plan''). The option plan provides that stock options, other equity interests or equity-based incentives in our Company may be granted to key personnel at an exercise price determined by our Compensation Committee, at the time the option is granted, taking into account the fair value of the common stock at the date of grant. The maximum term of any option granted pursuant to the option plan is ten years from the date of grant.

The stock options we granted to our employees are structured to qualify as incentive stock options (''ISOs''). Under current tax regulations, we do not receive a tax deduction for the issuance, exercise or disposition of ISOs if the employee meets specific holding requirements. If the employee does not meet the holding requirements, a disqualifying disposition occurs, at which time we will receive a tax deduction. We do not record tax benefits related to ISOs unless and until a disqualifying disposition occurs. In the event of a disqualifying disposition, the entire tax benefit is recorded as a reduction of income tax expense. We have not recognized any income tax benefit for share-based compensation arrangements due to the fact that we do not believe that we will recognize any deferred tax assets from such compensation cost recognized in the current period.

Effective January 1, 2006, we adopted ASC 505, *Equity-Based Payments to Non-Employees*, and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*), using the modified prospective method of transition. Under that transition method, compensation costs recognized in the years ended December 31, 2009, 2008 and 2007 include the costs for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of ASC 505 and ASC 718.

In accordance with ASC 505 and ASC 718, the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using the following weighted average assumptions amortized to expense over the options' vesting periods for the year ended December 31, 2009: risk-free interest rate of 2.11%, expected dividend yield of 0%, volatility factor of the expected market price of our common stock ranged from 77% to 79%, forfeiture rate of 6.9% and weighted average expected life of the option of 8.5 years. Since the trading market for our common stock has a limited history, the expected volatility rates are based on historical data from three companies similar in size and value to our company. The expected terms of options granted represent the period of time that options granted are estimated to be outstanding and are derived from the contractual terms of the options granted. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant. We amortize the fair value of each option over each option's vesting period.

During the year ended December 31, 2009, we granted stock options to our employees, members of the board of directors and consultants to purchase an aggregate of 627,666 shares of our common stock at a weighted average exercise price of $8.70. Our net loss for the years ended December 31, 2009, 2008 and 2007 includes compensation costs of $3.9 million, $3.4 million and $1.7 million, respectively, related to our stock-based compensation arrangements. No income tax benefit related to our stock-based compensation arrangement is included in our net losses.

Income Taxes

We account for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109, *Accounting for Income Taxes)*. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided for the deferred tax assets related to future years, including loss carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years.

Effective January 1, 2007, we adopted a provision ASC 740, *Income Taxes* (formerly Financial Accounting Standards Board FIN 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*), to account for uncertain tax positions. ASC 740 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 prescribes that we should use a ''more likely than not'' recognition threshold based on the technical merits of the tax position taken. Tax positions that meet the ''more likely than not'' recognition threshold should be measured in order to determine the tax benefit to be recognized in the financial statements. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

As a result of adopting ASC 740, we did not have any unrecognized tax benefits or liabilities, or any associated amounts for interest and penalties. As a result, there was no effect on our financial condition or results of operations as of and for the years ended December 31, 2009, 2008 and 2007.

Investments

Effective January 1, 2008, we adopted ASC 820-10, *Fair Value Measurements* (formerly SFAS No. 157, *Fair Value Measurements*). ASC 820-10 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

As of December 31, 2009, we had short-term investments that are classified as available for sale and consist of GSE securities and U.S. Treasury Notes, which total $47.0 million. The GSE securities have maturity dates ranging from January 2010 through July 2010. The U.S. Treasury Notes have maturity dates ranging from March 2010 to August 2010. Also as of December 31, 2009, we had long-term investments of $6.5 million, consisting of three GSE securities with maturity dates of March 2011.

During 2008 and 2009, we had investments in certain ARS that were classified as available for sale. The ARS investments were recorded at fair market value, with any unrealized gains and losses, net of tax, reported in the accompanying consolidated balance sheets. Realized gains and losses and declines in market value judged to be other-than-temporary on investments in marketable securities are included in investment (loss) income, net in the accompanying consolidated statements of operations. The cost of ARS investments sold were based on the specific identification method. Interest and dividends on ARS investments were included in investment (loss) income, net in the accompanying consolidated statements of operations.

In 2008, we had determined that these ARS investments had experienced an ''other-than-temporary'' impairment in fair value, and therefore had recorded a $13.4 million impairment loss. However, during the twelve months ended December 31, 2009, all of our ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52.4 million and a $5.8 million realized gain recorded in earnings on our consolidated statement of operations. In addition, we received a $7.2 million payment from the settlement of an arbitration claim relating to the investments in ARS made on our behalf. As of December 31, 2009, we did not have any investments in ARS.

See additional discussion regarding the liquidity of our investments in ''— Liquidity and Capital Resources.''

Results of Operations

Years Ended December 31, 2009 and 2008

Net loss for the year ended December 31, 2009 was $21.2 million, or $1.03 per diluted share, compared to net loss of $8.0 million, or $0.43 per diluted share, for the year ended December 31, 2008. The net loss in 2009 included a $5.8 million realized gain and a $7.2 million settlement payment related to our investments in ARS. The net loss in 2008 included a $39.3 million gain on the disposal of our orofacial therapeutic business, offset in part by a $13.4 million impairment loss on our ARS investments.

We anticipate that our operating losses, which are only partially offset by sales, revenues from royalty income, sublicense fee income and investment income, may continue over the next few years as we continue to fund our research and development activities and clinical trials and as we prepare for a future sales network to represent our products.

Product Sales

- In January 2008, we sold our orofacial therapeutic business (*GEM 21S*) to Luitpold, and we recorded a $39.3 million net gain on the transaction in 2008. As of December 31, 2009, we have received a total of $40.0 million in cash from the sale transaction, including $10.0 million in time-based payments received in 2009, and $3.4 million in cash from the sale of existing inventory. As a result of the sale, no product sales revenues, nor cost of sales, resulting from sales of *GEM 21S* have been recorded in 2008 and 2009.
- In November 2009, we received approval from Health Canada for the marketing and commercialization of Augment in Canada. Based upon this approval, we shipped our first order of Augment to our Canadian distributor, Joint Solutions Alliance Corporation, a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada. Accordingly, we recorded $0.1 million in revenue from product sales of Augment in December 2009.

Cost of Sales

Cost of sales for the year ended December 31, 2009 was minimal. No cost of sales was incurred in 2008. Cost of sales is comprised of the following costs: raw materials used in the production and manufacturing of vials and cups, testing fees for the vials and cups, labeling materials for the finished kits, packaging materials for inclusion in the finished kit, kit packing costs and scrap incurred during the production process. The cost of sales will vary in direct correlation to the volume of product sales of Augment kits. Certain raw materials were purchased in prior years before the Phase III clinical trials were completed. As a result, this pre-launch inventory was expensed. Therefore, we expect that the gross profit margins will decrease as we continue to replenish our raw materials and includes those production costs in the Cost of Sales.

ARS Investments

- In 2008, we had determined that our ARS investments had experienced an ''other-than-temporary'' impairment in fair value, and therefore had recorded a $13.4 million impairment loss on our consolidated statement of operations in 2008.
- In 2009, all of our ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52.4 million and a $5.8 million realized gain recorded to investment income on our consolidated statement of operations in 2009. In addition, we received a $7.2 million payment from the settlement of an arbitration claim relating to the investments in ARS made on our behalf. This $7.2 million settlement payment is recorded as a gain on arbitration settlement and is reflected on our consolidated statement of operations in 2009.
- As of December 31, 2009, we did not have any remaining investments in ARS.

Royalty and Sublicense Fee Income

- Royalty income for the year ended December 31, 2009 was $0.5 million, compared to $2.1 million for the same period in 2008. Royalty income is earned and received based on Luitpold's sale of the *GEM 21S* product during the year. In 2009, Luitpold's net sales of *GEM 21S* were $5.2 million, compared to $7.2 million in 2008. Royalty income decreased in 2009 compared to 2008 primarily due to the reimbursement received in 2008 for minimum royalty expenses that are contractually paid by us to independent third parties. There was no minimum royalty expense or reimbursement in 2009. In addition, we believe that the current economic downturn may have negatively impacted the demand for elective dental procedures, such as regenerative procedures using *GEM 21S,* potentially resulting in decreased sales compared to the prior year. Also, under the terms of the January 2008 sale of our orofacial therapeutic business discussed above, we expect to receive ongoing royalty payments from Luitpold based on net sales of *GEM 21S*.
- Sublicense fee income for the year ended December 31, 2009 was $1.0 million, compared to $1.0 million for the same period in 2008. Sublicense fee income is based on certain milestone payments previously received from Luitpold.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2009 were $21.1 million, compared to $24.6 million for the same period in 2008. The $3.5 million decrease resulted in part from:

- our focus on controlling costs in 2009,
- a decrease of $1.8 million in contract manufacturing expenses as certain clinical trials came to a close in 2009 and clinical supplies were no longer needed, and since 2008 costs included initial start-up costs of clinical trials,
- a decrease of $0.8 million in professional services for clinical costs as certain orthopedic clinical trials came to a close in 2009,
- a decrease of $0.6 million in professional services expenses for validation consulting, regulatory and outside R&D costs,
- a decrease of $0.3 million in salaries, payroll taxes, benefits, insurance, recruiting and relocation expenses, and general activities of the R&D programs.

We expect that research and development expenses will start to increase over the next few months as a result of new and ongoing clinical trials of Augment and our other product candidates in the United States, Canada, and the EU, as well as continuing expenses associated with pre-clinical studies and regulatory filings.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2009 were $11.5 million, compared to $11.3 million for the same period in 2008. The $0.2 million increase resulted in part from:

- an increase of $0.7 million in salaries, benefits, payroll taxes, and stock compensation costs,
- an increase of $0.1 million in fees paid to the board of directors resulting from the April 2008 approval of an increase in retainers and meeting fee payments,
- an increase of $1.1 million in professional fees primarily due to legal fees incurred for ongoing patent licensing agreements and the arbitration proceedings related to our ARS investments,
- a decrease of $0.1 million in utilities, rent and common area maintenance as a result of our focus on controlling costs in 2009, and,
- a decrease of $1.8 million in royalty expense as a result of lower sales of *GEM21S* by Luitpold as well as minimum royalty expense payments required in 2008 that were not required in 2009.

We have kept our organizational growth to a minimum as we are continuously monitoring expenses and have implemented cash-conservation measures wherever possible.

Depreciation and Capital Lease Amortization

Depreciation and capital lease amortization for the year ended December 31, 2009 was $1.3 million, compared to $1.4 million for the same period in 2008.

Patent License Fee Amortization

Patent license fee amortization for the year ended December 31, 2009 was $2.6 million, compared to $2.7 million for the same period in 2008. Ongoing amortization expense is attributable to the capitalization of patent license fees amounting to a cumulative $12.5 million as of December 31, 2009.

Interest and Investment Income

- Total net interest and investment income for the year ended December 31, 2009 was $6.6 million, compared to a net interest and investment loss of $10.5 million for the same period in 2008.
- The 2009 sales and redemptions of certain ARS investments resulted in a net realized gain on investments of $5.8 million recorded to investment income. Excluding this gain, total net interest and investment income was $0.8 million for the year ended December 31, 2009.

- The net interest and investment loss in 2008 included an "other-than-temporary" impairment loss of $13.4 million on our ARS investments. Excluding this loss, total net interest and investment income was $2.9 million for the year ended December 31, 2008.
- Interest rates earned on our cash and money market accounts ranged from 0.00% to 1.10% during the year ended December 31, 2009, which is a significant decrease from the same period in 2008 when interest rates ranged from 1.60% to 4.10%.
- Interest expense on our note payable for the year ended December 31, 2009 was $0.5 million, compared to $0.2 million for the same period in 2008. The increase in 2009 is because we held the note for only a portion of 2008 since the note was initially incurred in October 2008. The note was paid in full in December 2009.

Provision for Income Taxes

At December 31, 2009, we had federal net operating loss carryforwards of $63.3 million that will begin to expire in 2022. State net operating loss carryforwards at December 31, 2009 totaled $51.3 million and will expire between 2012 and 2028.

Our ability to use our net operating loss carryforwards could be limited. Our ability to use these net operating loss carryforwards to reduce our future federal income tax liabilities could be subject to annual limitations. Additionally, because U.S. tax laws limit the time during which net operating loss carryforwards may be applied against future taxable income and tax liabilities, we may not be able to take advantage of our net operating loss for federal income tax purposes.

Years Ended December 31, 2008 and 2007

Net loss for the year ended December 31, 2008 was $8.0 million, or $0.43 per diluted share, compared to net loss of $24.6 million, or $1.37 per diluted share, for the year ended December 31, 2007. The net loss in 2008 included a $39.3 million gain on the disposal of our orofacial therapeutic business, offset in part by a $13.4 million impairment loss on our ARS investments.

Revenue and Cost of Sales

- No product sales revenues, nor cost of sales, were recorded in 2008 due to the January 2008 sale of our orofacial therapeutic business. This compares to product sales revenues of $5.0 million, and cost of sales of $3.9 million, for the year ended December 31, 2007.
- Royalty income for the year ended December 31, 2008 was $2.1 million, compared to $1.2 million for the same period in 2007. Royalty income is earned and received based on Luitpold's sale of the *GEM 21S* product during the year. In 2008, Luitpold's net sales of *GEM 21S* were $7.2 million, compared to $7.5 million in 2007. Royalty income increased in 2008 compared to 2007 primarily due to the reimbursement for minimum royalty expenses that are contractually paid by us to independent third parties.
- Sublicense fee income for the year ended December 31, 2008 was $1.0 million, compared to $0.7 million for the same period in 2007. Sublicense fee income is based on certain milestone payments received from Luitpold.

Research and Development Expenses

- Research and development expenses for the year ended December 31, 2008 were $24.6 million, compared to $19.2 million for the same period in 2007.
- Professional fees and contract manufacturing expenses related to our clinical trials and research and development activities for orthopedic, sports medicine, and spine increased $2.2 million in the year ended December 31, 2008.
- Travel expenses for employees involved in clinical, research and development activities increased $0.2 million for the year ended December 31, 2008. Travel expenses were $0.8 million for the year ended December 31, 2008, compared to $0.6 million for the same period in 2007.

- As of December 31, 2008, we had 64 employees involved in research and development functions. During 2008, we hired four new employees to fill various research and development functions. In comparison, we hired 23 new employees in 2007. Many of the 2007 hires occurred in the later part of 2007, so a full year of salaries, payroll taxes, benefits and stock compensation expense was not recognized until 2008. As a result, our salaries, benefits, payroll taxes and stock compensation expenses increased $2.7 million for the year ended December 31, 2008.
- Milestone expenses were $0.3 million for the year ended December 31, 2008, compared to $0.1 million for the same period in 2007. In April 2008, we amended the agreement with Kensey Nash to provide for new payments from us to Kensey Nash for the accomplishment of development milestones for potential new products. In August 2008, however, we terminated the then current development project relating to a product for tendon and ligament injury treatment. This termination was effective in September 2008, at which time we stopped making the quarterly payments to Kensey Nash.

General and Administrative Expenses

- General and administrative expenses for the year ended December 31, 2008 were $11.3 million, compared to $8.8 million for the same period in 2007.
- Royalty expense was $2.1 million for the year ended December 31, 2008, compared to $1.2 million for the same period in 2007. The increase, which results from minimum royalty payment requirements set forth in our patent licensing agreements, was offset by an increase in royalty income received to reimburse us for royalty expenses paid to third parties in excess of the royalty income already received.
- Stock compensation expense was $1.6 million in the general and administrative functions for the year ended December 31, 2008, compared to $0.6 million for the same period in 2007. This increase was due to the expense related to a total of 653,181 new stock options awarded in 2008 at a weighted average exercise price of $13.31 per share.
- Corporate administration expenses increased by $0.5 million as a result of additional costs associated with our growing company, including insurance, board of directors' fees and travel costs, office supplies, small equipment, dues, subscriptions and conferences.

Depreciation and Capital Lease Amortization

Depreciation and capital lease amortization for the year ended December 31, 2008 was $1.4 million, compared to $1.1 million for the same period in 2007. For the year ended December 31, 2008, we purchased lab, manufacturing and office equipment, made leasehold improvements and incurred equipment engineering design and planning costs totaling $2.9 million. The increase in depreciation and capital lease amortization is attributable to these new purchases, excluding $2.3 million in equipment not yet placed in service.

Patent License Fee Amortization

Patent license fee amortization for the year ended December 31, 2008 was $2.7 million, compared to $2.2 million for the same period in 2007. Ongoing amortization expense is attributable to the capitalization of patent license fees amounting to a cumulative $13.2 million as of December 31, 2008.

Interest and Investment Income

- Total net interest and investment loss for the year ended December 31, 2008 was $10.5 million, compared to net interest and investment income of $3.7 million for the same period in 2007.
- We recorded an "other-than-temporary" impairment loss of $13.4 million on our ARS investments during the year ended December 31, 2008. This impairment loss is included in the investment loss as reflected on our consolidated statement of operations for the year ended December 31, 2008.
- The aggregate balance of cash and investments at December 31, 2008 includes the following significant cash events in 2008:

1. net proceeds of $33.4 million from the sale of our orofacial therapeutic business in January 2008, which was received in the first quarter of 2008, and
2. net proceeds of $39.1 million borrowed from an October 2008 promissory note credit facility.

The balances of cash and cash equivalents, short-term investments and long-term investments have increased due to the proceeds of these transactions, resulting in $2.6 million in investment income during the year ended December 31, 2008, excluding the impact of the impairment loss on our ARS investments. Our cash accounts earned $1.2 million less interest income in 2008 compared to the same period in 2007 partially as a result of reduced interest rates (which ranged from 1.60% to 4.10% during the year ended December 31, 2008, compared to a range of 4.10% to 5.27% for 2007), but also offset by $0.3 million interest expense in 2008 related to a promissory note credit facility.

Provision for Income Taxes

At December 31, 2008, we had federal net operating loss carryforwards of $42.2 million that will begin to expire in 2022. State net operating loss carryforwards at December 31, 2008 totaled $30.3 million and will expire between 2017 and 2023.

Liquidity and Capital Resources

Capital Shares

In February 2007, we completed a secondary public offering of 3,253,350 shares of our common stock, which included 424,350 shares sold upon full exercise of the underwriters' over-allotment option. Of the shares of common stock that were offered, we sold 2,517,111 shares of common stock and the remaining 736,239 shares of common stock were sold by certain selling stockholders. All of the shares of common stock were sold at a price of $17.15 per share. After deducting the underwriting discounts and commissions of $3.6 million ($2.8 million paid by us and $0.8 million paid by the selling stockholders) and other offering expenses of approximately $0.7 million paid by us in connection with the offering, the net proceeds from the offering were approximately $39.7 million to us and $11.8 million to the selling stockholders. We did not receive any proceeds from the sale of shares of our common stock by the selling stockholders.

In April 2009, we sold to InterWest Partners X, L.P. 941,177 shares of our common stock for a net aggregate purchase price of approximately $8.0 million, or $8.50 per share.

In June 2009, we completed a rights offering to sell 2,000,000 shares of our common stock to our existing stockholders of record as of April 21, 2009 (the ''record date''), other than with respect to shares held in the 401(k) plan. We received valid subscriptions for all of the shares purchasable in the rights offering, including shares subscribed for by certain of our stockholders in the exercise of their over-subscription rights, at a subscription price of $8.50 per share. We issued the shares to the participants in the rights offering on June 25, 2009. After deducting related expenses of approximately $0.4 million, the net proceeds of the rights offering, including the private placement to Novo A/S, was $16.6 million.

Sale of Orofacial Therapeutic Business and Milestones

In January 2008, we completed the sale to Luitpold of our remaining orofacial therapeutic business, including the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. In 2008, we received $30.0 million in cash as a result of the transaction, plus $3.4 million in cash from the sale of existing inventory. In 2009, under the terms of the sale agreement, we received an additional $10.0 million in time-based payments in cash, as well as ongoing royalty payments based on net sales of *GEM 21S*.

Under our agreement with Luitpold, upon approval of *GEM 21S* (now known as *GEMESIS*™ in Europe) in the EU, we are entitled to receive a $10.0 million milestone payment from Luitpold. Refer to ''— Milestone Payments'' discussed below for more information regarding this potential milestone payment.

Cash and Cash Equivalents and Investments

As of December 31, 2009, the remaining net proceeds from our capital offerings and sale of *GEM 21S* have been invested conservatively in cash and cash equivalents and in short-term and long-term investments in GSE securities and U.S. Treasury Notes.

At December 31, 2009, we had $21.6 million in cash and cash equivalents held in three financial institutions. Our excess cash reserves are invested in overnight sweep accounts, operating accounts and money market accounts. In addition to the balance of cash and cash equivalents as of December 31, 2009, we had $47.0 million in short-term investments classified as available for sale consisting of GSE securities totaling $36.1 million and U.S. Treasury Notes totaling $10.9 million. Also at December 31, 2009, we had $6.5 million in long-term investments in GSE securities. The GSE securities have maturity dates ranging from January 2010 through March 2011. The U.S. Treasury Notes have maturity dates ranging from March 2010 to August 2010.

During 2008 and 2009, we had investments in certain ARS investments that were classified as available for sale and recorded at fair value. We had determined that these ARS investments had experienced an "other-than-temporary" impairment in fair value, and therefore had recorded a $13.4 million impairment loss recorded to earnings as reflected on our consolidated statement of operations as of December 31, 2008. However, during 2009, all of our ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52.4 million and a $5.8 million realized gain recorded to earnings on our consolidated statement of operations as of December 31, 2009. In addition, in December 2009, we received a $7.2 million payment from the settlement of an arbitration claim relating to the investments in ARS made on our behalf. As of December 31, 2009, we did not have any investments in ARS.

In October 2008, to address the liquidity issues experienced with these ARS investments in the short-term, we entered into a Time Promissory Note ("Note") credit facility enabling us to borrow up to $39.1 million with certain of our ARS investments serving as collateral. We granted the issuer of the Note a first priority security interest in certain of our ARS investments having a total combined par value of $55.9 million as collateral. Under the terms of the Note, we were required to make monthly interest payments during the two-year term of the Note and all outstanding principal amounts were to be due and payable in full on the maturity date in October 2010. We had an election to pay back the full principal amount prior to the maturity date with no penalty. Absent our default or a sale of part of the collateral ARS investments, the issuer of the Note had no ability to withdraw, reduce or change the terms of the Note. Under the terms of the Note, and at our option, the interest rate was based on either LIBOR plus 0.50% or the Note issuer's Prime Rate minus 1.50%. The Note also provided that in the event that the issuer of the Note later offers an ARS lending program or settlement loan program to institutional clients that included either a lower interest rate or permitted borrowing of more than 70% of the par value of the collateral securities, then the terms of our Note and any existing loans issued under the Note would have modified to include the lower interest rate or higher borrowing base. With the redemptions and sales of all our remaining ARS investments during the year ended December 31, 2009, we have repaid in full the balance on the Note and the original promissory note has been returned to us marked "paid in full." In addition, the issuer of the Note has released us from the Note, and has terminated our security and pledge agreement and securities account control agreement and terminated any UCC filings made with respect to the Note and security agreements.

Cash Flows

For the year ended December 31, 2009, net cash used in operating activities was $22.9 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash provided by investing activities was $41.1 million for the year ended December 31, 2009 and included the time-based payments received in 2009 from the 2008 disposal of our orofacial therapeutic business, and the net sales and redemptions of our investments in ARS, offset by capitalized patent costs and engineering design and planning costs for the new manufacturing facility at our corporate headquarters. Net cash used in financing activities for the year ended December 31, 2009 consisted primarily of $39.1 million repayment of our October 2008 Note, offset by $24.6 million in net proceeds from stock offerings in 2009 and $0.3 million in net proceeds from issuance of common stock under our stock-compensation plans.

We believe that the December 31, 2009 balance of our cash and investments, which includes $24.6 million in net proceeds from stock offerings in 2009 and $10.0 million in milestone payments received from Luitpold in 2009, will be sufficient to meet our anticipated cash requirements at least through the middle of 2011.

We expect to devote substantial resources to continue our research and development efforts, including clinical trials. Clinical study costs are comprised of payments for work performed by contract research organizations, universities and hospitals.

Because of the significant time it will take for Augment or our other product candidates to complete the clinical trial process, obtain approval from regulatory authorities and successfully commercialize our products, we may require substantial additional capital resources. We may raise additional capital through public or private equity offerings, debt financings, corporate collaborations or other means. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. To the extent that we raise additional funds by issuance of equity securities, our stockholders will experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position. Additional financing may not be available on acceptable terms, if at all. Capital may become difficult or impossible to obtain due to poor market or other conditions outside of our control. If at any time sufficient capital is not available, either through existing capital resources or through raising additional funds, we may be required to delay, reduce the scope of, eliminate or divest one or more of our research, pre-clinical or clinical programs.

Seasonality

We have determined that the impact on seasonality on our results of operations is minimal; however, fluctuations in product sales revenues are the result of our evolving product commercialization efforts.

Segment Information

We have determined that we are principally engaged in one operating segment. Our product development efforts are primarily in the treatment of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications for the repair and regeneration of orthopedic tissues, including bone, cartilage, ligaments and tendons.

Comprehensive Loss

FASB ASC 220, *Comprehensive Income* (formerly SFAS No. 130, *Reporting Comprehensive Income*), establishes standards for reporting and display of comprehensive income (losses) and its components in the consolidated financial statements. Our comprehensive loss as defined by ASC 220 is the total of net loss and all other changes in equity resulting from non-owner sources including unrealized gains/losses on investments. The components of our comprehensive losses for the years ended December 31, 2009, 2008 and 2007 are as follows (in millions):

	2009	2008	2007
Net loss	$(21.2)	$(8.0)	$(24.6)
Other comprehensive loss:			
Net unrealized (loss) gain on investments classified as available for sale	(0.1)	0.1	—
Comprehensive loss	$(21.3)	$(7.9)	$(24.6)

Milestone Payments

Under our agreements with Luitpold, ZymoGenetics, Harvard, Kensey Nash Corporation (''Kensey Nash'') and Novartis Vaccines and Diagnostics (''Novartis''), various milestone payments are required. Luitpold is required to make certain milestone payments to us, and we were required to make certain milestone payments to ZymoGenetics, Harvard, Kensey Nash and Novartis, based on the occurrence of certain events.

Our first product, *GEM 21S*, received approval from the FDA in November 2005. As a result of the FDA approval, we received a $15.0 million milestone payment from Luitpold in December 2005. In December 2007, we received a $5.0 million milestone payment from Luitpold upon the second anniversary of the FDA approval. Also as a result of the FDA approval, we were required to make milestone payments of $5.0 million to Novartis and a total of $7.1 million to patent licensors. The patent license fees were paid to our licensors as a result of FDA approval and receipt of the milestone payments from Luitpold upon FDA approval, and were capitalized and amortized over the remaining life of the patents.

Under our 2008 agreements with Luitpold, upon approval of *GEMESIS* in the EU, we are entitled to receive a $10.0 million milestone payment from Luitpold, who now owns the *GEM 21S* and *GEMESIS* products, and markets *GEM 21S* through its Osteohealth Company. The European Medicines Agency ("EMA") previously determined that *GEMESIS* would be reviewed as a medicinal (i.e., a drug) combination product, and not as a medical device product which is how the product was reviewed in the United States and Canada. Accordingly, we filed a Marketing Authorization Application ("MAA") for *GEMESIS*, but the EMA rejected our application, due in part to the different clinical and quality requirements of a drug product in the EU compared to a medical device product in the United States. We appealed that decision, but our appeal has been denied. We are currently re-evaluating our regulatory strategy for *GEMESIS* in the EU, and are considering seeking reclassification of *GEMESIS* from a medicinal to a medical device based on recent changes in the Medical Device Directives ("MDD"). Because of uncertainties in the review process, we have excluded this milestone payment from our financial guidance for 2010.

In addition, we received an additional $10.0 million in time-based payments in cash in 2009, and we expect to receive ongoing royalty payments based on net sales of *GEM 21S*.

Contractual Obligations

Our major outstanding contractual obligations relate to our capital leases for office equipment, operating leases for our facilities, and purchase and supplier obligations for raw materials and equipment. See "Business — Lease Obligations" and "Business — Purchase and Supply Obligations" for more information.

We have summarized in the table below our fixed contractual obligations as of December 31, 2009:

	Payments Due by Period				
Contractual obligations	**Total**	**Less Than 1 Year**	**1 – 3 Years**	**3 – 5 Years**	**More Than 5 Years**
Capital lease obligations	$ 244,258	$ 61,867	$ 99,265	$ 83,126	$ —
Operating lease obligations	13,625,927	1,422,604	2,974,522	3,155,671	6,073,130
Purchase and supplier obligations – raw materials	7,259,083	1,799,854	5,459,229	—	—
Purchase and supplier obligations – equipment	604,035	54,760	549,275	—	—
Total	$21,733,303	$3,339,085	$9,082,291	$3,238,797	$6,073,130

Recent Accounting Pronouncements

The FASB Accounting Standards Codification™

In June 2009, the Financial Accounting Standards Board ("FASB") issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 168"), which establishes the FASB Accounting Standards Codification™ ("Codification"). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental U.S. generally accepted accounting principles. The Codification did not change U.S. generally accepted accounting principles but reorganizes the literature. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and is effective for interim and annual periods ending after September 15, 2009. Subsequent changes to the Codification will be released through Accounting Standards Updates ("ASU"), which serve to

update the Codification, provide background information about the guidance and provide the basis for conclusions on the changes in the Codification. We have has conformed our financial statements and related Notes to the new Codification for the year ended December 31, 2009.

In conjunction with the issuance of SFAS No. 168, the FASB issued ASU 2009-01 Topic 105, *Generally Accepted Accounting Principles* (''ASU 2009-01''). ASU 2009-01 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with U.S. generally accepted accounting principles. ASU 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this ASU did not have a material impact on our financial position or results of operation for the year ended December 31, 2009.

Fair Value Measurements and Other-Than-Temporary Impairments

In April 2009, the FASB issued Accounting Standards Codification (''ASC'') 320-10, *Investments — Debt and Equity Securities* (includes former Staff Position (''FSP'') No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*). The ASC changes existing guidance for determining whether impairment of debt securities is other-than-temporary. The ASC requires other-than-temporary impairment to be separated into the amount representing the decrease in cash flows expected to be collected from a security (referred to as credit losses), which is recognized in earnings, and the amount related to other factors, which is recognized in other comprehensive income. The non-credit loss component of the impairment can only be classified in other comprehensive income if the holder of the security concludes (1) that it does not intend to sell the security and (2) that it is more likely than not that it will not be required to sell the security before the security recovers its value. If these two conditions are not met, the non-credit loss component of the impairment must also be recognized in earnings. Upon adoption of the ASC, the entity is required to record a cumulative-effect adjustment, as of the beginning of the period of adoption, to reclassify the non-credit loss component of previously recognized other-than-temporary impairment from retained earnings to accumulated other comprehensive income.

In April 2009, the FASB issued ASC 820-10, *Fair Value Measurements and Disclosures* (includes former FSP No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). This ASC, while emphasizing that the objective of fair value measurement described in ASC 820 (formerly SFAS No. 157, *Fair Value Measurements*) remains unchanged, provides additional guidance for determining whether market activity for a financial asset or liability has significantly decreased, as well as for identifying circumstances that indicate that transactions are not orderly. The ASC reiterates that if a market is determined to be inactive and the related market price is deemed to be reflective of a ''distressed sale'' price, then management's judgment may be required to estimate fair value. The ASC identifies factors to be considered when determining whether or not a market is inactive.

In April 2009, the FASB issued ASC 825-10, *Financial Instruments* (includes former FSP No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*). This ASC requires disclosures about fair values of financial instruments in all interim financial statements, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Due to their short-term nature, the carrying amounts reported in our consolidated financial statements approximate the fair value for cash, cash equivalents, short-term and long-term investments, accounts receivable, accounts payable, accrued expenses and capital lease obligations.

The ASCs set forth above were effective for interim and annual periods ending after June 15, 2009. We adopted the ASCs set forth above, and the adoption of such ASCs did not have a material impact on our consolidated financial statements as of December 31, 2009.

Business Combinations

In April 2009, the FASB issued ASC 805-10, *Business Combinations* (includes former FSP No. FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*). This ASC amends and clarifies the provisions of ASC 805, formerly SFAS No. 141(R), *Business Combinations*, with respect to the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies associated with a business

combination. The provisions of the ASC are effective for business combinations occurring after January 1, 2009. The adoption of the ASC did not have a material impact on our consolidated financial statements as of December 31, 2009. The impact of adoption of the ASC on our future consolidated financial statements will depend on the nature, terms and size of future business combinations, if any.

Subsequent Events

In February 2010, the FASB issued ASU 2010-09 to amend ASC 855, *Subsequent Events*. ASC 855, which was originally issued by the FASB in May 2009 (as SFAS No. 165, *Subsequent Events*), provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. ASC 855 distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. As a result of ASU 2010-09, SEC registrants will not disclose the date through which management evaluated subsequent events in the financial statements, either in originally issued financial statements or reissued financial statements. ASC 855 was effective for interim and annual periods ending after June 15, 2009, and ASU 2010-09 is effective immediately. We have evaluated subsequent events in accordance with ASU 2010-09.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities, including the use of structured finance, special purpose entities or variable interest entities.

Effects of Inflation

Because our assets are, to an extent, liquid in nature, they are not significantly affected by inflation. However, the rate of inflation affects such expenses as employee compensation, office space leasing costs and research and development charges, which may not be readily recoverable during the period of time that we are bringing the product candidates to market. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations in certain businesses.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. We attempt to increase the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in investment grade securities. Declines in interest rates over time will, however, reduce our interest income while increases in interest rates over time will increase our interest expense. Due to the short-term nature of our cash and cash equivalents, we do not believe that we have any material exposure to interest rate risk arising from our cash and cash equivalents. Our cash accounts earned interest rates ranging from 0.0% to 0.8% during the year ended December 31, 2009. We have not used derivative financial instruments for speculation or trading purposes.

At December 31, 2009, we had $21.6 million in cash and cash equivalents held in three financial institutions. Our excess cash reserves are invested in overnight sweep accounts, operating accounts and money market accounts. In addition to the balance of cash and cash equivalents as of December 31, 2009, we had $47.0 million in short-term investments classified as available for sale consisting of GSE securities totaling $36.1 million and U.S. Treasury Notes totaling $10.9 million. Also at December 31, 2009, we had $6.5 million in long-term investments in GSE securities. The GSE securities have maturity dates ranging from January 2010 through March 2011. The U.S. Treasury Notes have maturity dates ranging from March 2010 to August 2010.

During 2008 and 2009, we had investments in certain ARS investments that were classified as available for sale and recorded at fair value. We had determined that these ARS investments had experienced an ‘‘other-than-temporary’’ impairment in fair value, and therefore had recorded a $13.4 million impairment loss recorded to earnings as reflected on our consolidated statement of operations as of December 31, 2008. However, during 2009, all of our ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52.4 million and a $5.8 million realized gain recorded to earnings on our consolidated statement of operations as of December 31, 2009. In addition, in December 2009, we received a

$7.2 million payment from the settlement of an arbitration claim relating to the investments in ARS made on our behalf. As of December 31, 2009, we did not have any investments in ARS.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required for each of the three years ended December 31, 2009 and the Report of Independent Registered Public Accounting Firm are indexed on page F-1 and are incorporated herein.

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

We maintain disclosure controls and procedures, as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934 (the ''Exchange Act''), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. These controls and procedures are designed to ensure that the required information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all errors, misstatements or fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). The 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 U.S. generally accepted accounting principles.

We carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as of December 31, 2009. 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 evaluation, management, with the participation of the Chief Executive Officer and the Chief Financial Officer, concluded that our disclosure controls and procedures and our internal control over financial reporting were effective as of December 31, 2009.

Report of Independent Registered Public Accounting Firm

Ernst & Young LLP, the independent registered public accounting firm that audited the Company’s consolidated financial statements included in this Form 10-K, has issued a report on the Company’s internal control over financial reporting, which is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
BioMimetic Therapeutics, Inc.

We have audited BioMimetic Therapeutics, Inc.'s (the ''Company'') internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the ''COSO criteria''). The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying ''Management's Report on Internal Control Over Financial Reporting.'' Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, BioMimetic Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of BioMimetic Therapeutics, Inc. as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009 of BioMimetic Therapeutics, Inc., and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 12, 2010

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2010 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2009.

Item 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2010 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2009.

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

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2010 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2009.

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

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2010 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2009.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2010 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2009.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All Financial Statements

Consolidated financial statements filed as part of this report are listed under Item 8. ‘‘Financial Statements and Supplementary Data.’’

2. Financial Statement Schedules

No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits listed on the accompanying Exhibit Index are filed or incorporated by reference as part of this report.

BIOMIMETIC THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Balance Sheets as of December 31, 2009 and 2008	F-3
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
BioMimetic Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of BioMimetic Therapeutics, Inc. (the ''Company'') as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 12, 2010

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,543,347	$ 17,534,963
Investments – short term	47,001,504	33,218,233
Receivables – trade	78,000	1,084
Receivables – other	612,020	11,635,778
Inventory	1,044,305	—
Prepaid expenses	647,156	503,032
Total current assets	70,926,332	62,893,090
Investments – long term	6,513,975	46,624,040
Inventory	—	1,261,987
Prepaid expenses – long term	5,418	58,673
Property and equipment, net	8,156,842	7,014,262
Capitalized patent license fees, net	2,924,614	4,983,729
Deposits	385,000	2,284,608
Total assets	$ 88,912,181	$125,120,389
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,255,748	$ 4,325,907
Accrued payroll, employee benefits and payroll taxes	2,299,237	2,304,016
Other accrued expenses	135,070	2,392,236
Current portion of capital lease obligations	56,520	18,187
Deferred revenue	971,188	971,188
Total current liabilities	5,717,763	10,011,534
Accrued rent – related party	418,305	399,256
Capital lease obligations	174,818	34,713
Deferred revenue	15,549,678	16,520,866
Note payable	—	39,100,000
Total liabilities	21,860,564	66,066,369
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized; no shares issued and outstanding as of December 31, 2009 and 2008	—	—
Common stock, $0.001 par value; 37,500,000 shares authorized; 21,825,028 shares issued and outstanding as of December 31, 2009; 18,714,067 shares issued and outstanding as of December 31, 2008	21,825	18,714
Additional paid-in capital	160,532,625	131,262,570
Accumulated other comprehensive income	17,387	135,542
Accumulated deficit	(93,520,220)	(72,362,806)
Total stockholders' equity	67,051,617	59,054,020
Total liabilities and stockholders' equity	$ 88,912,181	$125,120,389

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2009	2008	2007
Revenues:			
Product sales	$ 78,000	$ —	$ 5,039,608
Royalty income	522,038	2,144,234	1,213,481
Sublicense fee income	971,188	973,849	740,630
Other revenue	—	30,301	36,565
Total revenues	1,571,226	3,148,384	7,030,284
Costs and expenses:			
Cost of sales (exclusive of depreciation and amortization shown separately below)	5,666	—	3,939,538
Research and development (a)	21,095,429	24,560,975	19,218,378
General and administrative (b)	11,511,619	11,252,445	8,828,870
Depreciation and capital lease amortization	1,332,881	1,423,341	1,129,816
Patent license fee amortization	2,569,159	2,663,299	2,233,698
	36,514,754	39,900,060	35,350,300
Loss from operations	(34,943,528)	(36,751,676)	(28,320,016)
Interest (expense) income, net	(308,127)	247,134	1,710,085
Investment income (loss), net	6,863,834	(10,796,893)	1,951,545
Gain on disposal of equipment and other	11,137	5,025	2,343
Gain on arbitration settlement	7,219,270	—	—
Gain on disposal of orofacial therapeutic business	—	39,291,413	—
Loss before income taxes	(21,157,414)	(8,004,997)	(24,656,043)
Income taxes	—	—	(74,291)
Net loss	$(21,157,414)	$ (8,004,997)	$(24,581,752)
Basic and diluted net loss per share	$ (1.03)	$ (0.43)	$ (1.37)
Weighted average shares used to compute basic and diluted net loss per share	20,510,132	18,529,068	17,951,147
Related party disclosures:			
(a) — Research and development includes professional fees to related parties	$ 5,000	$ 5,000	$ 50,938
(b) — General and administrative includes rent and operating expenses to related parties	$ 1,271,243	$ 1,044,856	$ 1,045,109

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2009, 2008 and 2007

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2006	15,649,362	$15,649	$ 84,760,940	$ —	$(39,776,057)	$ 45,000,532
Secondary public offering – February 2007	2,517,111	2,517	39,733,990	—	—	39,736,507
Issuance of common stock	184,839	185	604,742	—	—	604,927
Compensation expense relating to common stock options granted	—	—	1,692,189	—	—	1,692,189
Net loss	—	—	—	—	(24,581,752)	(24,581,752)
Balance at December 31, 2007	18,351,312	18,351	126,791,861	—	(64,357,809)	62,452,403
Comprehensive loss:						
Net loss	—	—	—	—	(8,004,997)	(8,004,997)
Other comprehensive income:						
Net unrealized gain on investments				135,542	—	135,542
Total comprehensive loss				135,542	(8,004,997)	(7,869,455)
Issuance of common stock	362,755	363	1,060,794	—	—	1,061,157
Compensation expense relating to common stock options granted	—	—	3,409,915	—	—	3,409,915
Balance at December 31, 2008	18,714,067	18,714	131,262,570	135,542	(72,362,806)	59,054,020
Comprehensive loss:						
Net loss	—	—	—	—	(21,157,414)	(21,157,414)
Other comprehensive loss:						
Net unrealized loss on investments				(118,155)	—	(118,155)
Total comprehensive loss				(118,155)	(21,157,414)	(21,275,569)
Issuance of common stock	169,784	170	806,127	—	—	806,297
Private placement of common stock, net	941,177	941	7,982,638	—	—	7,983,579
Registration rights issuance of common stock, net	2,000,000	2,000	16,588,395	—	—	16,590,395
Compensation expense relating to common stock options granted	—	—	3,892,895	—	—	3,892,895
Balance at December 31, 2009	21,825,028	$21,825	$160,532,625	$ 17,387	$(93,520,220)	$ 67,051,617

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2009	2008	2007
Cash flows from operating activities			
Net loss	$(21,157,414)	$ (8,004,997)	$(24,581,752)
Adjustments to reconcile net loss attributable to common stockholders to net cash used in operating activities:			
Depreciation and capital lease amortization expense	1,332,881	1,423,341	1,129,816
Patent license fee amortization	2,569,159	2,663,299	2,233,698
Change in carrying value of marketable securities	(5,800,550)	13,375,960	—
Loss (gain) on disposal of equipment	32,074	(5,025)	(2,343)
Non-cash stock-based compensation expense	3,892,895	3,409,915	1,692,189
Non-cash issuance of common stock	374,211	—	133,471
Gain on disposal of orofacial therapeutic business	—	(39,291,413)	—
Non-cash interest income from disposal of business	(217,685)	(307,023)	—
Changes in operating assets and liabilities:			
Receivables	1,164,527	1,533,526	(1,441,393)
Inventory	217,682	(474,855)	(769,560)
Prepaid expenses	(17,509)	119,484	(77,827)
Deposits	—	—	(375,000)
Accounts payable, accrued payroll and other accrued expenses	(4,313,055)	2,042,006	3,757,898
Deferred liability	—	(1,250,000)	(1,250,000)
Deferred revenue	(971,188)	(973,850)	4,254,462
Net cash used in operating activities	(22,893,972)	(25,739,632)	(15,296,341)
Cash flows from investing activities			
Capitalized patent license fees	(510,044)	(1,643,707)	(807,302)
Proceeds from disposal of equipment	—	7,887	14,521
Purchases of property and equipment	(2,310,910)	(2,880,534)	(2,792,901)
Equipment deposits	1,899,608	194,215	(2,093,823)
Purchases of investments	(58,370,400)	(61,882,691)	(78,753,535)
Sales of investments	90,379,590	10,600,000	36,953,535
Redemption of certificate of deposit	—	—	1,000,000
Net proceeds from disposal of business	10,000,000	29,816,121	—
Proceeds from disposal of assets held for sale	—	3,436,911	—
Net cash provided by (used in) investing activities	41,087,844	(22,351,798)	(46,479,505)
Cash flows from financing activities			
Payments on capital lease obligations	(18,187)	(17,351)	(14,118)
Issuance of common stock under compensation plans	432,085	1,061,157	471,455
Payments related to shelf registration statement	(73,360)	—	—
Net proceeds from issuance of common stock	24,573,974	—	39,736,507
Net proceeds from drawdown of note payable	—	39,100,000	—
Payments on note payable	(39,100,000)	—	—
Net cash (used in) provided by financing activities	(14,185,488)	40,143,806	40,193,844
Net increase (decrease) in cash and cash equivalents	4,008,384	(7,947,624)	(21,582,002)
Cash and cash equivalents, beginning of period	17,534,963	25,482,587	47,064,589
Cash and cash equivalents, end of period	$ 21,543,347	$ 17,534,963	$ 25,482,587
Supplemental disclosures of cash flow information			
Interest paid	$ 529,265	$ 265,982	$ 3,106
Supplemental non-cash disclosures			
Acquisition of property and equipment through capital leases	$ 196,625	$ —	$ 23,214

See accompanying notes.

1. Nature of the Business, Background and Basis of Presentation

Nature of the Business

BioMimetic Therapeutics, Inc. (the ''Company'' and formerly BioMimetic Pharmaceuticals, Inc.) is a biotechnology company which develops and commercializes regenerative protein therapeutic-device combination products primarily used for bone and tissue regeneration for the repair and healing of musculoskeletal injuries and conditions affecting bones, tendons, ligaments and cartilage within orthopedic, spine and sports injury applications.

The Company's first product, *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), is a periodontal product and received marketing approval from the U.S. Food and Drug Administration (''FDA'') on November 18, 2005. Product sales revenue from sales of *GEM 21S* continued until January 2008, at which time the Company sold its orofacial therapeutic business, including GEM 21S, to Luitpold Pharmaceuticals, Inc. (''Luitpold''). The Company is focusing its expertise and development efforts on its orthopedic, spine and sports medicine product candidates, including its lead product candidates Augment™ Bone Graft (''Augment'') and Augment™ Injectable Bone Graft (''Augment Injectable''), as well as other product candidates in the pipeline, seeking to aggressively advance its pipeline of product candidates through clinical development and into commercialization.

Background

The Company was incorporated on April 14, 1999 in the state of Tennessee as BioMimetic Pharmaceuticals, Inc. Effective June 1, 2001, BioMimetic Pharmaceuticals, Inc., merged with and into BioMimetic Merger Corp., a Delaware corporation. As part of the merger agreement, BioMimetic Merger Corp. designated the surviving corporate name to be BioMimetic Pharmaceuticals, Inc., a Delaware corporation. The transactions described above have been accounted for as common control reorganizations. In July 2005, the Company changed its corporate name to BioMimetic Therapeutics, Inc.

Since inception, the Company has expended significant funds on business planning, obtaining financing, obtaining skilled employees, and developing its product and product candidates through pre-clinical studies and clinical trials in the United States, Canada and the European Union (''EU'').

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiaries, BioMimetic Therapeutics Limited in the United Kingdom (formed in October 2005) and BioMimetic Therapeutics Pty Ltd. in Australia (formed in October 2006). Inter-company balances and transactions are eliminated in consolidation. As of December 31, 2009, the subsidiaries have no employees and have no operating activities other than making and maintaining regulatory submissions for the Company's products in the EU and Australia.

The accompanying consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles and with the instructions to Form 10-K pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Operating results for the year ended December 31, 2009 are not necessarily indicative of the results that may be expected for any other future period.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

The Company considers cash on hand, deposits in banks, certificates of deposit and money market funds to be cash and cash equivalents.

Investments

The Company invests in marketable securities, which are classified as available-for-sale. These investments are stated at fair market value, with any unrealized gains and losses, net of tax, reported in the accompanying consolidated balance sheets. Realized gains and losses and declines in market value judged to be other-than-temporary on investments in marketable securities are included in investment income (loss) in the accompanying consolidated statements of operations. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income (loss) in the accompanying consolidated statements of operations.

Receivables — Trade

Trade receivables are recorded at the invoiced amount and do not bear interest. The trade receivables balance represents the amounts due from Joint Solutions Alliance Corporation (''Joint Solutions''), the Company's exclusive distributor of its Augment product in Canada, for Augment product sales in Canada and represents a legal and enforceable receivable under the Company's agreements with Luitpold. No allowance for doubtful accounts was deemed necessary as of year-end.

Receivables — Other

Receivables from others represent: (1) royalty income, (2) accrued interest receivable from investments in marketable securities, and (3) other receivables in the normal course of business transactions.

Inventory

Inventories are carried at the lower of cost (first-in, first-out) or net realizable value.

Valuation of Purchase Commitments

The Company has substantial firm purchase commitments with certain of its suppliers related to future inventory requirements. At each period end, the Company assesses the need for any provision for future losses associated with these future purchase commitments in accordance with ASC 330, *Inventory* and ASC 440, *Commitments* (formerly Accounting Research Bulletin (''ARB'') No. 43, *Restatement and Revision of Accounting Research Bulletins)*. As of December 31, 2009, no reserves have been recorded associated with these future purchase commitments.

Prepaid Expenses

Prepaid expenses consist of supplies, rent, annual maintenance and service agreements, insurance premiums and other expenditures in the normal course of business that the Company has paid in advance.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. The Company has determined the estimated useful lives of its property and equipment range from three to seven years.

Maintenance and repairs are charged to expense as incurred. The cost and accumulated depreciation of assets sold or otherwise disposed of are removed from the accounts and the resulting gain or loss is reflected in the accompanying consolidated statements of operations.

2. Summary of Significant Accounting Policies – (continued)

Capitalized Patent License Fees

The Company has capitalized certain costs including milestone and sub-license fees, related to obtaining patent licenses from non-related party institutions. The Company's policy is to capitalize and amortize these costs over the estimated life of the patents. Of the licensed patents that remain unexpired, the expirations, and thus the estimated useful lives, range from 2010 to 2025.

Impairment of Long-Lived Assets

The Company assesses the impairment of long-lived assets whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. Measurement of an impairment loss is required when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of a recognized impairment loss is the excess of an asset's carrying value over its fair value. The Company has not recognized any impairment losses on long-lived assets for the years ended December 31, 2009, 2008 and 2007.

Accrued Expenses and Deferred Liabilities

As part of the process of preparing its consolidated financial statements, management is required to estimate expenses that the Company has incurred for which it has not been invoiced. This process involves identifying services that have been performed on the Company's behalf and estimating the level of services performed by third parties and the associated cost incurred for such services where the Company has not been invoiced or otherwise notified of actual costs. Examples of expenses for which the Company accrues based on estimates include milestone payments, salaries and wages, unpaid vacation and sick pay, fees for services, such as those provided by clinical research and data management organizations, investigators and fees owed to contract manufacturers in conjunction with the manufacture of clinical trial materials. In connection with such service fees, these estimates are most affected by management's understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of the Company's service providers invoice the Company monthly in arrears for services performed. In the event that the Company does not identify certain costs that have begun to be incurred or the Company under- or over-estimates the level of services performed or the costs of such services, the actual expenses could differ from such estimates. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often subjective determinations. Management makes these estimates based upon the facts and circumstances known to it at the time and in accordance with U.S. generally accepted accounting principles. Milestone payments due within 12 months are considered short-term liabilities and those due in over 12 months are considered long-term liabilities.

Revenue Recognition

The Company follows the revenue recognition criteria outlined in ASC 605, *Revenue Recognition* (includes former Staff Accounting Bulletin 101, *Revenue Recognition in Financial Statements*, as amended by SAB 104, *Revenue Recognition*, Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables*, and Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists).*

Product sales

The Company generated its first revenues in December 2005 from the sale of *GEM 21S* to Luitpold after receiving FDA approval in November 2005. Product sales revenue was recognized upon delivery of the *GEM 21S* product to the customer, Luitpold. In January 2008, the Company sold to Luitpold its remaining orofacial therapeutic business. As such, no product sales revenue from sales of *GEM 21S* has been recorded for the years ended December 31, 2009 and 2008. See Note 4.

2. Summary of Significant Accounting Policies – (continued)

In November 2009, the Company received approval from Health Canada for the marketing and commercialization of Augment in Canada. Based upon this approval, the Company shipped its first order of Augment to its Canadian distributor, Joint Solutions, a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada, thus recording product sales revenue of Augment in 2009.

Royalty income

In exchange for the rights to the exclusive worldwide marketing, distribution and sales of *GEM 21S*, Luitpold is obligated to pay royalties to the Company based on net sales by Luitpold. The December 2007 agreement to sell the Company's remaining orofacial therapeutic business to Luitpold requires a continuation of royalty payments to the Company. Luitpold is required to report its sales and remit royalties to the Company on a quarterly basis. The Company's policy is to recognize royalty income when the information is received from Luitpold.

Sublicense fee income

The Company has an amended and restated exclusive sublicense agreement and an exclusive license agreement with Luitpold. Sublicense fees are due to the Company upon achievement of the milestone criteria. In December 2005, the Company received $15,000,000 from Luitpold upon receiving approval from the FDA for the Company's first product, *GEM 21S*. In December 2007, the Company received $5,000,000 from Luitpold upon the second anniversary of FDA approval of *GEM 21S*. Revenues from the sublicense agreement are recognized pursuant to the terms of the agreement and are being amortized over the remaining life of the agreement, which expires December 31, 2026. Payments received in advance of revenue recognized are recorded as deferred revenue. The timing of cash received from the Company's agreement differs from revenue recognized. The Company follows the revenue recognition criteria outlined in ASC 605, *Revenue Recognition*.

Other revenue

The Company subleased portions of its office headquarters in Franklin, Tennessee to two independent companies through August 2008. The resulting rental income related to subleased rental property, as well as other revenue items in the normal course of business, are recognized monthly as related payments are due and/or invoiced.

Research and Development

The Company expenses costs associated with research and development activities as incurred. The Company evaluates payments made to suppliers and other vendors in accordance with ASC 830, *Research and Development* (Formerly SFAS No. 2, *Accounting for Research and Development Costs)*, and determines the appropriate accounting treatment based on the nature of the services provided, the contractual terms, and the timing of the obligation. Research and development costs include payments to third parties that specifically relate to the Company's product candidates in clinical development, such as payments to contract research organizations, clinical investigators, manufacture of clinical material, product related consultants, contract manufacturing start-up costs, manufacturing scale-up costs, milestone payments and insurance premiums for clinical studies. In addition, employee costs (salaries, payroll taxes, benefits, and travel) for employees of the manufacturing, regulatory affairs, clinical affairs, quality assurance, quality control and research and development are classified as research and development costs. Research and development spending for past periods is not indicative of spending in future periods.

Income Taxes

The Company accounts for income taxes utilizing the asset and liability method prescribed by the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109, *Accounting for Income Taxes)*. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are

2. Summary of Significant Accounting Policies – (continued)

expected to reverse. A valuation allowance is provided for the deferred tax assets related to future years, including loss and credit carryforwards, if there is not sufficient evidence to indicate that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in future years.

Effective January 1, 2007, the Company adopted a provision of ASC 740, *Income Taxes* (formerly Financial Accounting Standards Board FIN 48, *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109* (''FIN 48'')), to account for uncertain tax positions. ASC 740 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 prescribes that the Company should use a ''more likely than not'' recognition threshold based on the technical merits of the tax position taken. Tax positions that meet the ''more likely than not'' recognition threshold should be measured in order to determine the tax benefit to be recognized in the financial statements. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Stock-Based Compensation

During 2001, the Company's board of directors approved the adoption of the 2001 Long-Term Stock Incentive Plan (the ''option plan''). The option plan provides that stock options, other equity interests or equity-based incentives in the Company may be granted to key personnel at an exercise price determined by the Company's Compensation Committee, at the time the option is granted, taking into account the fair value of the common stock at the date of grant. The maximum term of any option granted pursuant to the option plan is ten years from the date of grant.

The employee stock options granted by the Company are structured to qualify as ''incentive stock options'' (''ISOs''). Under current tax regulations, the Company does not receive a tax deduction for the issuance, exercise or disposition of ISOs if the employee meets specific holding requirements. If the employee does not meet the holding requirements, a disqualifying disposition occurs, at which time the Company will receive a tax deduction. The Company does not record tax benefits related to ISOs unless and until a disqualifying disposition occurs. In the event of a disqualifying disposition, the entire tax benefit is recorded as a reduction of income tax expense. The Company has not recognized any income tax benefit for the three years ended December 31, 2009 for share-based compensation arrangements due to the fact that it does not believe that it will recognize any deferred tax assets from such compensation cost recognized in the current period.

Effective January 1, 2006, we adopted ASC 505, *Equity-Based Payments to Non-Employees*, and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*), using the modified prospective method of transition. Under that transition method, compensation cost recognized in the three years ended December 31, 2009 includes: (a) compensation costs for all share-based payments granted prior to January 1, 2006 are based on the intrinsic value method proscribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (''APB Opinion No. 25''), and (b) compensation costs for all share-based payments granted subsequent to January 1, 2006 are based on the grant date fair value estimated in accordance with the provisions of ASC 505 and ASC 718.

In accordance with ASC 505 and ASC 718, the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using weighted average assumptions amortized to expense over the options' vesting periods. These assumptions include the risk free interest rate, expected dividend yield, volatility factor of the expected market price, forfeiture rate and weighted average expected life of the option. Since the trading market for the Company's common stock has a limited history, the expected volatility rates are based on historical data from three companies similar in size and value to the Company. The expected terms of options granted represents the period of time that options granted are expected to be outstanding and is derived from the contractual terms of the options granted. The Company amortizes the fair value of each option over each option's vesting period. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant.

2. Summary of Significant Accounting Policies – (continued)

Comprehensive Loss

FASB ASC 220, *Comprehensive Income* (formerly SFAS No. 130, *Reporting Comprehensive Income*), establishes standards for reporting and display of comprehensive income (losses) and its components in the consolidated financial statements. The Company's comprehensive loss as defined by ASC 220 is the total of net loss and all other changes in equity resulting from non-owner sources including unrealized gains/losses on investments.

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 and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value of Financial Instruments

ASC 825-10, *Financial Instruments* (formerly SFAS No. 107), requires disclosures of fair value information about financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Due to their short-term nature, the carrying amounts reported in the consolidated financial statements approximate the fair value for cash, cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and capital lease obligations.

The Company's Time Promissory Note (the ''Note'') credit facility, upon which the Company borrowed $39,100,000 in October 2008, had a carrying amount that approximated the fair value as of December 31, 2008. In December 2009, the Company repaid in full the remaining balance on the Note.

For information on the fair value of the Company's investments, see Note 10.

Concentration of Credit Risk and Limited Suppliers

Cash and cash equivalents and investments consist of financial instruments that potentially subject the Company to concentrations of credit risk to the extent recorded on the consolidated balance sheets. The Company maintains cash in financial institutions in excess of Federal Deposit Insurance Corporation limitations. The Company believes that it has established guidelines for investment of its excess cash with the intent to maintain principal and liquidity through its policies on diversification and investment maturity.

As of December 31, 2009, the Company had short-term investments of $47,001,504 that are classified as available for sale and consist of U.S. government sponsored enterprise (''GSE'') securities totaling $36,127,229 and U.S. Treasury Notes totaling $10,874,275. The GSE securities have maturity dates ranging from January 2010 through July 2010. The U.S. Treasury Notes have maturity dates ranging from March 2010 to August 2010. Also as of December 31, 2009, the Company had long-term investments of $6,513,975, consisting of three GSE securities with maturity dates of March 2011.

In 2009, the Company had investments in certain auction rate securities (''ARS''). During the year ended December 31, 2009, all of the Company's ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52,424,590. As of December 31, 2009, the Company did not have any investments in ARS.

The Company relies on certain materials used in its development process that are procured from a single source supplier as well as certain third-party contract manufacturers that make its product candidates. The failure of its supplier or contract manufacturers to deliver on schedule, or at all, could delay or interrupt the development process and adversely affect the Company's clinical trials, and ultimately, operating results.

2. Summary of Significant Accounting Policies – (continued)

Segment Information

The Company has determined that it is principally engaged in one operating segment. The Company's product development efforts are primarily in the treatment of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications for the repair and regeneration of orthopedic tissues, including bone, cartilage, ligaments or tendons.

Seasonality

The Company has determined that the impact on seasonality on its results of operations is minimal; however, fluctuations in product sales revenues are the result of evolving product commercialization efforts by the Company.

Recent Accounting Pronouncements

The FASB Accounting Standards Codification™

In June 2009, the Financial Accounting Standards Board (''FASB'') issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles* (''SFAS No. 168''), which establishes the FASB Accounting Standards Codification™ (''Codification''). The Codification supersedes all existing accounting standard documents and will become the single source of authoritative non-governmental U.S. generally accepted accounting principles. The Codification did not change U.S. generally accepted accounting principles but reorganizes the literature. All other accounting literature not included in the Codification will be considered non-authoritative. The Codification was implemented on July 1, 2009 and is effective for interim and annual periods ending after September 15, 2009. Subsequent changes to the Codification will be released through Accounting Standards Updates (''ASU''), which serve to update the Codification, provide background information about the guidance and provide the basis for conclusions on the changes in the Codification. The Company has conformed its consolidated financial statements and related Notes to the new Codification for the year ended December 31, 2009.

In conjunction with the issuance of SFAS No. 168, the FASB issued ASU 2009-01 Topic 105, *Generally Accepted Accounting Principles* (''ASU 2009-01''). ASU 2009-01 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of non-governmental entities that are presented in conformity with U.S. generally accepted accounting principles. ASU 2009-01 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of this ASU did not have a material impact on the Company's financial position or results of operation for the year ended December 31, 2009.

Fair Value Measurements and Other-Than-Temporary Impairments

In April 2009, the FASB issued Accounting Standards Codification (''ASC'') 320-10, *Investments — Debt and Equity Securities* (includes former Staff Position (''FSP'') No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*). The ASC changes existing guidance for determining whether impairment of debt securities is other-than-temporary. The ASC requires other-than-temporary impairment to be separated into the amount representing the decrease in cash flows expected to be collected from a security (referred to as credit losses), which is recognized in earnings, and the amount related to other factors, which is recognized in other comprehensive income. The non-credit loss component of the impairment can only be classified in other comprehensive income if the holder of the security concludes (1) that it does not intend to sell the security and (2) that it is more likely than not that it will not be required to sell the security before the security recovers its value. If these two conditions are not met, the non-credit loss component of the impairment must also be recognized in earnings. Upon adoption of the ASC, the entity is required to record a cumulative-effect adjustment, as of the beginning of the period of adoption, to reclassify the non-credit loss component of previously recognized other-than-temporary impairment from retained earnings to accumulated other comprehensive income.

2. Summary of Significant Accounting Policies – (continued)

In April 2009, the FASB issued ASC 820-10, *Fair Value Measurements and Disclosures* (includes former FSP No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly*). This ASC, while emphasizing that the objective of fair value measurement described in ASC 820 (formerly SFAS No. 157, *Fair Value Measurements*) remains unchanged, provides additional guidance for determining whether market activity for a financial asset or liability has significantly decreased, as well as for identifying circumstances that indicate that transactions are not orderly. The ASC reiterates that if a market is determined to be inactive and the related market price is deemed to be reflective of a ''distressed sale'' price, then management's judgment may be required to estimate fair value. The ASC identifies factors to be considered when determining whether or not a market is inactive.

In April 2009, the FASB issued ASC 825-10, *Financial Instruments* (includes former FSP No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*). This ASC requires disclosures about fair values of financial instruments in all interim financial statements, whether or not recognized in the balance sheet, for which it is practicable to estimate that value. Due to their short-term nature, the carrying amounts reported in the Company's condensed consolidated financial statements approximate the fair value for cash, cash equivalents, short-term investments, accounts receivable, accounts payable, accrued expenses and capital lease obligations.

The ASCs set forth above were effective for interim and annual periods ending after June 15, 2009. The Company adopted the ASCs set forth above, and the adoption of such ASCs did not have a material impact on the Company's consolidated financial statements as of December 31, 2009.

Business Combinations

In April 2009, the FASB issued ASC 805-10, *Business Combinations* (includes former FSP No. FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies*). This ASC amends and clarifies the provisions of ASC 805, formerly SFAS No. 141(R), *Business Combinations*, with respect to the initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies associated with a business combination. The provisions of the ASC are effective, for the Company, for business combinations occurring after January 1, 2009. The adoption of the ASC did not have a material impact on the Company's condensed consolidated financial statements as of December 31, 2009. The impact of adoption of the ASC on the Company's future consolidated financial statements will depend on the nature, terms and size of future business combinations, if any.

Subsequent Events

In February 2010, the FASB issued ASU 2010-09 to amend ASC 855, *Subsequent Events*. ASC 855, which was originally issued by the FASB in May 2009 (as SFAS No. 165, *Subsequent Events*), provides guidance on events that occur after the balance sheet date but prior to the issuance of the financial statements. ASC 855 distinguishes events requiring recognition in the financial statements and those that may require disclosure in the financial statements. As a result of ASU 2010-09, SEC registrants will not disclose the date through which management evaluated subsequent events in the financial statements, either in originally issued financial statements or reissued financial statements. ASC 855 was effective for interim and annual periods ending after June 15, 2009, and ASU 2010-09 is effective immediately. The Company has evaluated subsequent events in accordance with ASU 2010-09.

3. Net Loss Per Share

The Company calculates net loss per share in accordance with ASC 260, *Earnings Per Share* (formerly SFAS No. 128, *Earnings Per Share).* Under the provisions of ASC 260, basic net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock and dilutive common stock equivalents then outstanding. Common stock equivalents consist of shares of common stock issuable upon the exercise of stock options.

The Company had potentially dilutive common stock equivalents outstanding of 2,543,235, 2,117,392 and 1,946,902 shares as of December 31, 2009, 2008 and 2007, respectively. These common stock equivalents consist of issued and outstanding common stock options, and are not included in the above diluted net loss per common share historical calculations as the effect of their inclusion was anti-dilutive. Therefore, the diluted earnings per share is the same as basic earnings per share.

4. Luitpold Pharmaceuticals, Inc.

The Company has agreements with Luitpold that cover an exclusive worldwide sublicense and license, trademark license, concurrent use, supply and royalty income relationship.

In January 2008, the Company completed the sale of its orofacial therapeutic business, including *GEM 21S,* to Luitpold. As part of the sale transaction, in 2008, the Company had recorded a $39,291,413 net gain on the disposal of its orofacial therapeutic business, and had received $30,000,000 in cash from the sale transaction and $3,389,832 in cash from the sale of existing inventory. At December 31, 2008, the Company had recorded a receivable for $9,782,315, which represents the discounted balance of an additional $10,000,000 in time-based payments that was received in 2009 under terms of the sale agreement. As of December 31, 2009, the balance of these time-based payments had been received in full. The Company recorded $217,685 and $272,279 of interest income from the accretion of the receivable during the years ended December 31, 2009 and 2008, respectively.

Under the sale transaction, the Company terminated certain 2003 agreements with Luitpold relating to its manufacture and supply of *GEM 21S* and Luitpold's distribution and marketing of *GEM21S*, and the Company amended and restated certain other 2003 agreements relating to intellectual property.

In addition, under the 2008 transaction, Luitpold acquired: (1) the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S;* (2) all rights to the *GEM* trademark family; (3) certain rights to adapt the Company's future orthopedic and sports medicine products to dental applications; and (4) certain rights to negotiate on other growth factors and product improvements that the Company licenses from third parties. Through the Company's existing commercial supply agreement with Novartis Vaccines and Diagnostics, Inc. (''Novartis''), the Company remains the sole source supplier of bulk rhPDGF-BB to Luitpold. In addition, the Company's U.S. and Canadian regulatory approvals, including the *GEM 21S* PMA, have been or will be transferred to Luitpold, and with the exception of the EU regulatory filings, Luitpold now has responsibility for all future filings with respect to *GEM 21S*. The rights to the *GEM 21S* (now known as *GEMESIS*™ in Europe) EU regulatory approval will be transferred once approval is obtained. The Company has agreed not to compete with Luitpold in the orofacial therapeutic business for a specified period of time. Also as part of this transaction each party agreed to indemnify the other party for certain losses.

As a result of the agreements with Luitpold, the Company had recognized *GEM 21S* product sales revenue, royalty income and sublicense fee income. Subsequent to the January 2008 sale of the Company's remaining orofacial therapeutic business to Luitpold, no product sales revenue for net sales of *GEM 21S* was recorded for the years ended December 31, 2009 and 2008.

4. Luitpold Pharmaceuticals, Inc. – (continued)

Under the 2003 exclusive sublicense agreement with Luitpold, in exchange for the rights to the exclusive worldwide marketing, distribution and sales of *GEM 21S*, Luitpold was obligated to pay royalties on its net sales to the Company. Luitpold was required to report its sales and remit royalties to the Company on a quarterly basis. As part of the agreement to sell the Company's orofacial therapeutic business to Luitpold, the Company expects to continue to receive ongoing royalty payments based on net sales of *GEM 21S* at least through 2026.

The FDA approved the marketing of *GEM 21S* on November 18, 2005. As a result, the Company received an initial milestone payment related to the 2003 exclusive sublicense agreement in the amount of $15,000,000 from Luitpold. In December 2007, the Company received an additional $5,000,000 from Luitpold for the second anniversary of the *GEM 21S* approval. In accordance with the provisions of ASC 605-25, *Revenue Recognition, Multiple-Element Arrangements* (formerly EITF 00-21, *Revenue Arrangements with Multiple Deliverables*), and the specific accounting guidance regarding biotechnology license, research and development and contract manufacturing agreements, the Company is amortizing the $15,000,000 and $5,000,000 proceeds over the term of the amended and restated sublicense agreement with Luitpold, which expires on December 31, 2026. Sublicense fee revenue represents the current amortization of the $20,000,000 proceeds.

5. Inventory

Inventory at December 31 is summarized as follows:

	2009	2008
Raw materials	$ 814,925	$1,261,987
Finished goods	229,380	—
	$1,044,305	$1,261,987

Raw materials inventory consists of bulk drug substances, labeling materials, cup trays, cup lids, and other packaging materials used in the manufacturing of the Company's orthopedic products. Finished goods inventory consists of finished cups and vials ready for packaging, as well as packed Augment kits ready for sale. Shipping and handling costs are included in the cost of sales of the product. The Company has classified its inventory as current as of December 31, 2009, and as non-current as of December 31, 2008. No allowance has been recorded for obsolescence, shrinkage and potential scrapping of product batches that may not be released for sale as of December 31, 2009 and 2008.

Cost of sales is comprised of the following costs: raw materials used in the production and manufacturing of vials and cups, testing fees for the vials and cups, labeling materials for the finished kits, packaging materials for inclusion in the finished kit, kit packing costs, freight and scrap incurred during the production process.

6. Property and Equipment

Property and equipment at December 31 is summarized as follows:

	2009	2008
Equipment, computers and purchased software	$ 3,061,623	$ 2,811,856
Equipment, computers and purchased software, not placed in service	4,182,898	2,302,516
Furniture and fixtures	722,920	722,920
Leased equipment	188,963	99,486
Construction in process	993,457	795,696
Leasehold improvements	4,047,159	4,047,159
	13,197,020	10,779,633
Less accumulated depreciation and amortization	(5,040,178)	(3,765,371)
	$ 8,156,842	$ 7,014,262

In August 2007, the Company entered into a new lease agreement for approximately 30,000 square feet of space in a new building in Franklin, Tennessee intended to house certain of its manufacturing operations. The new building shell was completed in October 2009, and rent expense commenced at that time. The Company intends to move certain of its manufacturing operations to the new facility. See Note 13.

Engineering design and planning costs related to the new manufacturing facility totaling $993,457 have been incurred as of December 31, 2009 and are included in construction in process. Also, the Company has purchased equipment, computers and purchased software which has not yet been placed into service. These purchases, including equipment that is intended to be used in the new manufacturing facility, amounted to $4,164,646 and $2,282,573 as of December 31, 2009 and 2008, respectively.

In addition, under agreements with various equipment suppliers for the manufacture of the equipment for the new manufacturing facility, as of December 31, 2009, the Company has estimated purchase commitments of $604,035 remaining to be paid through the year 2012. See Note 13.

7. Deposits

The Company paid a refundable deposit of $10,000 related to its lease of office space at its headquarters. In addition, the Company paid a refundable deposit of $375,000 upon signing a lease agreement in August 2007 for approximately 30,000 square feet of space in the new manufacturing facility intended to house certain of its manufacturing operations.

Deposits for equipment relating to the new manufacturing facility reflected on the consolidated balance sheet at December 31, 2008 have been reclassified from ‘‘Deposits’’ to ‘‘Property and equipment’’ at December 31, 2009 and represent equipment completed by the vendor but not yet delivered (i.e., recorded to equipment not placed in service). See Note 6.

8. Capitalized Patent License Fees

The Company has incurred, and continues to incur, costs related to patent license fees and patent applications for Augment, Augment injectable and the Company’s other product candidates. These payments have been capitalized as patent license fees and are being amortized over their remaining patent life.

In June 2005, the Company filed an Investigational New Drug Application (‘‘IND’’) with the FDA for its orthopedic product. The IND filing triggered a milestone payment of $500,000 to ZymoGenetics, Inc. (‘‘ZymoGenetics’’) under the Company’s January 2003 patent license agreement with ZymoGenetics.

In November 2005, the Company acquired patent licenses from the Institute of Molecular Biology (‘‘IMB’’), incurring costs of $327,820. The acquisition of IMB patent licenses triggered a $20,000 milestone payment to Harvard University (‘‘Harvard’’) under the Company’s license agreement.

8. Capitalized Patent License Fees – (continued)

The November 2005 FDA approval of the Company's first product, *GEM 21S*, triggered a $50,000 milestone payment to Harvard under the Company's license agreement with Harvard. In addition, the Company was required to pay $4,000,000 to ZymoGenetics within 10 days of the FDA's approval of *GEM 21S* and an additional $1,000,000 within 30 days of the approval.

The November 2005 milestone receipt of $15,000,000 from Luitpold and the December 2007 milestone receipt of $5,000,000 from Luitpold (see Note 4) triggered sublicense patent fee payments of $1,500,000 and $500,000, respectively, to Harvard under the Company's patent license agreement.

In June 2006, the Company initiated a registration trial for its orthopedic product *GEM OS1*. The trial triggered a milestone payment of $500,000 to ZymoGenetics under the Company's January 2003 patent license agreement with ZymoGenetics. The payment has been capitalized as patent license fees and will be amortized over the remaining patent life.

In October 2008, the Company paid a $1,250,000 milestone payment to ZymoGenetics as required upon filing the Device License Application (''DLA'') with Health Canada. The DLA is required in Canada for approval of the commercialization of Augment as a medical device for use in the treatment of foot and ankle fusions.

Each of these milestone transactions has been capitalized as a patent license fee and is being amortized over the life of the patent licenses. The Company has capitalized costs totaling $12,532,346, $12,378,492 and $11,128,492 as of December 31, 2009, 2008 and 2007, respectively, related to the acquisition of its patent licenses.

Based on agreements in place and payments made as of December 31, 2009, amortization expense related to capitalized patent license fees is expected to be $1,650,028 for the year ended December 31, 2010, and $37,360 for the four years ended December 31, 2014 (at $9,340 per year).

9. Investments

As of December 31, 2009, the Company had short-term investments of $47,001,504 that are classified as available for sale and consist of U.S. government sponsored enterprise (''GSE'') securities totaling $36,127,229 and U.S. Treasury Notes totaling $10,874,275. The GSE securities have maturity dates ranging from January 2010 through July 2010. The U.S. Treasury Notes have maturity dates ranging from March 2010 to August 2010. Also as of December 31, 2009, the Company had long-term investments of $6,513,975, consisting of three GSE securities with maturity dates of March 2011.

In 2008 and 2009, the Company had investments in certain auction rate securities (''ARS''). In 2008, the Company had determined that its ARS investments had experienced an ''other-than-temporary'' impairment in fair value. The Company had estimated the fair value to be $46,624,040 as of December 31, 2008, representing an impairment loss of $13,375,960. In 2009, all of the Company's ARS investments were sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52,424,590 and a net realized gain of $5,800,550 reclassified from unrealized gains and recorded in earnings in its consolidated statement of operations for the year ended December 31, 2009.

In February 2009, the Company filed an arbitration claim with the Financial Industry Regulatory Authority, Inc. (''FINRA'') asserting various claims relating to investments in certain auction rate securities made on the Company's behalf. In December 2009, after finalizing the sale of all of the remaining securities at issue in that arbitration proceeding, the Company settled the arbitration claim and dismissed the case upon receipt of a $7,219,270 payment from the respondent in the arbitration.

10. Fair Value Measurements

As of January 1, 2008, the Company adopted ASC 820-10, *Fair Value Measurements* (formerly SFAS No. 157, *Fair Value Measurements*), which defines fair value, establishes a framework for measuring fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 — quoted prices in active markets for identical assets and liabilities;

Level 2 — inputs other than Level 1 quoted prices that are directly or indirectly observable; and

Level 3 — unobservable inputs that are not corroborated by market data.

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period. This determination requires significant judgments to be made by the Company.

As of December 31, 2009, financial assets and liabilities subject to fair value measurements were as follows:

Assets	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$21,543,347	$—	$—	$21,543,347
Short-term investments (GSE securities and U.S. Treasury Notes)	47,001,504	—	—	47,001,504
Long-term investments (GSE securities)	6,513,975	—	—	6,513,975
Total cash and investments	$75,058,826	$—	$—	$75,058,826

Fair value estimate

The Company's cash and cash equivalents include cash on hand, deposits in banks, certificates of deposit and money market funds. Due to their short-term nature, the carrying amounts reported in the consolidated balance sheets approximate the fair value of cash and cash equivalents.

The Company's short-term investments include GSE securities and U.S. Treasury Notes classified as available for sale. The Company's long-term investments consist of three GSE securities with maturity dates of March 2011. The carrying amounts reported in the consolidated balance sheets approximate the fair value of the Company's short-term and long-term investments.

During 2008 and 2009, the Company had investments in ARS classified as available-for-sale and recorded at fair value. Fair value measures for the Company's investments in ARS were estimated using cash flow discounting with a Monte Carlo simulation and other information. The valuation model reflected various assumptions that market participants would use in pricing the ARS investments, including, among others, (1) the maximum interest rate paid when an auction failed, (2) the discount spread over the expected life of each bond, (3) all required cash would be available to pay the bond interest and principal since the majority of the student loans backing the bonds were government guaranteed, (4) the collateralization underlying the ARS investments, (5) the creditworthiness of the counterparty, (6) the last known control or data point in assisting the Company with the overall analysis of the fair value modules prepared, and (6) the expected future cash flows and the risks associated with uncertainties in the current market.

The Monte Carlo simulation randomly generated the London Interbank Offered Rate ("LIBOR"), U.S. Treasury Bill and Commercial Paper rates for each month out to a bond's expected life. In each month, a coupon level was calculated using the Maximum Interest Rate formula, and applied to the bond's notional to obtain a cash flow. The cash flow was then discounted using the realized (random) LIBOR rates, plus a spread. The simulated rates were assumed to have a mean based on the yield curve for each type of rate. For one-month LIBOR, 91-day U.S. Treasury Bills and three-month Commercial Paper, the relevant rates were

10. Fair Value Measurements – (continued)

calculated as forward rates for each month. A historical study of the three time series over the past five years was run to determine the standard deviation and correlation of each series, which were then used to drive the simulation. Commercial paper rates beyond September 30, 2009 were not available, so the commercial paper rates were estimated based on the equivalent LIBOR forward rate.

As of December 31, 2009, all of the Company's ARS investments had been sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52,424,590 for the year ended December 31, 2009.

The following table summarizes the activity related to the Company's ARS investments which have fair value measurements based on significant unobservable inputs (Level 3) during the year ended December 31, 2009:

Balance at December 31, 2008	$ 46,624,040
Unrealized gain reported in equity through accumulated other comprehensive income for the three months ended March 31, 2009	1,479,160
Balance at March 31, 2009	48,103,200
Realized gain reclassified from unrealized gains and reported in earnings on securities sold or redeemed	(1,688,840)
Redemption and sales for the three months ended June 30, 2009	(9,192,160)
Unrealized gain reported in equity through accumulated other comprehensive income for the three months ended June 30, 2009	2,750,850
Balance at June 30, 2009	39,973,050
Realized gain reclassified from unrealized gains and reported in earnings on securities redeemed	(402,810)
Redemptions for the three months ended September 30, 2009	(997,190)
Unrealized gain reported in equity through accumulated other comprehensive income for the three months ended September 30, 2009	431,550
Balance at September 30, 2009	39,004,600
Realized gain reclassified from unrealized gains and reported in earnings on securities redeemed	(3,708,900)
Redemptions and sales for the three months ended December 31, 2009	(36,434,690)
Unrealized gain reported in equity through accumulated other comprehensive income for the three months ended December 31, 2009	1,138,990
Balance at December 31, 2009	$ —

11. Note Payable

In October 2008, the Company executed a Time Promissory Note (the "Note") credit facility enabling the Company to borrow up to $39,130,000. The Company granted the issuer of the Note a first priority security interest in certain of its ARS investments having a total combined par value of $55,900,000 as collateral. Under the terms of the Note, the Company was required to make monthly interest payments during the two-year term of the Note and all outstanding principal amounts were to be due and payable in full on the maturity date in October 2010. The Company had an election to pay back the full principal amount prior to the maturity date with no penalty. Absent a Company default or a sale of part of the collateral ARS investments, the issuer of the Note had no ability to withdraw, reduce or change the terms of the Note. Under the terms of the Note, and at the Company's option, the interest rate was based on either the London Interbank Offered Rate ("LIBOR") plus 0.50% or the Note issuer's Prime Rate minus 1.50%. The Company recorded interest expense on the Note of $525,247 and $158,029 for the years ended December 31, 2009 and 2008, respectively, at a weighted average interest rate of 1.84% and 2.27%. The Note also provided that in the event that the issuer of the Note later offers an ARS lending program or settlement loan program to institutional

11. Note Payable – (continued)

clients that included either a lower interest rate or permitted borrowing of more than 70% of the par value of the collateral securities, then the terms of the Company's Note and any existing loans issued under the Note would have been modified to include the lower interest rate or higher borrowing base.

During the year ended December 31, 2009, all of the Company's ARS investments were redeemed by the issuers at par or sold at a discount. In accordance with the terms of the Note, as of December 31, 2009, the Company has repaid in full the balance on the Note and the original promissory note has been returned to the Company marked ''paid in full.'' In addition, the issuer of the Note has released the Company from the Note, and has terminated the Company's security and pledge agreement and securities account control agreement and terminated any UCC filings made with respect to the Note and security agreements.

12. Other Accrued Expenses

Other accrued expenses at December 31 are summarized as follows:

	2009	2008
Royalties payable	$ 89,954	$1,724,283
Professional fees	5,000	409,211
Taxes and licenses	30,817	195,875
Other	9,299	62,867
	$135,070	$2,392,236

13. Commitments and Contingencies

Operating Leases

The Company maintains operating leases for the use of office space at the Company's headquarters in Franklin, Tennessee, as well as for the use of certain business equipment.

In May 2007, the Company entered into a lease agreement effective January 1, 2007 with Noblegene Development LLC (''Noblegene''), replacing in its entirety the Company's previous lease with Noblegene dated April 2004, as amended in July 2005. This lease extends the lease term and includes additional office space of approximately 9,000 square feet, bringing the total space to approximately 32,000 square feet at the Company's headquarters in Franklin, Tennessee. Under the terms of the lease, in 2009 the Company paid Noblegene monthly rent of $50,017 to $51,517, as adjusted, plus additional proportionate operating and insurance costs associated with the building and the business campus. The lease agreement contains annual scheduled rate increases equivalent to a minimum of three percent. The Company has recognized rent expense on a straight line basis over the life of the lease, beginning with the date the Company gained access to the premises. The initial term of the lease continues until December 31, 2016, and the Company has the option to extend the lease for two additional five-year terms. Under the terms of the lease, the Company agrees to indemnify Noblegene under specific circumstances.

Under the original lease terms, the Company had been provided a rent credit of $106,831 to be used towards improvements. In connection with the new lease agreement and related to the additional space, the Company was provided with an additional rent credit resulting in a total rent credit of $5 per usable square foot (or $160,000). This rent credit was used toward leasehold improvements in 2007. Pursuant to ASC 840, *Leases* (including former SFAS No. 13, *Accounting for Leases*, and FASB Technical Bulletin 88-1, *Issues Relating to Accounting for Leases)*, the Company had recorded these tenant-funded improvements and the related deferred rent in its consolidated balance sheets. The deferred rent is being amortized as a reduction to lease expense over the life of the lease.

In August 2007, the Company entered into a lease agreement with Noblegene for approximately 30,000 square feet of space in a new building located in the same complex as the Company's headquarters in Franklin, Tennessee. The Company intends to move certain of its manufacturing operations to the new space.

13. Commitments and Contingencies – (continued)

The lease provides for a tenant improvement allowance of $2,500,000 to reimburse the Company for construction costs associated with building out the leased space. The Company expects to receive the tenant improvement allowance within 30 days of the earlier of: (a) two years after the date the Company obtains a Certificate of Occupancy for the new space; or (b) upon Noblegene obtaining a permanent mortgage on the new building. The initial term of the lease continues 10 years from the October 2009 commencement date. The Company has the option to extend the term of the lease for two additional five-year terms. Under the terms of the lease, the Company agrees to indemnify Noblegene under specific circumstances. Upon initiation of the lease, the Company paid a deposit of $375,000 to Noblegene for the new building. The Company has recorded this deposit in its consolidated balance sheet.

In January 2008, the Company entered into an amendment to its two existing lease agreements described above with Noblegene. The amendment added certain additional exclusions to the definition of ''operating costs'' in both of the lease agreements. The amendment also provided for the Company to pay $56,686 to Noblegene as a final payment of 2007 operating costs under the May 2007 lease agreement.

In January 2009, the Company amended its August 2007 lease agreement with Noblegene. The amendment increased the base rent by $1.00 to $26.00 per rentable square foot (or, $65,000 per month) and provided for a one-time payment of $200,000 from the Company to Noblegene. The Company agreed to the increase in rent, and the one-time payment, to compensate Noblegene for increased construction costs due to the Company's requested changes in the building design. The Company's lease rate will be reduced at various intervals if the building's occupancy increases. In all other respects, the lease agreement remains the same.

The Company recognized rent expense of $1,159,076, $884,996 and $869,105 for all operating leases associated with the office space and new manufacturing space for the years ended December 31, 2009, 2008 and 2007, respectively.

The future commitments as of December 31, 2009 under these operating lease agreements are as follows:

2010	$ 1,422,604
2011	1,465,282
2012	1,509,240
2013	1,554,518
2014	1,601,153
Thereafter	6,073,130
Total	$13,625,927

Capital Leases

The Company leases certain computer equipment and copiers under agreements classified as capital leases. The leased assets serve as security for these liabilities. The net book value of such equipment at December 31, 2009 and 2008 totaled $179,625 and $50,104, respectively.

13. Commitments and Contingencies – (continued)

The future commitments as of December 31, 2009 under these capital lease agreements are as follows:

	Principal	Interest	Total
2010	$ 56,520	$ 5,347	$ 61,867
2011	51,141	3,481	54,622
2012	42,384	2,259	44,643
2013	40,210	1,353	41,563
2014	41,083	480	41,563
Total	$231,338	$12,920	$244,258

Manufacturing Equipment

The Company has executed agreements with various equipment suppliers for the manufacture of equipment that will be used in the new manufacturing facility described above in "— Operating Leases." As of December 31, 2009, the Company has paid a total of $4,164,646 for the equipment, which is classified as equipment not placed in service (see Note 6). In addition, under these agreements, the Company has estimated remaining purchase commitments of $54,760 for 2010, $487,275 for 2011 and $62,000 for 2012.

Litigation

In the ordinary course of business, the Company is subject to legal claims and assessments. In February 2009, the Company filed an arbitration claim with the Financial Industry Regulatory Authority, Inc. ("FINRA") asserting various claims relating to investments in certain auction rate securities made on the Company's behalf. In December 2009, the Company sold all of the remaining securities at issue in that arbitration proceeding. In addition, following receipt of a payment in the amount of $7,219,270 from the respondent in the arbitration, the Company settled the arbitration claim and dismissed the case.

Employment Agreements

The Company has employment contracts with several individuals, which provide for annual base salaries and potential bonuses. These contracts contain certain change of control, termination and severance clauses that require the Company to make payments to these employees if certain events occur as defined in their respective contracts.

Supply Agreements

The Company has executed supply agreements with Novartis and with Cam Bioceramics BV ("Cam Bioceramics"). Under these agreements, the Company has agreed to certain minimum purchase commitments and/or binding orders of which there are commitments of $1,799,854 for 2010 and estimated commitments of $2,305,961 and $3,153,268 for 2011 and 2012, respectively.

14. Capital Shares

Sale of Common Stock to InterWest Partners

In April 2009, the Company sold to InterWest Partners X, L.P. 941,177 shares of common stock for an aggregate purchase price of approximately $8,000,000, or $8.50 per share. Prior to such purchase, affiliates of InterWest Partners X, L.P., including InterWest Partners VIII, L.P., beneficially owned 4.7% of the Company's outstanding shares of common stock. After giving effect to the purchase and to the rights offering discussed below, InterWest Partners X, L.P. and its affiliates beneficially owned 8.4% of the Company's outstanding shares of common stock at December 31, 2009. Chris Ehrlich, one of the Company's directors, is a Venture Member of InterWest Management Partners VIII, L.L.C., which serves as the general partner of InterWest Partners VIII, L.P., InterWest Investors Q VIII, L.P. and InterWest Investors VIII, L.P. and as Manager of InterWest Management Partners X, L.L.C., which serves as the general partner of InterWest Partners X, L.P. In connection with the purchase transaction, the Company agreed to pay the reasonable fees and expenses of

14. Capital Shares – (continued)

InterWest Partners X, L.P.'s counsel in connection with the purchase agreement, in an amount not to exceed $15,000. In July 2009, the Company filed a registration statement with the SEC in connection with the resale of the shares purchased by InterWest Partners pursuant to the purchase agreement, and other shares of common stock beneficially owned by its affiliates.

Rights Offering

In June 2009, the Company completed a rights offering to sell 2,000,000 shares of the Company's common stock to its existing stockholders of record as of April 21, 2009 (the ''record date''), other than with respect to shares held in the 401(k) plan. The Company received valid subscriptions for all of the shares purchasable in the rights offering, including shares subscribed for by certain of the Company's stockholders in the exercise of their over-subscription rights, at a subscription price of $8.50 per share. The Company issued the shares to the participants in the rights offering on June 25, 2009. Concurrent with the rights offering, the Company sold to Novo A/S, a stockholder of the Company, 343,406 shares of the Company's common stock in a private placement, which represents the number of shares that Novo A/S could have purchased pursuant to its basic subscription privilege in the rights offering. The purchase price of such shares was $8.50 per share, the same as the subscription price of the shares in the rights offering. Prior to the rights offering, Novo A/S beneficially owned 17.2% of the Company's outstanding shares of common stock. After giving effect to the private placement, Novo A/S and its affiliates beneficially owned 17.0% of the Company's outstanding shares of common stock at December 31, 2009. The Company agreed to reimburse Novo A/S for all of its attorneys' fees incurred in connection with the standby purchase agreement and the standby purchase, subject to a maximum of $20,000. In July 2009, the Company filed a registration statement with the SEC in connection with the resale of the shares purchased by Novo A/S. Total gross proceeds of the rights offering, including the private placement to Novo A/S, was $17,000,000.

Shelf Registration Statement

In July 2009, the Company filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (''SEC''). Under the shelf registration statement, the Company may from time to time, in one or more series, separately or together, sell common stock, preferred stock, debt securities or warrants to purchase its common stock or any combination of such securities. The aggregate public offering price of the securities that the Company may offer pursuant to the registration statement is up to $150,000,000.

15. Stock-Based Compensation

2001 Long-Term Stock Incentive Plan

During 2001, the Company's board of directors approved the adoption of the 2001 Long-Term Stock Incentive Plan (the ''option plan''). The option plan provides that awards of stock options, other equity interests or equity-based incentives in the Company may be granted to key personnel at an exercise price determined by the Company's Compensation Committee, at the time the award is granted, taking into account the fair value of the common stock at the date of grant. The maximum term of any award granted pursuant to the option plan is 10 years from the date of grant.

The employee stock options granted by the Company are structured to qualify as ''incentive stock options'' (''ISOs''). Under current tax regulations, the Company does not receive a tax deduction for the issuance, exercise or disposition of ISOs if the grantee meets specific holding requirements. If the grantee does not meet the holding requirements, a disqualifying disposition occurs, at which time the Company will receive a tax deduction. The Company does not record tax benefits related to ISOs unless and until a disqualifying disposition occurs. Upon a disqualifying disposition, the entire tax benefit is recorded as a reduction of income tax expense. The Company has not recognized any income tax benefit for the three years ended December 31, 2009 for share-based compensation arrangements as the Company does not believe that it will recognize any deferred tax assets from such compensation costs recognized in the current period.

15. Stock-Based Compensation – (continued)

In general, stock option awards granted under the option plan vest 25% per year for four years. In March 2008, the Company's board of directors amended the option plan to provide that upon a change in control all outstanding ISO awards held by a qualified employee may under certain circumstances be accelerated and exercisable immediately. Upon a change in control, the vesting percentage of the employee's ISO award depends upon the number of years of employment at the time of the change in control as follows: 25% vested if employed less than one year, 50% vested if employed more than one year but less than two years, 75% vested if employed more than two years but less than three years, and 100% vested if employed three or more years.

As of December 31, 2009, a total of 4,019,723 shares of common stock have been authorized by the board of directors for issuance under the option plan. Also as of December 31, 2009, a total of 2,543,235 options for shares of common stock were issued and outstanding and a total of 846,511 shares of common stock had been issued upon the exercise of outstanding options, leaving a total of 629,977 shares of common stock remaining available for future issuance in connection with the option plan. The options vest over a period of not greater than five years and remain exercisable for up to 10 years from the date of grant.

Effective January 1, 2006, the Company adopted ASC 505, *Equity-Based Payments to Non-Employees*, and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*), using the modified prospective method of transition. Under that transition method, compensation expense recognized in the three years ended December 31, 2009 includes: (a) compensation costs for all share-based payments granted prior to January 1, 2006, which are based on the intrinsic value method proscribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and (b) compensation costs for all share-based payments granted subsequent to January 1, 2006, which are based on the grant date fair value estimated in accordance with the provisions of ASC 505 and ASC 718.

In accordance with ASC 505 and ASC 718, the fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model using weighted average assumptions amortized to expense over the options' vesting periods for the three years ended December 31, 2009 as follows:

	2009	2008	2007
Risk free interest rate	2.11%	2.85%	4.65%
Expected dividend yield	—	—	—
Volatility factor of the expected market price	77% – 79%	79%	80%
Forfeiture rate	6.9%	6.2%	2.9%
Weighted average expected life of the option	8.5 years	8.0 years	7.0 years

Since the trading market for the Company's common stock has a limited history, the expected volatility and forfeiture rates are based on historical data from three companies similar in size and value to the Company. The expected terms of options granted represent the period of time that options granted are expected to be outstanding and are derived from the contractual terms of the options granted. The fair value of each option is amortized over each option's vesting period. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant.

15. Stock-Based Compensation – (continued)

Roll-forward information relating to the Company's stock option plan is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (millions)
Options at January 1, 2007	1,509,839	$ 3.38		
Granted	652,901	$14.28		
Exercised	(166,178)	$ 1.90		
Forfeited, tendered or expired	(49,660)	$ 8.30		
Options at December 31, 2007	1,946,902	$ 7.03		
Granted	653,181	$13.31		
Exercised	(337,695)	$ 2.49		
Forfeited, tendered or expired	(144,996)	$ 9.69		
Options at December 31, 2008	2,117,392	$ 9.41		
Granted	627,666	$ 8.70		
Exercised	(110,438)	$ 4.10		
Forfeited, tendered or expired	(91,385)	$ 9.71		
Options at December 31, 2009	2,543,235	$ 9.45	8.5 years	$22.0
Options exercisable at December 31, 2009	1,134,986	$ 7.29	7.2 years	$ 5.2

The weighted-average grant-date fair value of options granted during the years ended December 31, 2009, 2008 and 2007 was $8.70, $13.31 and $14.28, respectively. The total intrinsic value of options exercised during the years ended December 31, 2009, 2008 and 2007 was $955,904, $2,293,814 and $2,528,894, respectively. The fair value of nonvested shares is determined based on the trading price of the Company's shares on the grant date.

A summary of the status of the Company's nonvested shares of stock options at December 31, 2009, and changes during the year ended December 31, 2009, is as follows:

	Shares	Weighted Average Grant-Date Fair Value
Nonvested at January 1, 2009	1,290,439	$11.62
Granted	627,666	$ 8.70
Vested	(446,719)	$ 8.88
Forfeited or expired (net of tenders)	(63,137)	$11.43
Nonvested at December 31, 2009	1,408,249	$11.20

Based on the Company's stock option grants outstanding at December 31, 2009, the Company has estimated the remaining unrecognized stock-based compensation expense to be $5,975,515 with a weighted average remaining amortization period of 2.4 years.

15. Stock-Based Compensation – (continued)

2005 Employee Stock Purchase Plan

During 2005, the Company's board of directors approved the adoption of the 2005 Employee Stock Purchase Plan (the ''purchase plan''). The Company's purchase plan incorporates the provisions of Section 423 of the Internal Revenue Code of 1986, as amended. The Company has reserved 200,000 shares of common stock for purchase by employees under the purchase plan. The purchase plan provides for offer periods of three months to eligible employees. Under the purchase plan, eligible employees can purchase through payroll deductions up to 15% of their eligible base compensation, at a price equivalent to 85% of the lower of the beginning or ending quarterly market price.

Employees became eligible to participate in the purchase plan beginning July 1, 2006. As of December 31, 2009, there were 131,857 shares remaining available for issuance under the purchase plan. In accordance with the provisions of ASC 718, the Company recorded stock-based compensation expense in connection with the purchase plan of $34,260, $33,380 and $23,742 during the years ended December 31, 2009, 2008 and 2007, respectively.

401(k) Profit Sharing Plan

Effective January 1, 2004, the Company began sponsoring a defined contribution retirement plan (the ''401(k) plan'') covering substantially all its employees fulfilling minimum age and service requirements. Participation in the plan is optional. The Company provides matching contributions at the discretion of the board of directors, and generally consists of matching contributions in shares of the Company's common stock valued at up to four percent of eligible employee compensation. Such matching contributions, if approved, are generally awarded during the first quarter of each calendar year, and cover the previous calendar year just ended. As of December 31, 2009, there were 59,659 shares remaining available for issuance under the 401(k) plan. In accordance with the provisions of ASC 718, the Company recorded stock-based compensation expense in connection with the 401(k) plan of $339,950, $0 and $133,753 for the years ended December 31, 2009, 2008 and 2007, respectively.

16. Income Taxes

At December 31, 2009, the Company had federal net operating loss (''NOL'') carryforwards of $63,345,331 that will begin to expire in 2022. State NOL carryforwards at December 31, 2009 totaled $51,309,910 and will expire between 2012 and 2028. The use of deferred tax assets, including federal net operating losses, is limited to future taxable earnings. Based on the required analysis of future taxable income under the provisions of ASC 740, *Income Taxes* (formerly SFAS No. 109 *Accounting for Income Taxes)*, management believes that there is not sufficient evidence at December 31, 2009 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2009. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including loss carryforwards.

The Company's ability to use its NOL carryforwards could be limited and subject to annual limitations. In connection with future offerings, the Company may realize a ''more than 50% change in ownership'' which could further limit its ability to use its NOL carryforwards accumulated to date to reduce future taxable income and tax liabilities. Additionally, because U.S. tax laws limit the time during which NOL carryforwards may be applied against future taxable income and tax liabilities, the Company may not be able to take advantage of all or portions of its NOL carryforwards for federal income tax purposes.

In 2003, the Company paid alternative minimum taxes of $69,862. The tax payment was reflected as a federal income tax expense in the 2003 financial statements. In 2007, the IRS refunded the payment. The refund amounted to $74,291, including accrued interest, and is reflected on the Company's consolidated statement of operations as a federal income tax benefit for the year ended December 31, 2007.

The Company incurred net operating losses for the three years ended December 31, 2009.

16. Income Taxes – (continued)

Effective January 1, 2007, the Company adopted a provision of ASC 740 (formerly FIN 48) to account for uncertain tax positions. ASC 740 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 prescribes that the Company should use a ''more likely than not'' recognition threshold based on the technical merits of the tax position taken. Tax positions that meet the ''more likely than not'' recognition threshold should be measured in order to determine the tax benefit to be recognized in the financial statements. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

As a result of implementing ASC 740, the Company did not have any unrecognized tax benefits or liabilities, or any associated amounts for interest and penalties. As a result, there was no effect on its financial position or results of operations as of and for the three years ended December 31, 2009.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. With few exceptions, the Company is no longer subject to U.S. federal examinations or state and local income tax examinations by tax authorities for years before 2003.

The provision (benefit) for income taxes consists of the following amounts:

	Years Ended December 31,		
	2009	2008	2007
Current:			
Federal	$ —	$ —	$ (74,291)
State	—	—	—
Total current	—	—	(74,291)
Deferred:			
Federal	(6,575,611)	(2,349,485)	(7,798,703)
State	(284,703)	(95,857)	(603,261)
Total deferred	(6,860,314)	(2,445,342)	(8,401,964)
Total benefit, before valuation allowance	(6,860,314)	(2,445,342)	(8,476,255)
Change in valuation allowance	6,860,314	2,445,342	8,401,964
Total provision (benefit), after valuation allowance	$ —	$ —	$ (74,291)

16. Income Taxes – (continued)

The net deferred income taxes as of December 31 include the following amounts of deferred income tax assets and liabilities:

	2009	2008
Deferred tax assets (liabilities) — current:		
Deferred revenue	$ 370,509	$ 368,275
Accrued salaries and paid time off	811,380	615,492
Accrued charitable contributions	—	114,272
Other	10,654	58,938
Subtotal deferred tax assets — current	1,192,543	1,156,977
Deferred revenue — GEM 21S	(9,528)	(3,709,454)
Subtotal deferred tax liabilities — current	(9,528)	(3,709,454)
Total net deferred tax assets (liabilities) — current	$ 1,183,015	$ (2,552,477)
Deferred tax assets (liabilities) — noncurrent:		
Net operating loss carryforwards	$ 23,744,004	$ 15,641,673
Fixed assets (tax basis difference)	760,538	538,428
Intangibles (tax basis difference)	261,978	225,459
Deferred revenue	5,932,202	6,264,712
Deferred compensation on stock options	247,231	215,017
Unrealized loss on auction rate securities	2,895	5,072,164
Other	283,850	150,423
Subtotal deferred tax assets — noncurrent	31,232,698	28,107,876
Valuation allowance to offset current deferred assets (liabilities)	—	(2,552,477)
Total deferred tax assets (liabilities) — noncurrent	31,232,698	25,555,399
Net deferred tax assets (liabilities)	32,415,713	25,555,399
Valuation allowance	(32,415,713)	(25,555,399)
Net deferred tax assets (liabilities)	$ —	$ —

The provision for income taxes differs from the amount computed by applying the statutory federal income tax rate to income before the provision for income taxes.

The sources and tax effects of the differences are as follows:

	2009	2008	2007
Federal income tax benefit at U.S. statutory rates	$(7,193,521)	$(2,721,699)	$(8,383,055)
State income taxes, net of federal benefit	(737,533)	(218,690)	(909,784)
Permanent differences	1,151,082	824,902	598,220
Change in valuation allowance	6,860,314	2,445,342	8,401,964
Other	(80,342)	(329,855)	218,364
Total income tax (benefit) for continuing operations	$ —	$ —	$ (74,291)

17. Employee Benefits

Section 125 Cafeteria Plan

Effective May 10, 2004, the Company began offering employees the benefit of participating in a Section 125 Cafeteria Plan, which covers employee benefit coverage such as health, dental, life and disability insurance. Participation in the plan is optional. The Company made contributions of $46,127, $74,882 and $200,625 for the years ended December 31, 2009, 2008 and 2007, respectively.

18. Related Party Transactions

Intellectual Property

Dr. Samuel E. Lynch, the Company's President and Chief Executive Officer, was a faculty member at Harvard and in such position was the co-inventor of certain intellectual property. As part of his employment arrangement with Harvard, he assigned all of his rights to the intellectual property to Harvard. The Company currently has a license agreement with Harvard with respect to certain portions of this intellectual property. As is customary, Harvard often shares some of the royalties it receives from successful intellectual property licenses with the faculty members that invented such intellectual property. During the year ended December 31, 2009, Harvard had paid to Dr. Lynch a total of $48,220, for a cumulative total of $940,352 as of December 31, 2009, with respect to the Company's payment of milestones and royalties to Harvard and the intellectual property licensed to the Company as compensation to Dr. Lynch as the co-inventor of the intellectual property that the Company licenses from Harvard. Additional payments may be due in the future.

Lease Agreement

The Company maintains operating lease agreements with Noblegene for the use of office and manufacturing space at the Company's headquarters in Franklin, Tennessee. Dr. Lynch is a former partner in Noblegene but maintained an ownership interest at the time the Company entered into the lease agreements. In March 2008, Dr. Lynch sold his ownership interest back to Noblegene. Since the owner of Noblegene is the brother-in-law of Dr. Lynch's wife, Noblegene continues to be a related party. Other than the consideration to buy Dr. Lynch's interest in Noblegene, Dr. Lynch has not received any amounts from Noblegene for the lease because Noblegene had operated at a loss and did not make any distributions of profits to its members prior to Dr. Lynch's divestiture of his interest in Noblegene. Dr. Lynch will not receive any future amounts from Noblegene in connection with the lease.

Membership on the Board of Directors of a Third Party Company

Dr. Lynch, the Company's President and Chief Executive Officer, is currently a member of the board of directors of GreenBankshares, Inc., which serves as the bank holding company for GreenBank, a Tennessee chartered commercial bank. He is currently serving a three-year term expiring at the 2011 annual meeting. As of December 31, 2009, the Company maintained accounts at GreenBank, including a portion of its cash and cash equivalents.

Consulting Agreement with a member of the Board of Directors

In August 2009, the Company entered into a two-year consulting agreement with Gary E. Friedlaender, M.D. for consulting services relating to the use of biological products to treat orthopedic injuries and conditions. The 2009 agreement extends the consulting relationship that the Company had with Dr. Friedlaender pursuant to an August 2007 consulting agreement.

In September 2006, the Company appointed Dr. Friedlaender as a member of its board of directors. Prior to the August 2006 agreement and the September 2006 appointment, the Company compensated Dr. Friedlaender for his consulting through stock option grants. As part of his consulting compensation, Dr. Friedlaender received option awards on July 15, 2001 to purchase 7,500 shares of common stock at an exercise price of $0.67, and on February 26, 2006 to purchase 20,250 shares of common stock at an exercise price of $3.63. The option awards were 100% vested upon issuance. For the year ended December 31, 2009, 2008 and 2007, the Company paid Dr. Friedlaender $5,000, $5,000 and $50,938, respectively, for consulting services performed pursuant to the consulting agreements.

19. Unaudited Information

The following table presents unaudited quarterly financial data of the Company. The Company's quarterly results of operations for these periods are not necessarily indicative of future results.

Year ended December 31, 2009	Revenue	Loss From Operations	Net Income (Loss)	Net Income (Loss) Per Share – Basic	Net Income (Loss) Per Share – Diluted
1st Quarter	$378,605	$(8,315,255)	$(8,031,351)	$(0.43)	$(0.43)
2nd Quarter	373,360	(8,210,056)	(6,304,929)	(0.32)	(0.32)
3rd Quarter	374,542	(8,454,457)	(7,916,133)	(0.36)	(0.36)
4th Quarter	444,719	(9,963,760)	1,094,999	0.05	0.05

In the 4th quarter of 2009, the Company recognized a gain of $3,708,900 on the sale of its remaining auction rate securities and recognized a gain of $7,219,270 when funds were received from the respondent in the arbitration claim. See Note 13.

Year ended December 31, 2008	Revenue	Loss From Operations	Net Income (Loss)	Net Income (Loss) Per Share – Basic	Net Income (Loss) Per Share – Diluted
1st Quarter	$ 487,735	$(8,969,930)	$ 31,303,215	$ 1.70	$ 1.62
2nd Quarter	457,665	(9,852,170)	(9,172,152)	(0.50)	(0.50)
3rd Quarter	418,969	(8,466,302)	(17,968,653)	(0.97)	(0.97)
4th Quarter	1,784,015	(9,463,274)	(12,167,407)	(0.65)	(0.65)

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.

Dated: March 12, 2010

BIOMIMETIC THERAPEUTICS, INC.

By: /s/ Samuel E. Lynch
Samuel E. Lynch, D.M.D., D.M.Sc.
Chief Executive Officer and President

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

Signatures	Capacity	Date
/s/ Samuel E. Lynch Samuel E. Lynch, D.M.D., D.M.Sc.	Chief Executive Officer and President (Principal Executive Officer)	March 12, 2010
/s/ Larry Bullock Larry Bullock	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2010
/s/ Larry W. Papasan Larry W. Papasan	Chairman of the Board of Directors	March 12, 2010
/s/ Thorkil K. Christensen Thorkil K. Christensen	Director	March 12, 2010
/s/ Chris Ehrlich Chris Ehrlich	Director	March 12, 2010
/s/ Charles Federico Charles Federico	Director	March 12, 2010
/s/ Gary E. Friedlaender, M.D. Gary E. Friedlaender, M.D.	Director	March 12, 2010
/s/ James G. Murphy James G. Murphy	Director	March 12, 2010
/s/ Douglas Watson Douglas Watson	Director	March 12, 2010

EXHIBIT INDEX

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (Incorporated by reference to the registrant's Form 10-Q for the quarter ended June 30, 2006)
3.2	Second Amended and Restated Bylaws (Incorporated by reference to the registrant's Form 8-K filed on June 16, 2008)
4.1	Form of certificate representing shares of common stock (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on April 26, 2006)
10.1**	License Agreement between the registrant and President and Fellows of Harvard College, dated as of April 10, 2001 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 8, 2006)
10.2**	Exclusive Patent License Agreement between the registrant and ZymoGenetics, Inc., dated as of March 28, 2001 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 10, 2006)
10.3**	Second Exclusive Patent License Agreement between the registrant and ZymoGenetics, Inc., dated as of January 21, 2003 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 10, 2006)
10.4**	Letter Agreement between the registrant and ZymoGenetics, Inc., dated October 17, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 8, 2006)
10.5**	Manufacturing and Supply Agreement between the registrant and Chiron Corporation, dated as of July 28, 2004 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 8, 2006)
10.6**	Supply Agreement between the registrant and Orthovita, Inc. dated as of August 2, 2002 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.7**	Exclusive Sublicense Agreement between the registrant and Luitpold Pharmaceuticals, Inc., dated as of December 9, 2003 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 10, 2006)
10.8	Research, Development and Marketing Agreement between the registrant and Luitpold Pharmaceuticals, Inc., dated as of December 9, 2003 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 8, 2006)
10.9**	Manufacturing and Supply Agreement between the registrant and Luitpold Pharmaceuticals, Inc., dated as of December 9, 2003 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 8, 2006)
10.10**	Development, Manufacturing and Supply Agreement between the registrant and Kensey Nash Corporation, dated as of June 28, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.11*	2001 Long-Term Stock Incentive Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.12*	2005 Employee Stock Purchase Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.13*	Employment Agreement, effective as of November 30, 2004, by and between the registrant and Dr. Samuel E. Lynch (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.14*	Amendment to Employment Agreement, effective as of December 1, 2004, by and between the registrant and Dr. Samuel E. Lynch (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)

Exhibit No.	Description
10.15*	Employment Agreement, effective as of September 1, 2002, by and between the registrant and James Monsor (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.16*	Employment Agreement, effective as of July 5, 2005, by and between the registrant and Steven N. Hirsch (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.17*	Employment Agreement, effective as of May 31, 2005, by and between the registrant and Earl Douglas (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.18**	Patent Purchase Agreement by and among the registrant and Institute of Molecular Biology, Inc. dated November 16, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.19	Amendment No. 1 to Exclusive Sublicense Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated as of December 21, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.20	Amendment No. 1 to Manufacturing and Supply Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated as of December 21, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.21**	Letter Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated as of December 21, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on February 10, 2006)
10.22	Form of indemnification agreement by and between the registrant and each executive officer and director (Incorporated by reference to the registrant's Form 8-K filed on June 22, 2006)
10.23	Amended and Restated Information and Registration Rights Agreement dated October 21, 2004 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on March 31, 2006)
10.24	Amendment to the Amended and Restated Information and Registration Rights Agreement dated April 29, 2005 (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on March 31, 2006)
10.25*	Amendment to 2001 Long-Term Stock Incentive Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on April 26, 2006)
10.26*	Second Amendment to 2001 Long-Term Stock Incentive Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on April 26, 2006)
10.27*	Third Amendment to 2001 Long-Term Stock Incentive Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-131718) filed on May 5, 2006)
10.28*	Amendment to 2005 Employee Stock Purchase Plan (Incorporated by reference to the registrant's Registration Statement on Form S-1 (SEC File No. 333-139291) filed on December 12, 2006)
10.29	Lease Agreement between the registrant and Noblegene Development, LLC effective January 1, 2007 (Incorporated by reference to the registrant's Form 8-K filed on May 7, 2007)
10.30	Lease Agreement between the registrant and Noblegene Development, LLC dated August 17, 2007 (Incorporated by reference to the registrant's Form 8-K filed on August 21, 2007)
10.31**	Asset Purchase Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated December 14, 2007 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).

Exhibit No.	Description
10.32**	Amended and Restated Exclusive Sublicense Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.33**	Exclusive License Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.34**	Supply Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.35	Agreement Terminating Research, Development and Marketing Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.36	Agreement Terminating Manufacturing and Supply Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.37	Amendment and Waiver Agreement with respect to Asset Purchase Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated January 4, 2008 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.38*	Employment Agreement, effective as of January 1, 2008, by and between the registrant and Dr. Samuel E. Lynch (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2007).
10.39	Amendment to Lease Agreement between the registrant and Noblegene Development, LLC dated January 22, 2008 (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008).
10.40*	Amendment to 2001 Long-Term Stock Incentive Plan dated March 27, 2008 (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008).
10.41**	Distribution Agreement between the registrant and Joint Solutions Alliance Corporation dated April 18, 2008 (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008).
10.42*	Employment Agreement, effective as of September 5, 2008, between the registrant and Larry Bullock dated September 30, 2008 (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008).
10.43	Separation Agreement and Full Release between the registrant and Dr. Charles Hart dated September 30, 2008 (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2008).
10.44	Time Promissory Note dated as of October 27, 2008. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.45	Borrower Security and Pledge Agreement dated as of October 27, 2008. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.46	Securities Account Control Agreement dated as of October 27, 2008. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.47	Bank Commitment Letter dated October 27, 2008. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).
10.48	Second Amendment to Lease Agreement between registrant and Noblegene Development, LLC dated January 9, 2009. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2008).

Exhibit No.	Description
10.49	Purchase Agreement between the registrant and InterWest Partners, dated April 3, 2009 (Incorporated by reference to the registrant's Form 8-K filed on April 7, 2009).
10.50	Standby Purchase Agreement between the registrant and Novo A/S, dated April 4, 2009 (Incorporated by reference to the registrant's Form 8-K filed on April 7, 2009).
10.51*	Employment Agreement, effective as of July 17, 2009, between the registrant and Dr. Samuel E. Lynch (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.52*	Employment Agreement, effective as of July 17, 2009, between the registrant and Steven Hirsch (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.53*	Employment Agreement, effective as of July 17, 2009, between the registrant and Larry Bullock (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.54*	Employment Agreement, effective as of July 17, 2009, between the registrant and Earl Douglas (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.55*	Employment Agreement, effective as of July 17, 2009, between the registrant and Dr. Russell Pagano (Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009).
10.56**	Amended and Restated Manufacturing and Supply Agreement, effective as of December 1, 2009, between the registrant and Novartis Vaccines and Diagnostics, Inc.
10.57**	Release and Settlement Agreement, effective as of December 21, 2009.
21.1	Subsidiaries of the registrant
23.1	Consent of Ernst & Young LLP
31.1	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer
31.2	Rule 13a-14(a)/15d-14(a) Certification of the Chief Financial Officer
32.1	Section 1350 Certification of the Chief Executive Officer
32.2	Section 1350 Certification of the Chief Financial Officer

* Indicates management contract or compensatory plan or arrangement

** Confidential treatment has been requested for portions of this exhibit

EXHIBIT 31.1

Certification of Chief Executive Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Dr. Samuel E. Lynch, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioMimetic Therapeutics, Inc.;

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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 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 report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this 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 (or persons performing the equivalent functions):

   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 12, 2010

/s/ Samuel E. Lynch

Dr. Samuel E. Lynch
Chief Executive Officer and President

EXHIBIT 31.2

Certification of Chief Financial Officer
Pursuant to Rule 13a-14(a) or Rule 15d-14(a)
Under the Securities Exchange Act of 1934

I, Larry Bullock, certify that:

1. I have reviewed this Annual Report on Form 10-K of BioMimetic Therapeutics, Inc.;

2. Based on my knowledge, this 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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 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 report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this 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 (or persons performing the equivalent functions):

   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 12, 2010

/s/ Larry Bullock

Larry Bullock
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION

In connection with the Annual Report of BioMimetic Therapeutics, Inc. (the ''Company'') on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the ''Report''), I, Dr. Samuel E. Lynch, Chief Executive Officer and President of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, ''filed'' with the Securities and Exchange Commission.

Date: March 12, 2010

/s/ Samuel E. Lynch

Dr. Samuel E. Lynch
Chief Executive Officer and President

EXHIBIT 32.2

CERTIFICATION

In connection with the Annual Report of BioMimetic Therapeutics, Inc. (the ''Company'') on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the ''Report''), I, Larry Bullock, Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, ''filed'' with the Securities and Exchange Commission.

Date: March 12, 2010

/s/ Larry Bullock

Larry Bullock
Chief Financial Officer