BIOMIMETIC
THERAPEUTICS

2010

ANNUAL REPORT

Imagine the future of orthopedic medicine.

We have.

Corporate Profile

BioMimetic Therapeutics is a biotechnology company specializing in the development and commercialization of innovative bioactive products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications. All of our products are based upon recombinant human platelet-derived growth factor (rhPDGF-BB) platform technology, which is a synthetic form of PDGF, one of the body's principal agents to stimulate and direct healing and tissue regeneration. Through the commercialization of this patented technology, we seek to become the leading company in the field of regenerative medicine by providing new treatment options for the repair of bone, cartilage, tendons and ligaments, thus helping patients recover faster from their orthopedic injuries. According to *The Journal of the American Medical Association*, musculoskeletal conditions account for more disability and more costs to the U.S. healthcare system than any other condition, and with the aging of the population, this burden to society will increase.

One Step Closer…

With the filing of our Pre-Market Approval (PMA) application with the U.S. Food and Drug Administration (FDA) in May 2010 and the scheduling of our orthopedic advisory panel for May 2011, BioMimetic Therapeutics moved one step closer to U.S. approval of Augment™ Bone Graft for use in hindfoot and ankle fusion surgery.

Imagine harnessing the regenerative properties of a single molecule to transition standard treatment from passive, mechanical implants to innovative biological solutions.

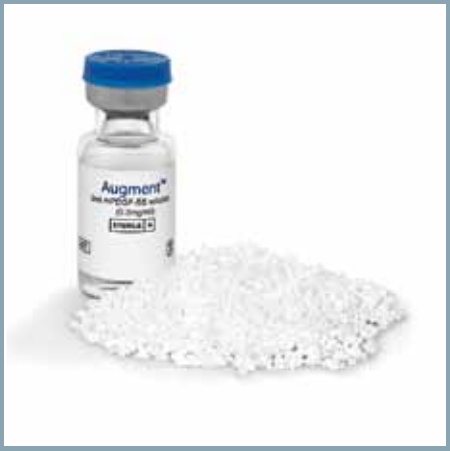
Over two decades ago, we first imagined the possibilities of using platelet-derived growth factor (PDGF) to stimulate bone and tissue growth as an alternative to current standards of care.

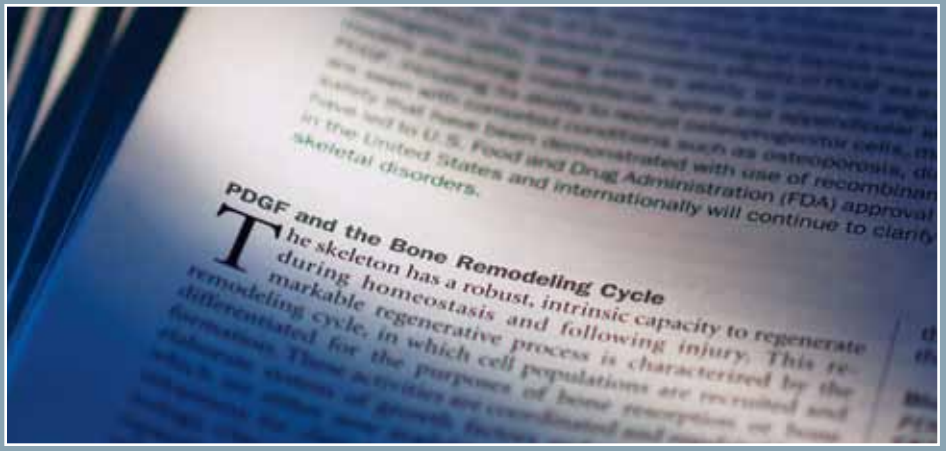
DEAR FELLOW SHAREHOLDER:

2010 was a significant year for BioMimetic Therapeutics, as we achieved an important corporate milestone by filing our PMA application for Augment Bone Graft (Augment) with the FDA. The PMA submission is based on the positive 6- and 12-month efficacy and safety data from our North American pivotal trial comparing Augment Bone Graft a synthetic, off-the-shelf product, to autologous bone graft (autograft), the current gold standard in bone grafting, for the treatment of foot and ankle fusions. In addition to meeting the primary endpoint (50 percent osseous bridging on CT scans at six months), these data demonstrated that 15 of 16 secondary endpoints were statistically significant at 12 months and that Augment Bone Graft provides comparable benefits without the pain and morbidity associated with harvesting autograft.

We look forward to the opportunity to present our findings during an Orthopedic and Rehabilitation Devices Panel meeting on May 12, 2011. Assuming the panel determines that the product's benefits outweigh potential risks, we expect approval of Augment by the FDA within six months following the panel meeting.

Nearly 750 patients have been enrolled in rigorous orthopedic clinical trials evaluating Augment Bone Graft and our second generation orthopedic product candidate, Augment™ Injectable Bone Graft (Augment Injectable), over the past four years and we have already demonstrated that our technology is safe and effective in stimulating bone regeneration as evidenced by the Canadian regulatory approval of Augment Bone Graft in 2009. Additionally, since 2005, approximately 200,000 patients have been treated with our first approved product, GEM 21S®, for the treatment of periodontally related bone defects. Augment Bone Graft and GEM 21S are essentially the same products, both containing rhPDGF-BB and ß-tricalcium phosphate (ß-TCP), but with a different TCP particle size. To date, each of these products has demonstrated a strong record of efficacy and safety.





The launch of Augment represents a transformative event for BioMimetic, as it will mark our emergence as a commercial organization. We believe the Augment technology has the potential to change the standard of care for the treatment of musculoskeletal injuries requiring bone grafting and conditions affecting tendons, ligaments and cartilage repair and regeneration.

Upon approval, Augment Bone Graft would be the first, new recombinant protein technology for orthopedics introduced to the market in nearly a decade and the first and only cost effective, fully synthetic replacement for autograft with level 1 data supporting its safety and efficacy.

Science Behind Our Platform Technology

The ability to develop human biopharmaceutical products using recombinant technology has produced new treatment options for patients and established multi-billion dollar commercial market opportunities. One of the best examples are blood growth factors, such as erythropoietin, which promote red blood cell production and reduce the need for blood transfusions that are expensive, painful, and put the patient at the risk of contracting other diseases such as human immunodeficiency virus, or HIV.

Similarly, over two decades ago, we first imagined the possibilities of using platelet-derived growth factor (PDGF) to stimulate bone and tissue growth as an alternative to current standards of care. The make-up of most of the Company's product candidates combines rhPDGF-BB and tissue specific scaffold materials. In the case of bone defects, the scaffold is comprised of a synthetic bone matrix such as ß-TCP, which has a strong history of safety, purity and biocompatibility. For tendon and ligament tears, the scaffold consists of a collagen matrix. Like its naturally occurring counterpart, the growth factor rhPDGF-BB activates the healing process by providing the biological stimulus for tissue repair, while the scaffold provides a framework for the new bone, tendon, ligament or cartilage formation and regeneration to occur.

Like erythropoietin, PDGF is one of numerous naturally occurring molecules capable of stimulating cellular growth, proliferation and differentiation. In particular, PDGF is an essential component of the wound-healing cascade that stimulates key processes for musculoskeletal repair, each of which is well described in scientific literature.

Today, all of the lead product candidates in our pipeline are based upon rhPDGF-BB platform technology, which has the same functionality, potency and specificity as naturally occurring PDGF, but is available in a well characterized, purified and concentrated preparation. This core technology has consistently demonstrated efficacy and safety across multiple Augment clinical studies to date, including the largest clinical study ever performed in foot and ankle fusion indications.

Through the commercialization of this patented technology, BioMimetic seeks to address a large unmet medical need for improving the repair of bone, cartilage, tendons and ligaments that exceeds $6 billion annually in the U.S. alone.

Augment Advantage

Addressing Diverse Markets

We believe our regenerative biologics platform holds great promise in promoting the repair of injury to both bone and soft tissue and provides significant advantages over existing therapies. Whether stimulating bone growth in connection with hindfoot and ankle fusion or spine fusion procedures, soft tissue growth in sports medicine injuries such as rotator cuff, or combined bone and cartilage growth in osteochondral defects of the knee, our Augment family of product candidates is designed to effectively reinforce the surgical repair and promote long-term tissue regeneration across large and diverse markets. In fact, according to the 2008 National Health Interview Survey, an estimated 110 million adults—approximately half of the adult U.S. population—reported having a disabling musculoskeletal condition.

Safety and Convenience

The Augment products are an off-the-shelf alternative to the current standards of care and require minimal preparation before being applied to the surgical site. Specifically, Augment and Augment Injectable are intended to alleviate the need for autograft, which would save the surgeon and hospital the time and cost associated with harvesting the bone and spare the patient the pain and potential complications that can accompany this second surgery required when using autograft. Major limitations with autograft include donor site morbidity, such as pain and infection, limited supply of available bone, and inconsistent osteogenic activity due to variations in the number of viable mesenchymal and osteoprogenitor stem cells that are present in the specimen. An example of the complications of harvesting autograft was realized in our North American Augment pivotal trial, which demonstrated 44 percent of autograft patients still reported pain at the harvest site 12 months post surgery. Because Augment patients do not require harvesting bone from a separate site, patients are spared the pain caused by this second surgery.

Cost Effective

Beyond the scientific and clinical advantages of Augment, BioMimetic is also committed to delivering cost effective products to physicians, hospitals and patients. For example, a recent study concluded that the cost of harvesting autograft in foot and ankle fusion procedures is between $1,100 and $2,400 per patient depending on the harvest site. We believe this study will provide a strong economic argument for reimbursement of Augment as an alternative to harvesting autograft in foot and ankle procedures.

Advancing a Robust Pipeline

Differences in the injury or surgical method require alternative delivery formats and biomaterial consistency to adequately address the myriad of opportunities. The right combination of rhPDGF-BB and appropriate scaffold materials will be key to the success of bioactive products to promote the healing of a broad array of musculoskeletal injuries and diseases within general orthopedic, spine and sports injury applications.

Imagine a complete family of product candidates that help musculoskeletal injuries heal stronger, safer and with less pain as compared to traditional techniques.

The Augment products are an off-the-shelf alternative to the current standards of care and require minimal preparation before being applied to the surgical site.

Beyond our significant regulatory progress in 2010 with Augment Bone Graft, we have completed and have ongoing clinical trials with two additional product candidates, Augment Injectable Bone Graft and Augment™ Rotator Cuff Graft, in orthopedic and sports medicine indications, respectively.

Augment Injectable Bone Graft

Augment Injectable combines rhPDGF-BB with B-TCP and collagen matrices and is designed for easy, controlled delivery to open surgical sites, to complement minimally invasive surgery or to be used as a means to treat fractures and bone defects percutaneously. In clinical studies, Augment Injectable has been evaluated as a healing adjunct to fusion in hindfoot and ankle surgeries and distal radius fractures.

In September 2010, we announced receipt of a determination letter from the FDA's Office of Combination Products indicating that the Augment Injectable review will follow a medical device pathway in the United States and accordingly has been assigned to the FDA's Center for Devices and Radiologic Health (CDRH) for lead review. In early 2011, the FDA approved the initiation of enrollment in our North American pivotal trial comparing Augment Injectable to autograft in hindfoot fusion indications. The study is expected to enroll approximately 200 patients and be fully enrolled around the end of 2011.

Additionally, in June 2010, we completed enrollment of 75 patients in a Canadian Augment Injectable hindfoot and ankle fusion pivotal study comparing Augment to autograft. The Company plans to file the Device License Application (DLA) in Canada and release data from the study in the second half of 2011.

Augment Rotator Cuff Graft

Sports medicine represents a significant, untapped market for our rhPDGF-BB technology platform, which has been shown to stimulate the repair of tendons, ligaments and cartilage in pre-clinical studies.

Rotator cuff tears are among the most common shoulder injuries, and rotator cuff repair is one of the most commonly performed orthopedic soft tissue procedures in the U.S. It is estimated that there will be approximately 450,000 rotator cuff repair procedures performed in the U.S. in 2011, with an additional 275,000 in other parts of the world. These numbers are expected to increase at a rate of 6.5 percent annually due to the increasingly active aging population suffering acute sports-related injuries and various degenerative overuse conditions that ultimately require surgical repair. Operative repair of rotator cuff tears may improve pain and function, however previous studies have demonstrated that a significant percentage of these repairs fail to heal when evaluated

Imagine being able to serve the needs of patients across the world.

Whether returning an athlete to the game sooner or allowing a grandparent to play with their grandchildren later in life, Augment has the potential to improve patient outcomes.

radiologically and results of revision surgeries are less than optimal. Currently, there are no approved recombinant therapies for facilitating the repair of tendons after injury.

Based on our extensive pre-clinical studies, we believe Augment Rotator Cuff has the potential to speed healing, thus shortening recovery and facilitating faster return to sport and other activities and making re-injury less likely. In December 2010, we initiated enrollment in a pilot clinical trial in Canada to assess the safety and clinical utility of Augment Rotator Cuff, an interpositional graft consisting of a collagen matrix hydrated with rhPDGF-BB, for the repair of large rotator cuff tears. The trial is designed to evaluate safety and performance of Augment Rotator Cuff as compared to standard suture repair for primary surgical treatment of full thickness rotator cuff tears. The study is expected to be fully enrolled with 30 patients in the second quarter of 2011 and interim data should be available in the first half of 2012.

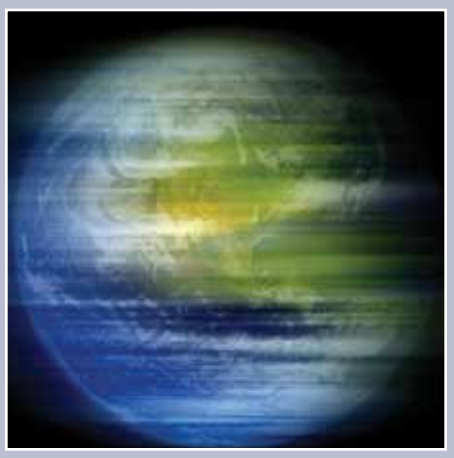
Tendonopathies, Cartilage and Spine

As described above, the Company has three product candidates in clinical trials, including Augment Bone Graft, which is pending FDA panel, Augment Injectable, which is in pivotal trials, and Augment Rotator Cuff, which is in a pilot trial. In addition, we have three product candidates ready to enter clinical trials, including Augment OCD for osteochondral (combined bone and cartilage) defects of the knee, Augment Tendonopathies for chronic (overuse) tendon injuries, and Augment Bone Graft for spine fusions. We have received orphan drug designation from the FDA for rhPDGF-BB to be used in conjunction with autograft and/or commercially available osteochondral allograft for the treatment of osteochondritis dissecans (OCD) of the knee, elbow or ankle and released pre-clinical data in this indication demonstrating the beneficial effects of BioMimetic's technology on cartilage and bone repair in the knee. Additionally, we recently released positive pre-clinical data in Achilles tendon repair from two preclinical models as well as a large animal (ovine) spine fusion model. We plan to initiate a clinical trial in one of these indications by the end of 2011.

Global Commercialization Strategy

United States

We are actively preparing for commercial launch of Augment Bone Graft in the United States, European Union and many other parts of the world and have completed a detailed analysis of the requisite commercialization infrastructure. In this regard, we recently hired a vice president of global sales and marketing whose expertise and relationships in the lower extremities' space will be an asset as we move closer toward the potential approval and commercialization of Augment.



Our commercialization strategy is to sell Augment Bone Graft through a hybrid network of at least 100 independent sales agents and direct representatives who already have established working relationships with our target surgeons. These sales consultants will focus on high volume orthopedic foot and ankle and podiatric surgeons and will be supported by product and reimbursement specialists that will provide technical expertise, training and key account support. Half of the foot and ankle fusions are performed in 200 facilities in the U.S., and we have determined that about 90 sales reps can cover more than 70 percent of all foot and ankle surgeons and facilities. We are confident we can build a very effective sales organization to cover these institutions and others across the country.

European Union

In the second quarter of 2011, we plan to submit a CE Mark dossier to seek Augment Bone Graft approval from European regulatory authorities. We expect a regulatory decision in 2012. We are currently pursuing representation through a partnership or distributor network for the sale of Augment in Europe and expect to be ready to commercialize upon approval. The European data we released in the summer of 2010 confirms the consistent safety and clinical performance of Augment. We believe that these data will be an important factor in the regulatory and reimbursement approvals of Augment in the European markets.

Australia

In February 2010, we filed an application with the Therapeutic Goods Administration (TGA), the regulatory body for medical products in Australia, to seek approval for Augment in foot and ankle fusion indications. We submitted the pivotal trial data from both our Canadian and North American studies and expect that this will be suitable for approval in Australia, which we anticipate occurring in late 2011. We have already contracted with Surgical Specialties of Australia as our exclusive distributor for the sale of Augment and Augment Injectable in Australia and New Zealand.

Barriers to Entry

We have been successful in securing multiple new patents for the protection of our product pipeline in the U.S., Canada and E.U. The addition of these patents, which provides coverage through 2026, continues to strengthen our existing patent portfolio, which also includes Australia, New Zealand, South Africa and Mexico, and provides us with long-term protection for our current and future product candidates in major markets around the world.

In addition to our strong patent protection, we amended our agreement with Novartis for exclusive supply of bulk rhPDGF-BB to BioMimetic. The agreement sets forth a clear and strengthened mutual exclusivity commitment for Novartis to manufacture rhPDGF-BB exclusively for BioMimetic for therapeutic applications covering bone, cartilage, tendon and ligaments.

Imagine the difference we will make for the broad spectrum of patients suffering from musculoskeletal injuries or disease.

The Company expects FDA approval of Augment Bone Graft later this year making it available to hospitals and patients throughout North America.

The Future

We imagine the future of regenerative orthopedic medicine being shaped by our Augment line of products. Whether returning an athlete to the game sooner or allowing a grandparent to play with their grandchildren later in life, Augment has the potential to improve patient outcomes. As we continue to develop innovative products to promote the healing of musculoskeletal injuries and diseases that are safe, effective and economically advantageous, we remain confident in our belief that BioMimetic has great potential in the orthobiologics market.

As we look ahead, 2011 promises to be another exciting year for BioMimetic Therapeutics as we progress toward approval for Augment Bone Graft, continue to execute on our commercialization plan and advance our proprietary rhPDGF-BB product pipeline. With a solid cash position, no debt, strong patent portfolio, and proven, talented product development staff, we have never been better positioned to deliver improved, safer therapies for patients with musculoskeletal injuries.

Of course, none of this would be possible without the support of our employees, shareholders, physicians and the patients who have participated in our studies. In addition to extending our gratitude to all of them, we thank you for your continued support and investment in BioMimetic.

Sincerely,

Samuel E. Lynch, D.M.D., D.M.Sc.
President and
Chief Executive Officer

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, 2010

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 Select 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, 2010, the last business day of the registrant's most recently completed second fiscal quarter, was $167.1 million.

As of March 4, 2011, a total of 27,933,329 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 2011 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, 2010. 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 27A of the Securities Act and Section 21E of the Exchange 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™ Bone Graft (''Augment'') in Canada and for our product candidates generally;
- actions by regulatory authorities;
- our regulatory strategy and decisions regarding the classification of a product as a device or a drug;
- 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 uncertainty.

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 this Annual Report on Form 10-K and in the reports we file, from time to time, with the Securities and Exchange Commission (the ''SEC''). In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances contained in this Annual Report on Form 10-K 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 on Form 10-K 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 the forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. 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 and we don't have a policy of doing so. You should, however, review the factors and risks we describe in this Annual Report on Form 10-K and in any future filings we may make from time to time, with the SEC.

PART I

Item 1. BUSINESS

Overview

We are a biotechnology company specializing in the development and commercialization of innovative products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, sports medicine and spine applications. Our product and product candidates use purified recombinant human platelet derived growth factor (''rhPDGF-BB''), one of the principal wound healing and tissue repair stimulators in the body, in combination with tissue specific matrices when appropriate, as our primary technology platform for promoting tissue healing and regeneration. The matrices are synthetic or natural scaffold materials, such as beta-tricalcium phosphate (''ß-TCP''), which have a history of demonstrated safety and efficacy in previous uses. This platform regenerative technology may offer physicians advanced biological solutions to actively stimulate the body's natural tissue regenerative process. We believe that our product candidates, if approved by the appropriate regulatory authorities, may offer new, effective and less invasive treatment options to improve the quality of life for millions of patients suffering injuries or deterioration of bones, ligaments, tendons and cartilage. Through the commercialization of this technology, we seek to become the leading company in the field of orthopedic regenerative medicine.

We have already demonstrated that our 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''). Both *GEM 21S* and Augment are fully synthetic, off-the-shelf bone growth factor products for the treatment of bone defects and injuries. In addition, we have demonstrated that our platform regenerative technology is safe and effective in our target applications with the positive results from our numerous clinical and non-clinical studies, including our Augment and Augment™ Injectable Bone Graft (''Augment Injectable'') clinical studies.

Currently, our primary focus is obtaining marketing approval for Augment, and preparing for the anticipated commercial launch of Augment in the United States, the European Union (''EU'') and Australia. In addition, we are focused on the continued development of our other product candidates, the commercial adoption of Augment in Canada, and managing our cash and investments.

A key priority is the approval of Augment in the United States. 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 provided the primary data set used to support potential regulatory approval in the United States, as well as in the EU and Australia. In 2010, we submitted data from this trial to the U.S. Food and Drug Administration (''FDA'') as part of our Pre-Marketing Approval (''PMA'') application for Augment, and we completed our 100-day PMA meeting with the FDA. In January 2011, the FDA's Medical Devices Advisory Committee tentatively scheduled a May 12, 2011 meeting of the Orthopedic and Rehabilitation Devices Panel (the ''panel'') to review our PMA application for Augment for the treatment of foot and ankle fusions in the United States. If the panel determines that there is a reasonable assurance that Augment is safe and effective and that Augment's benefits outweigh any potential risks, we anticipate approval of Augment by the FDA within three to six months after the panel meeting. We believe that, if approved, Augment will provide U.S. physicians and patients with a safe and important new therapeutic option for the treatment of foot and ankle fusions without the pain and morbidity associated with autograft, the current gold standard for foot and ankle fusions. Autograft requires the harvesting of autogenous bone from elsewhere in the patient's body, often requiring a second surgical procedure. If approved, Augment will be the first new recombinant bone and tissue growth factor technology to be introduced for orthopedic uses in the United States in nearly a decade.

In addition to Augment, we are developing a number of other product candidates, including Augment Injectable, an orthopedic product candidate, and Augment™ Rotator Cuff Graft (''Augment Rotator Cuff''), a sports medicine product candidate. Recent clinical activities on these product candidates include the following:

- In June 2010, we closed enrollment in a Canadian Augment Injectable pivotal clinical study with a total of 75 patients enrolled. This Canadian study is a randomized controlled trial comparing Augment Injectable to autograft for use in hindfoot and ankle fusion surgery.

- In December 2010, we announced the initiation of enrollment in a Canadian pilot clinical trial to assess the safety and clinical utility of Augment Rotator Cuff for the repair of large rotator cuff tears. This Canadian Augment Rotator Cuff study is a randomized, controlled pilot trial and is expected to include enrollment of up to 30 patients. To date, 18 patients have been treated and we anticipate that enrollment will be complete in the third quarter of 2011 with an interim data release in the first half of 2012.
- In the first quarter of 2011, we expect to initiate enrollment in the United States for a North American Augment Injectable pivotal study. This study is a randomized controlled trial comparing Augment Injectable to autograft for use in hindfoot fusion indications. We expect to enroll approximately 200 patients and to complete enrollment around the end of 2011.

We also remain focused on the commercial adoption of Augment in Canada, which was approved by Health Canada in the fourth quarter of 2009. We have now completed our transition from a single exclusive distributor to a network of independent sales agents who are more closely managed by us through our Canadian National Sales Manager. We now have over 30 independent sales representatives representing Augment throughout Canada. We have supplemented these efforts with three additional Regional Product Specialists based in the United States, providing technical product support to sales representatives, surgeons and hospital administration. Although we have now begun to see an increase in sales as a result of our restructured distribution, the Canadian market for Augment is limited and we do not anticipate significant revenues from sales of Augment in Canada.

Since our inception in 1999, we have incurred losses from operations each year. As of December 31, 2010, our accumulated deficit was $127.5 million. Our revenues remain limited, which at $1.5 million for the year ended December 31, 2010 consist of product sales, royalty income and sublicense fee income. We received regulatory approval from Health Canada to market Augment in Canada in late 2009. To date, our product sales revenues have been limited. Furthermore, while we currently do not yet have a product approved by the FDA for commercialization in the United States, we are incurring expenses in connection with our preparation for an anticipated U.S. commercial launch of Augment. 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 several years as we continue to fund our research and development activities, clinical trials, and regulatory and commercialization efforts.

In view of our limited revenue at this time, we continue to closely monitor our cash and investments balance and manage expenses. The continuing volatile business and economic environment, as well as the ensuing market instability and uncertainty, may continue 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 certain of our product candidates, or may impact the pricing that we may set for our products, if approved. Accordingly, the impact of the economy on commercial opportunities, such as our anticipated commercial launch of Augment in the United States, remains uncertain. We have responded to the current economic uncertainty by raising capital through the sale of common stock, by investing our cash and investments conservatively, and by employing cost control measures to conserve cash and manage expenses, such as limiting growth in staff, controlling expenditures and postponing certain product development activities where appropriate. However, now that the FDA panel meeting has been tentatively scheduled for May 12, 2011, we believe that we are nearing regulatory approval of Augment in the United States. We have therefore reassessed certain of these measures and plan to increase our staffing, particularly in the area of sales and marketing, and will accelerate certain activities relating to the build-out of our warehouse, distribution and manufacturing facility.

Market Opportunities

According to industry data, the worldwide orthopedic market was estimated at $32 billion in 2009. This includes joint fusion and 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. Traditionally, the orthopedic and sports medicine markets have been dominated by companies that market metallic implants and related instrumentation. However over the last several years, these markets have experienced increased demand for innovative, biologically active treatments which seek to stimulate the human body's own capabilities for regeneration of tissue. The growth and development of the osteobiologics market is a good example of this trend. The osteobiologics market currently represents a meaningful proportion of revenue within the orthopedic and sports medicine market segments. According to market research reports published in 2010, the osteobiologics market accounted for $1.5 billion of revenue in the United States alone. This segment is forecasted to grow at a compounded annual rate of 8%, resulting in a projected market size of $2.3 billion by 2015. We believe that our product and product candidates, which utilize our platform regenerative technology, are positioned to improve upon a variety of existing therapies in these markets.

One of the key drivers of the osteobiologics market has been the impressive market performance of the Medtronic, Inc. (''Medtronic'') product INFUSE® Bone Graft (''INFUSE'') for the treatment of certain spinal fusions and bone fractures. Since market introduction of the product in the United States in 2002, cumulative worldwide sales of INFUSE are approximately $5 billion. Performance of this product in the market underscores the demand, receptivity and acceptance of protein-based therapeutic products in orthopedics.

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. We believe that certain of our product candidates, which may be used in such minimally invasive procedures, will be positioned to capitalize on this growth and will enhance the outcomes in such procedures.

Product Candidates

Currently, there are limited biological therapies to stimulate the healing and regeneration of human 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 the fundamental mode of action driving our platform regenerative technology to promote tissue regeneration suggests that it may be effective in a broad array of musculoskeletal applications. Consequently, our platform regenerative technology may ultimately address unmet medical needs in bone fusions and fractures, spinal fusions and fractures, and sports injuries.

We are pursuing product candidates that utilize our platform regenerative technology to compete in certain key market opportunities. Our most advanced product candidates are targeted to be used in the open surgical treatment of bone fusions (using Augment or Augment Injectable), in sports injury applications targeting cartilage, ligament and tendon repair and regeneration (using Augment Rotator Cuff, for example), in open or closed non-surgical or minimally invasive treatment of fractures (using Augment or Augment Injectable) and in spine fusion applications (using Augment).

Ultimately, our goal is to commercialize our product candidates for a broad range of orthopedic tissue grafting indications. Our numerous clinical studies, including the Augment and Augment Injectable studies, as well as our numerous non-clinical programs, suggest that our platform technology may be effective in our target applications. Refer to the ''Product Development Programs'' section below for details regarding our recently completed or ongoing clinical studies.

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

Market	Product Candidate	Target Indication
Orthopedic	Augment Bone Graft	Open (surgical) fracture and fusion treatment.
	Augment Injectable Bone Graft	Open or closed (non-surgical) fracture treatment. Minimally invasive fracture/fusion treatment.
Sports Injury	Augment Rotator Cuff Graft	Rotator cuff tendon to bone repair.
	Augment OCD	Osteochondritis dissecans (cartilage and bone repair).
	Product Name TBD	Injuries due to tendon overuse.
Spine	Augment Bone Graft	Spine fusion

Augment™ Bone Graft

Augment combines rhPDGF-BB with a particulate ß-TCP. Augment is targeted to be used in the open (surgical) treatment of 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. Additionally, Augment may be useful in the future to be used in open fractures. 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. To date, nearly 650 patients have been enrolled in Augment orthopedic clinical trials over the past four years. We have already demonstrated that our technology is safe and effective in stimulating bone regeneration with the Canadian regulatory approval of Augment in 2009. A key priority requiring our management's attention is the approval of Augment in the United States. 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. The FDA's Medical Devices Advisory Committee has tentatively scheduled a May 12, 2011 meeting of the Orthopedic and Rehabilitation Devices Panel (the ''panel'') to review our PMA application for Augment. During the panel meeting, the panel will determine if there is reasonable assurance that Augment is safe and effective for use in hindfoot and ankle fusion surgery, and if the product's benefits outweigh any potential risks. If there is a favorable panel outcome, we anticipate approval of Augment by the FDA within three to six months after the panel meeting.

Augment™ Injectable Bone Graft

Augment Injectable combines rhPDGF-BB with an injectable bone matrix consisting of ß-TCP and collagen, and is targeted to be used in either open (surgical) treatment of fusions and fractures or the closed (non-surgical) or minimally invasive treatment of fractures. Augment Injectable can be injected into a fusion or fracture site during an open surgical procedure, or it can be injected through the skin into a fracture site, in either case locally delivering rhPDGF-BB to promote fusion or fracture repair. Therefore, not only can Augment Injectable potentially address the fusions and corrective surgeries of the foot and ankle and the open surgical treatment of fractures of the long bones noted above, but Augment Injectable may also potentially address the approximately 11 million fractures of the radius, humerus, tibia, fibula and femur that occur annually in the United States and which are addressed with closed, non-surgical treatment. An estimated 5% to 10% of the approximately 11 million fractures treated annually in the United States have impaired or delayed healing due to patient specific factors such as smoking, diabetes and osteoporosis.

Our initial clinical development program for Augment Injectable has focused on open indications. In 2009, we filed an Investigational Device Exemptions (''IDE'') application with the FDA in an effort to initiate a pivotal trial evaluating the safety and effectiveness of Augment Injectable in hindfoot fusion indications. In January 2011, the FDA conditionally approved the initiation of enrollment in our North American pivotal trial, and we expect to initiate patient enrollment in the United States in the first quarter of 2011. The trial is

expected to enroll approximately 200 patients and be fully enrolled around the end of 2011. We expect to file a PMA for Augment Injectable with the final 12 month data from this trial. The trial is a randomized controlled non-inferiority trial comparing Augment Injectable to autograft, with the two treatments randomized 2:1, respectively, and has been approved to enroll patients at 25 institutions. The trial design leverages previous data generated in our Augment pivotal trial, which is currently under FDA review. Although our goal is to ultimately pool the study's patients with the patients that we have enrolled under the Canadian Augment Injectable ITA and with the control patients included in our Augment pivotal study, there can be no assurance that the FDA will permit such pooling.

In 2010, we closed enrollment in a Canadian Augment Injectable pivotal clinical study with a total of 75 patients enrolled. This study is a randomized controlled trial, which compares Augment Injectable to autograft for use in hindfoot and ankle fusion surgery. The study includes five sites in Canada, and treatment was randomized 5:1, Augment to autograft. The primary endpoint of the study is non-inferiority of Augment to autograft at six months after the procedure was performed, based on the percent of patients achieving at least 50% osseous bridging on CT scans. We plan to file the Device License Application (''DLA'') in Canada and release data from the study in the second half of 2011.

We have also completed a pilot clinical study in Sweden enrolling 21 patients to investigate the use of Augment Injectable in patients being treated for fractures of the distal radius (wrist). The product candidate was demonstrated to be safe, with no reported adverse events related to the study device.

Augment™ Rotator Cuff Graft

Our first sports medicine product candidate Augment Rotator Cuff is an inter-positional graft consisting of a collagen matrix hyrdrated with rhPDGF-BB, and is targeted to be used in the repair of large rotator cuff tears. Tendon-to-bone injuries are a frequent source of patient 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.

In December 2010, we announced that we initiated enrollment in a pilot clinical trial in Canada to assess the safety and clinical utility of Augment Rotator Cuff for the repair of large rotator cuff tears. The study's objective is to evaluate the safety and performance of Augment Rotator Cuff for primary surgical treatment of full thickness (≥ 2 cm to < 5 cm) rotator cuff tears. Under the study protocol, the graft is positioned between the humerus and torn rotator cuff tendon(s) during standard surgical suture repair. To date, 18 patients have been treated. The study is expected to enroll up to 30 patients, with 20 patients receiving Augment Rotator Cuff plus standard suture repair and 10 patients receiving standard suture repair alone. Enrollment is expected to be complete in the third quarter of 2011 with an interim data release in the first half of 2012.

Other Product Candidate Opportunities 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 regenerative technology to develop product candidates which address unmet medical needs in sports injury applications by targeting cartilage, ligament and tendon repair and regeneration. Platelet derived growth factor (''PDGF'') has been documented as a potent mitogen for cell types impacted by these injuries (e.g. tenocytes and chondrocytes) and, when delivered appropriately, PDGF can induce rapid increases in vascularity (i.e. angiogenesis), cell proliferation (i.e. mitogenesis) and cell recruitment (i.e. chemotaxis).

Tendon Injuries. Tendons are the tissue structures that connect muscles to bone, and are crucial to the biomechanical functions of the body. Injuries to tendons 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 tendons.

Chronic tendon injuries due to overuse are 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. The application of rhPDGF-BB has been explored in various delivery methods for use in tendon injury in several pre-clinical studies. The current focus is on the direct injection of rhPDGF-BB into tendons to treat tendinosis, or tendon overuse injury.

Cartilage Repair. 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, negatively impacting the underlying bone and 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. The application of rhPDGF-BB into osteochondral defects (defects involving both cartilage and bone) appears promising based on large animal pre-clinical studies.

In August 2010, we announced that we received orphan drug designation from the FDA for rhPDGF-BB to be used in conjunction with autograft and/or commercially available osteochondral allograft for the treatment of osteochondritis dissecans (''OCD'') of the knee, elbow or ankle. In addition to a possible seven years of marketing exclusivity from the date of drug approval, drugs that receive orphan drug designation obtain tax credits for clinical investigation costs, marketing application filing fee waivers and assistance from the FDA in the drug development process. Orphan drug designation does require clinical data to gain market approval authorization through the Investigational New Drug (''IND'') process.

Other Product Candidate Opportunities for Orthopedic and Spine Indications

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 from 2004 to 2008 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.

In February 2011, at the American Academy of Orthopedic Surgeons (''AAOS'') annual meeting we announced results of our pre-clinical study of interbody lumbar spine fusion. The purpose of the spine fusion study was to determine the ability of Augment and Augment Injectable to promote interbody fusion (bony bridging) of the L2/L3 and L4/L5 vertebral bodies in an ovine spinal fusion model with the goal of demonstrating comparable interbody fusion between autograft and our Augment™ line of products and product candidates. Each group received an un-instrumented, double-level, lateral interbody lumbar spinal fusion procedure using a polyether ether ketone (''PEEK'') spacer to deliver the graft materials. The four-arm study included treatment with an empty PEEK spacer, iliac crest autograft, Augment and Augment Injectable. The 44 fusion sites were assessed by microCT and histolologic analyses at 24 weeks.

The Augment treated specimens demonstrated the highest fusion scores of all groups evaluated. Augment significantly promoted interbody spine fusion as compared to empty PEEK spacers and showed equivalency to autograft, the gold standard in lumbar spine fusion procedures. Augment Injectable also demonstrated

equivalency to autograft. In humans, the Augment product candidates used in spine fusion procedures would spare the patient the increased pain and morbidity associated with harvesting autograft.

We believe these data continue to substantiate the promise of our platform regenerative technology to enhance healing. Consistent with previous data, we believe these results demonstrate that, when combined with tissue specific matrices, rhPDGF-BB is equivalent to autograft without the associated complications and has the potential to stimulate healing in a broad array of indications. While still early, we believe, Augment holds significant promise as a new therapeutic option for the treatment of spine fusions.

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 is based on our platform PDGF technology may help stimulate the biological interlock with the prosthesis, which could improve outcomes in these procedures.

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 tissue healing applications of rhPDGF. • Clinical and non-clinical data for Augment and Augment Injectable suggest potential fusion and fracture healing with increased safety.
Multiple applications	• rhPDGF-BB represents a platform technology that may have multiple applications in musculoskeletal repair. • rhPDGF-BB 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 fusion and fracture procedures in the axial (spine) and appendicular (long bone) skeleton as well as the extremities (hand and foot).

Familiar regulatory path for lead product candidates	• 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-BB products. • Commercial manufacturing and production previously established for *GEM 21S*. Good Manufacturing Practices compliance found acceptable and International Organization for Standardization (''ISO'') certification obtained. • Safety profile and bioactivity of rhPDGF-BB clearly established.
Industry trend towards regenerative protein therapeutic-device combination products	• rhPDGF-BB 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.).

The BioMimetic Advantage

We believe we are positioned to improve upon a variety of existing therapies, many of which are discussed in the ''Current Therapies for Bone Disorders and Injuries'' and ''Current Therapies for Cartilage, Tendon and Ligament Injuries'' sections below. Our platform regenerative technology involves the addition of a biologically active growth factor to an injury site that will stimulate tissue regeneration and repair. 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-BB 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-BB, 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-BB, 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-BB, 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 lead product candidates are regenerative protein therapeutic 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-BB.

- *Lower potential for adverse side effects than allograft and less pain and shorter surgical procedure time than autograft.* Because our product candidates do 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, our product candidates do 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-BB have been either cleared or approved by the FDA 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-BB are the primary components of our previously developed products, *GEM 21S* and Augment. For example, *GEM 21S*, which contains both β-TCP and rhPDGF-BB, 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-BB included in our product candidates. We source rhPDGF-BB from Novartis Vaccines and Diagnostics, Inc., a division of the Novartis Group (''Novartis''). Novartis is also the sole supplier of the rhPDGF-BB used in Regranex®. Novartis manufactures rhPDGF-BB 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 platelet rich plasma. Additionally, we have multiple business relationships that cover the different matrices that we combine with rhPDGF-BB 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.

Business Strategy

Our objective is to be a leader in the development and commercialization of novel, biologically active regenerative protein therapeutic 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 products that are superior to current solutions 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 shorten the product development cycle. We intend to repeat this process of using FDA-cleared or approved components in our subsequent product candidates as appropriate.

- *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-BB 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 intend to 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.
- *Capitalize on the broad healing activity of rhPDGF-BB.* *GEM 21S* and all our initial regenerative protein therapeutic-device combination product candidates utilize rhPDGF-BB to enhance the activity of the device component, such as β-TCP. PDGF 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.

Sales, Marketing and Distribution

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 employed 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 anticipate that by the end of the first year of sales in the United States, we will have a sales force of approximately 100 people representing Augment in the market. In February 2011, we hired a Vice President of Global Sales and Marketing to support the development of the sales and marketing teams and lead our global launch of Augment.

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 November 2009, we announced that we received approval from Health Canada to begin marketing our lead orthopedic product, Augment, as an alternative to the use of autograft in foot and ankle fusion indications in Canada. In January 2010, we commercially launched Augment in Canada through an independent exclusive distributor. In November 2010, we announced a change in our distribution strategy in Canada, and began transitioning from a single exclusive distributor to a network of independent sales agents who are managed by us through our internal Canadian National Sales Manager. We entered into a logistical support agreement with Joint Solutions, our former exclusive Canadian distributor, wherein they will warehouse our Augment product and ship the product to Canadian end users, when and as directed by us. We will retain ownership of all

devices stored at Joint Solutions. Our Canadian National Sales Manager is developing a new network of independent sales agencies who will sell Augment throughout Canada. Currently, we have over 30 sales representatives, covering all of Canada. We have supplemented these efforts with three additional Regional Product Specialists based in the United States, providing technical product support to sales representatives, surgeons and hospital administration.

Manufacturing

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

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-BB. 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 agreements with Kensey Nash Corporation (''Kensey Nash'') for development and supply of specific scaffolds for use in orthopedic applications, and with Integra LifeSciences Corporation (''Integra'') for development and supply of collagen matrices for the Sports Medicine product candidates. These agreements provide us with the key constituents of our lead product candidates. Based on a similar supply chain strategy we used successfully for *GEM 21S*, 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-BB component. For the Augment product, 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, warehousing and distribution 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-BB production, ß-TCP cup filling, component and final kit sterilization and international distribution. The building shell was completed in late 2009, and we expect the build out of our warehouse and distribution center will be complete in 2011, and the build out for our manufacturing operations will begin in the next two years. 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 manufacturing facility will be approved for commercial operations within two years of our starting the manufacturing build out. We cannot be certain, however, whether the FDA will approve the manufacturing or warehouse facilities.

Product Development Strategy

Our product candidates use rhPDGF-BB, which is one of the body's principal naturally occurring wound healing stimulators, to kick start the tissue regeneration process. 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 matrix is key to the overall effectiveness of our lead product candidates. For example, the synthetic matrix used in Augment is ß-TCP, which is a synthetic 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 approved 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 resorbable bone void filler and rhPDGF-BB 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 approved and 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 lead 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. We were able to obtain approval of *GEM 21S* in less than five years. Marketing approval of *GEM 21S* in the United States and Canada was 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. 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 product candidates for a broad range of orthopedic indications. We believe that we are well positioned to capitalize on the orthopedic industry's transformation to more advanced bio-active products.

We have established strong clinical contacts, manufacturing facilities and a regulatory pathway to product development, and have begun to establish the necessary internal commercialization infrastructure and to develop a sales and distribution network. These resources, together with the well characterized biology and history of safe use of rhPDGF-BB and the clinically proven efficacy of our platform technology, position us to become a leader in the development and commercialization of biologically-active devices that can capitalize on the growing market for these products in orthopedic, spine and sports injury applications.

We believe that rhPDGF-BB 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-BB were key elements in our selection of this growth factor as the primary biological ingredient in *GEM 21S* and our 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-BB, including bone forming cells, cartilage forming cells, bone and cartilage-lineage forming cells and tendon and ligament forming cells. The observation that naturally occurring PDGF is contained in platelets and released specifically at injury sites

during blood clotting to initiate events critical to healing has led to PDGF being termed nature's ''wound healing protein.'' The rhPDGF-BB used in our product candidates is a synthetic version of PDGF 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-BB to stimulate tissue healing, we believe that our pipeline of product candidates has the potential to positively impact patient care and to influence a new generation of orthopedic and sports injury therapies. We believe our management expertise in the development of regenerative protein therapeutic products, combined with our intellectual property position and the proven biology and safety of rhPDGF-BB, position us to become a leader in the development and commercialization of novel therapeutics for the treatment of orthopedic injuries.

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.

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	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	Canada	Foot and Ankle Fusions	Enrollment Completed
Pivotal	Augment Injectable	United States and Canada	Hindfoot Fusions	Enrollment Pending
Pilot	Augment Rotator Cuff	Canada	Large Rotator Cuff Tears	Initiated Enrollment

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, Augment Injectable 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 involves harvesting bone from another location within the patient's own body, to facilitate fusion in a foot and ankle procedure, and often requires a second surgical 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 FDA approval to commence 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 Phase III 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 was 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.

We have pursued a modular approach for filing our Pre-Marketing Application (''PMA'') for FDA approval of Augment. The first two PMA modules (i.e. the pre-clinical pharmacology / toxicology module and the quality / manufacturing module) were submitted in the second quarter of 2009. In February 2010, we submitted the clinical module to the FDA, which is the third and final PMA module and contains the 24-week clinical data from our Augment pivotal study.

In March 2010, we announced additional data from our Augment pivotal study at the annual AAOS meeting. The lead investigator of the Augment pivotal study, Dr. Christopher DiGiovanni, presented additional data regarding the 24 week results of the study. The data are based on the ''modified intent-to-treat'' (''mITT'') patient population, which is the pre-specified primary study population. The results presented were 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. Previously reported top-line results from our Augment pivotal study, as well as the secondary clinical endpoints not previously reported, included additional radiographic (Plain Film Union for 2 and 3 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 16 additional secondary endpoints, 12 met the test for non-inferiority 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.

In July 2010, we announced the one-year results of our Augment pivotal study. The data was presented by Dr. Timothy Daniels, associate professor of orthopedic surgery at the University of Toronto and St. Michael's Hospital, at the American Orthopaedic Foot and Ankle Society (''AOFAS'') summer meeting. We reported the primary endpoint and secondary endpoint 52-week data set, which demonstrates that out of 16 secondary endpoints measured at the 52-week time point, 15 were statistically significant for non-inferiority. Clinically and radiographically, Augment was comparable to autograft with 52-week clinical healing rates of 87.8% and 88.3%, and therapeutic failure rates of 7.3% and 8.0%, respectively.

In September 2010, we announced that we completed our 100-day PMA meeting with the FDA regarding our Augment PMA. The FDA generally meets with the PMA sponsor approximately 100 days after the filing of the PMA to discuss the status of the application.

In January 2011, the FDA's Medical Devices Advisory Committee tentatively scheduled a May 12, 2011 meeting of the Orthopedic and Rehabilitation Devices Panel (the ''panel'') to review our Augment PMA. Confirmation and details of the meeting will be published in the Federal Register approximately six weeks prior to the scheduled meeting date. Until this panel meeting is announced in the Federal Register, it is considered tentative and could be postponed or cancelled. If the panel determines that there is a reasonable assurance that Augment is safe and effective and that Augment's benefits outweigh any potential risks, we anticipate approval of Augment by the FDA within three to six months after the panel meeting.

(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 up to 60 patients from the original 20 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 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 as an alternative to the use of autograft in foot and ankle fusion indications in Canada.

(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 (''EU Augment Study''). In November 2008, we completed the enrollment with a total of 108 patients at 11 clinical centers in Europe. This study is an open label trial, and will be used to support the safety of Augment. In July 2010, we reported results from the EU Augment Study. This study demonstrated only a seven percent revision rate, which is consistent with the therapeutic failure rate observed in the U.S. pivotal trial for Augment and autograft (7.3% – 8.0%) and the Canadian registration trial (10%). This study also demonstrated a safety profile that is consistent with all other studies of Augment to date. 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. We anticipate that we will file an application for marketing approval of Augment in the EU by the end of the first quarter of 2011.

(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 (ten Augment patients and nine control 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 demonstrate 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 a 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) Canadian Augment Injectable Pivotal Study — Foot and Ankle Fusions. In 2009, we filed an Investigational Testing Authorization (''ITA'') application with Health Canada to initiate a pivotal trial evaluating the safety and effectiveness of Augment Injectable as a substitute for autograft in foot and ankle fusion procedures. Health Canada approved the Augment Injectable ITA, and in October 2009, we initiated patient enrollment in Canada. In June 2010, we closed enrollment with a total of 75 patients enrolled in the study. This study is a randomized controlled trial, which compares Augment to autograft for use in hindfoot and ankle fusion surgery. The study includes five sites in Canada, and treatment was randomized 5:1, Augment to autograft. The primary endpoint of the study is non-inferiority of Augment to autograft at six months after the procedure was performed, based on the percent of patients achieving at least 50% osseous bridging on CT scans. We plan to file the DLA in Canada and release data from the study in the second half of 2011.

(9) North American Augment Injectable Pivotal Study — Hindfoot Fusions.

In 2009, we filed an IDE application with the FDA in an effort to initiate a pivotal trial evaluating the safety and effectiveness of Augment Injectable in hindfoot fusion indications. In January 2011, the FDA conditionally approved the initiation of enrollment in our North American pivotal trial, and we expect to initiate patient enrollment in the United States in the first quarter of 2011. The trial is expected to enroll approximately 200 patients and be fully enrolled around the end of 2011. The PMA filing is expected to be submitted with the final 12 month data, and the product will follow a medical device approval pathway and has been assigned to the FDA's Center for Devices and Radiological Health (''CDRH''). The trial is a randomized controlled non-inferiority trial comparing Augment Injectable to autograft, with the two treatments randomized 2:1, respectively, and has been approved to enroll patients at 25 institutions. The design leverages previous data generated in our Augment pivotal trial, which is under FDA review. Although our goal is to ultimately pool the study's patients with the patients that we have enrolled under the Canadian Augment Injectable ITA and with the control patients included in our Augment pivotal study, there can be no assurance that the FDA will permit such pooling.

The clinical trials we have completed, including those for *GEM 21S*, have provided us with clinical data for three anatomic sites: the foot and ankle, the distal radius, and the jaw. The collective data 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 in 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-BB can stimulate the various structural cell types that make up cartilage, ligaments and tendons, we believe that rhPDGF-BB 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. PDGF 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 PDGF 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-BB is a candidate for development in the sports medicine area where these types of tissues are similarly involved. We have commenced pre-clinical studies to evaluate matrix materials that can be combined with rhPDGF-BB 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-BB 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 presented *in vitro* data supporting rhPDGF-BB's ability to influence tenocytes. 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.

We currently have several pre-clinical studies and a clinical trial for sports medicine indications that have been completed or that are ongoing, which seek to establish the safety, clinical utility and/or effectiveness of Augment Rotator Cuff and our other product candidates in certain of our sports injury target indications discussed above. In particular, the following study is currently in progress:

Augment™ Rotator Cuff Graft

Canadian Augment Rotator Cuff Pilot Trial. In December 2010, we announced that we initiated enrollment in a pilot clinical trial in Canada to assess the safety and clinical utility of Augment Rotator Cuff for the repair of large rotator cuff tears. The study's objective is to evaluate the safety and performance of Augment Rotator Cuff for primary surgical treatment of full thickness (≥ 2 cm to < 5 cm) rotator cuff tears. Augment Rotator Cuff is an inter-positional graft consisting of a collagen matrix hydrated with rhPDGF-BB. The graft is positioned between the humerus and torn rotator cuff tendon(s) during standard surgical suture repair.

The trial is designed as a multi-center, randomized (2:1), controlled study and is expected to enroll up to 30 patients with 20 patients receiving Augment Rotator Cuff plus standard suture repair and 10 patients receiving standard suture repair alone. The primary endpoint of the trial is safety, which will be evaluated by a comparison of adverse events between the two groups. MRIs will also be reviewed to evaluate the safety and durability of the device. To date, 18 patients have been treated in the study. We anticipate completing enrollment in the third quarter of 2011 with an interim data release in the first half of 2012.

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 in the patient's body (i.e. 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 provide physicians flexibility in treating injured or defective bone. Allograft and xenograft bone are of varying quality depending on the donor, the process and techniques used to prepare the bone tissue and the facility at which they are 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 may 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 there may be potential benefits of using autologous platelets to treat orthopedic injuries and defects. PRP systems involve taking blood from a patient, concentrating the platelets from the blood and activating the platelets to release growth factors, including PDGF (albeit in much smaller and unpredictable quantities). While PRP does 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 have exceeded $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. These 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, Olympus 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 the PMA applicant’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 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. Patients own bone material.	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. Limited or no bio-active proteins.
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 cells. Concentrates natural proteins. Does not require painful graft harvesting.	Increased procedure time. Requires specialized equipment. Variable quality. Requires scaffold. Technique dependent. Concentrates inflammatory proteins.
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. Requires refrigeration.

Therapy	Advantages	Disadvantages
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. Low and transient antibody detection, indicating no lasting immune system response. Positive clinical data from pivotal and pilot studies demonstrate safety and non-inferiority to Autograft. Consistent quality and convenient handling.	Higher cost than currently available synthetics. Requires refrigeration. Limited initial indications.

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 cell-based replacement techniques, such as autologous chondrocyte implantation (''ACI'') and matrix autologous chondrocyte implantation or (''MACI'') that attempt to repair small defects to cartilage have shown promise. ACI and MACI require two surgeries over a period of eight weeks and require the cultivation of the patient's own cartilage cells in a laboratory, resulting in a very high treatment cost. Procedures such as viscosupplementation, 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. When these more conservative forms of treatment fail or when a patient is unlikely to succeed with lesser therapies, the last option to treat defective cartilage is to replace all or part of the joint. There are more than 300,000 total knee replacements in the United States each year.

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. PRP systems 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.

Scientific Background

PDGF Family of Growth Factors

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. 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-BB, as part of our platform regenerative technology for certain indications, 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-BB 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. In certain other indications, a direct injection of rhPDGF alone in the absence of a scaffold matrix material may be effective in promoting tissue repair. In tendon repair for example, the single application of rhPDGF-BB injection within the tendon sheath could provide a stimulation of tenocyte activity. Because the tendon structure is contained within the tendon sheath, the anatomical location may provide its own ''tissue matrix.''

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

We have validated our platform regenerative technology, which combines rhPDGF-BB with resorbable scaffold materials, through the successful development of *GEM 21S* for use in periodontal bone and tissue regeneration in the United States and Canada, 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-BB 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-BB 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 demonstrate 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 Pharmaceuticals, Inc. (''Luitpold''). As part of 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.

Pursuant to 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. 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.

The rights to the *GEM 21S* (now known as *GEMESIS*™ in Europe) regulatory approval in the EU will be transferred once approval is obtained, if at all. In November 2010, we executed three agreements that amended agreements that were part of our 2008 transaction with Luitpold: (1) Amendment No. 1 to Amended and Restated Exclusive Sublicense Agreement, (2) Amendment No. 1 to Asset Purchase Agreement, and (3) Amendment No. 1 to Agreement Terminating Research, Development and Marketing Agreement. Under these amendments, we continue to have the right to seek European regulatory approval for *GEMESIS*, and are still entitled to receive a $10.0 million milestone payment from Luitpold upon obtaining such approval and providing Luitpold with the documentation necessary to transfer such approval to them. We, however, were required to obtain a reclassification of *GEMESIS* from a drug product to a medical device prior to March 31, 2011. Such reclassification was obtained on November 12, 2010. We are now permitted to continue to seek European approval of *GEMESIS* for a period of 18 months following the date of the reclassification until May 12, 2012. If we do not obtain European approval by May 12, 2012, we will lose our right to seek European approval of *GEMESIS* and we will not be able to earn the $10.0 million milestone payment. In addition, if we successfully resolve all European regulatory issues necessary for *GEMESIS* product approval by May 12, 2012 except for quality and/or manufacturing issues relating solely to Luitpold's quality and/or manufacturing operations, we will be deemed to have obtained constructive European approval, and will be entitled to receive 90% of the $10.0 million milestone payment. Thereafter, we and Luitpold will work together to obtain the final European approval at which time we would be entitled to receive the remainder of the payment. In order to trigger a milestone payment, any European approval or constructive approval of *GEMESIS* must contain the same dosing as currently approved in the United States and Canada, include approved indications for the use of *GEMESIS* in the treatment of periodontal and gingival defects as a stand-alone product, and permit Luitpold to market *GEMESIS* as currently manufactured by Luitpold at its facility.

Scientific Advisory Boards

We currently have two scientific advisory boards, including an Orthopedic Scientific Advisory Board and a Sports Medicine Scientific Advisory Board. Our scientific advisory boards bring to us expertise and clinical experience in orthopedics and sports medicine, as well as FDA experience. During 2010, there was one meeting of the orthopedic scientific advisory board and one meeting of the sports medicine scientific advisory board. We consult individual members of our scientific advisory boards separately from time to time on clinical and pre-clinical study design, product and product candidate formulation, clinical indications and on applications of tissue engineering, focusing on orthopedic and sports medicine indications.

We pay consulting fees to members of our scientific advisory boards 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 $32,276, $29,944 and $52,664 during the years ended December 31, 2010, 2009 and 2008, respectively. In addition, we granted options to purchase an aggregate of 5,000 shares of our common stock to current members of our scientific advisory boards in each of the years ended December 31, 2009 and 2008. We did not grant any stock options to current members of our scientific advisory boards during the year ended December 31, 2010.

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; Father of Chris Ehrlich (a Director of BioMimetic)
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
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

The current members of our sports medicine scientific advisory board are:

Name	Professional affiliation
Asheesh Bedi, M.D.	Assistant Professor of Sports Medicine and Shoulder Surgery, University of Michigan Medical Center. Fellowship trained orthopedic surgeon specializing in sports medicine and shoulder surgery in Ann Arbor, MI.
Brian Cole, M.D., M.B.A.	Professor Orthopedics, Rush University Medical Center with a conjoint appointment in the Department of Anatomy and Cell Biology at Rush University Medical Center in Chicago, Illinois. He is also the section head of the Cartilage Research Program at Rush University Medical Center and the Cartilage Restoration Center at Rush, a multidisciplinary program specializing in the restoration of articular cartilage and meniscal deficiency.
David Dines, M.D.	Attending Orthopedic Surgeon at HHS in New York, Professor at Weill Cornell Medical College, and Chairman and Professor of Orthopedic Surgery at the Albert Einstein College of Medicine at North Shore-Long Island Jewish Medical Center in New York.
Josh Dines, M.D.	Sports Medicine and Shoulder Service at the Hospital for Special Surgery (HSS) focused on shoulder repair. He is a team doctor for the US Davis Cup tennis team and a consultant for the LA Dodgers. Additionally, he is a team orthopedist for the LI Ducks Minor league baseball team.
Robert Litchfield, M.D., F.R.C.S.C.	Medical Director of the Fowler Kennedy Sport Medicine Clinic in London, Ontario, and an Associate Professor in the Department of Surgery at the University of Western Ontario.
Scott Rodeo, M.D.	Associate Professor of Orthopaedic Surgery at Weill Cornell Medical College and Co-Chief of the Sports Medicine and Shoulder Service at Hospital for Special Surgery (HSS).
William Stanish, M.D., F.R.C.S.C., F.A.C.S.	Director of the Orthopaedic and Sport Medicine Clinic of Nova Scotia and Professor of Surgery at Dalhousie University, within the Division of Orthopaedic Surgery.

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 2010 we paid Noblegene monthly rent of $53,642, 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 3%. 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 that we 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 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. Under the terms of the January 2009 amended lease, in 2010 we paid Noblegene monthly rent of $66,950, as adjusted.

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.

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 those liabilities.

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 and 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 rights and obligations. Under the terms of the amended and restated agreement, Novartis agreed 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 certain minimum purchase commitments for 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 amended and restated 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 pre-specified 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 the first commercial sale of a product developed under the agreement does not occur within seven years of the effective date of the agreement. 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.

In September 2010, we amended the agreement with Kensey Nash to amend a development plan, as well as material and product specifications, pricing and conformance, for our Augment Injectable product candidate and to provide for new payments from us to Kensey Nash for the accomplishment of certain development milestones.

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.

Integra LifeSciences Corporation

In July 2010, we entered into a supply agreement with Integra under which Integra will supply their Collatape product to us for use as a matrix for our Augment Rotator Cuff product candidate. The agreement provides that Integra shall be the exclusive provider of this matrix to us. We are responsible for the clinical development of the product candidate including clinical studies and regulatory approval. The agreements includes a maximum amount of matrix for which Integra is obligated to supply, and does not include a minimum purchase obligation. In the event that we terminate the agreement for cause, or Integra fails to renew the agreement at the end of the initial seven-year term or terminates the agreement during a renewal term without cause, then Integra is required, at our option, to provide to us a pre-specified minimum quantity of its Collatape matrix.

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, 2010, we have paid a total of $4.2 million for certain equipment that has been finished but not yet placed in service. In addition, under these agreements, we have estimated remaining purchase commitments of $0.9 million remaining to be paid through the year 2012.

Certain of our suppliers have 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 and Royalty Payments

Various milestone payments were 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 may be required to make certain milestone payments to us, and we may be required to make certain milestone payments to Kensey Nash based on the occurrence of certain events.

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. In January 2008, we completed the sale of our orofacial therapeutic business to Luitpold, which includes the rights to the downstream forumulation, fill, finish, manufacturing and kitting of *GEM 21S* (now known as *GEMESIS*™ in Europe). Under the sale and asset purchase agreements 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. Also, we are entitled to receive a $10.0 million milestone payment from Luitpold upon European regulatory approval of *GEMESIS*. As described more fully in ''Business — Divestiture of Orofacial Therapeutic Business,'' in November 2010, we executed certain agreements with Luitpold pursuant to which we must obtain EU regulatory approval of *GEMESIS* by May 12, 2012 in order to trigger the $10.0 million payment. Because of uncertainties in the regulatory review process, we have excluded this milestone payment from our financial guidance for 2011.

In addition, 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. Further, 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 may be required to make milestone payments to Kensey Nash in connection with the initiation of certain clinical trials, regulatory filings, product approvals, and/or commercial launch of Augment Injectable. In addition, there are certain time-based milestone payments, triggered by such events, payable to Kensey Nash.

Many of the events triggering a milestone 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* prior to May 12, 2012. Excluding this Luitpold payment, and assuming that all future contingencies are met and all payments are made (not taking into account any expiration of the relevant agreements before such contingencies are met), we anticipate that the milestone payments that we are required to make will result in a net payment by us of approximately $3.3 million in the near term (from 2011 to 2012) and approximately $7.1 million in the long term (from 2013 to 2015).

We have licensed a number of U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. As a part of the licensing agreement relating to such patents, we agreed to pay royalties based on net sales of licensed products under the agreement on a country-by-country basis during the term of the agreement. In accordance with such agreement, we are required to make minimum royalty payments for sales of an orthopedic product as follows: $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. Based upon the 2009 Canadian regulatory approval of Augment, we shipped our first order of Augment to a Canadian distributor in December 2009. Accordingly, we recorded $1.0 million in royalty expense on our consolidated statement of operations for the year ended December 31, 2010.

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 develop; (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/or *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 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 was issued in September 2010, and is also based on technology that we developed internally. This patent covers certain methods of treating impaired bone to facilitate strengthening and healing of the bone by applying compositions of PDGF with a TCP or a TCP/collagen matrix having certain defined particle size and porosity characteristics. This patent will provide protection until at least January 2026. The third 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 and Trademark 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.

Outside of the United States, Augment, Augment Injectable and *GEM 21S* are protected in all major European markets, Canada, Australia, New Zealand, Mexico and South Africa by issued patents that are counterparts to our U.S. patents noted above that were issued in January 2009 and September 2010. Counterparts to these patents are also pending in numerous additional countries around the world including Japan, China, Korea, Brazil and India. Like the U.S. patent, the issued foreign patents will expire in 2025, and we expect that any of the other pending patent applications, if approved, will also expire 2025.

In February 2011, the Canadian Intellectual Property Office issued Canadian patent No. 2,583,823 titled ''Platelet Derived Growth Factor (PDGF) Compositions and Methods of Use Thereof.'' The new patent will remain in force until October 2025, during which time it will prohibit the marketing of similar or generic versions of the Augment orthopedic product line and certain other rhPDGF-BB product formulations. This patent is the first patent issued to us providing protection in Canada and will expand our already strong patent portfolio, which also includes patent protection in the United States, most of the EU, Australia, New Zealand, South Africa and Mexico.

In March 2011, the U.S. Patent and Trademark Office allowed our U.S. patent application No. 12/368,242 titled ''Treatment of Distraction Osteogenesis Using PDGF.'' The allowed claims within this patent application cover methods of stimulating osteogenesis (i.e., formation and development of bone) in a bone distraction procedure, which is a surgical process wherein two bone segments are gradually separated over time so that new bone will form between them. Such procedures are typically used to reconstruct skeletal deformities or lengthen the long bones of the human body. Under the allowed patent claims, certain platelet derived growth factor (''PDGF'') compositions are applied to the distraction site to stimulate bone formation. The PDGF compositions include PDGF combined with certain matrix materials having defined characteristics, and includes Augment, Augment Injectable, *GEM 21S* and potentially other product candidates we have in development. Following the issuance of the new patent, it will remain in force until February 2029, during which time it will prohibit the marketing of similar or generic versions of Augment, Augment Injectable, or *GEM 21S* for use in distraction osteogenesis procedures.

Although the U.S. and various foreign patents were granted, there can be no assurance 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 Canada by a patent licensed from ZymoGenetics, which expires in 2015.

As of December 31, 2010, we owned or co-owned approximately five non-expired U.S. patents, approximately one U.S. patent which non-expired due to a patent term extension, approximately 52 foreign patents, and numerous pending U.S. and foreign patent applications. Furthermore, we have exclusively licensed approximately four non-expired U.S. patents and approximately 32 non-expired 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, as of December 31, 2010, we owned approximately 25 non-expired issued patents in the United States, various European countries, Australia, New Zealand, Mexico 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 or co-own approximately three non-expired U.S. patents, approximately one U.S. patent which is non expired patent due to a patent term extension, and approximately 29 non-expired foreign 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 the non-expired U.S. patents, one of which remains in force only as a result of a patent term extension based on the regulatory review period of *GEM21S*. 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-BB 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 from ZymoGenetics approximately four non-expired U.S. patents and approximately 32 non-expired foreign patents covering various formulations of PDGF or manufacturing process for PDGF.

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, provided us with rights to develop rhPDGF-BB 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 were 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 were 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. Since the last licensed ZymoGenetics' U.S. patent covering our Augment and Augment Injectable product candidates expired in October 2010, the ZymoGenetics license has expired in the United States with respect to these product candidates. Therefore, no royalties or milestones will be due to ZymoGenetics based upon U.S. sales if the FDA ultimately approves these product candidates and we commercialize them in the United States.

Trademarks

Augment™, *OsteoMimetic*™ and our stylized BioMimetic Therapeutics logo are our only trademarks. Augment is a registered trademark in Canada, and its registration in the United States is pending. *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. Academic institutions, government agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize competitive products or technologies on their own or through collaborations with life sciences companies.

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, including Augment and Augment Injectable, will compete with an array of synthetic bone graft materials, ranging from resorbable pure phase ß-TCP granules to calcium sulfate pre-formed pellets. They will also compete with a wide variety of allograft based tissue products including demineralized bone matrix and particulate allograft. 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, Olympus Corporation). INFUSE and OP-1 may also 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 and/or develop 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, Smith & Nephew and Arteriocyte Medical Systems also market platelet rich plasma systems (''PRP'') systems, while Wright Medical's Ignite system and Orthovita's Imbibe are systems designed to concentrate bone marrow aspirate (''BMA''). Since PRP and BMA contain relatively small concentrations of naturally occurring proteins (including growth factors), medical professionals may view these products as alternatives to Augment and our product candidates, even though Augment and our product candidates contain a much higher concentration of growth factor.

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-BB). 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. Augment Rotator Cuff, however, is being reviewed as a drug by CDER with participation by CDRH. As a result the governmental review requirements for Augment Rotator Cuff may vary in some respects as compared to the review of Augment and Augment Injectable. For example, additional and/or different data may be required. The FDA may also determine that certain of our other product candidates should be regulated as drugs with CDER as the lead Center and CDRH as the consulting Center.

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, Augment Injectable, and Augment Rotator Cuff 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 reasonable assurance 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 will convene a panel of clinicians, statisticians and other industry experts to review the application and determine if they believe there is a reasonable assurance that the device is safe and effective, and if the benefits of the device outweigh any risks posed by the device. The FDA is not bound by the advisory panel decision, but historically the FDA has often adopted the panel's determinations. 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. There can be no assurance 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:

- non-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.

Non-clinical tests include laboratory evaluations of the drug's chemistry, toxicity and formulation, as well as animal studies. The results of the non-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 humans 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. There can be no assurance 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 panel, 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 there can be no assurance 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. The European Medicines Agency (''EMA'') previously determined that *GEMESIS* would be reviewed as a medicinal (i.e., a drug) product, and not as a medical device product, which is how the product was reviewed in the United States and Canada. In November 2010, however, our EU notified Body, BSi Group (''BSi''), confirmed their acceptance of the classification of *GEMESIS*, Augment and Augment Injectable as Class III medical devices under the European Medical Device Directives. BSi's classification determination was based in part on recent changes to the European Medical Device Directives that were made after EMA's previous determination. We will now be submitting to BSi applications for CE Marks for *GEMESIS*, Augment, and Augment Injectable. A CE Mark is the approval by a European regulatory body, and the presence of a CE Mark is required before a medical device can be marketed in any country in the EU. We expect that the applications for *GEMESIS* and Augment will be submitted by the end of the first quarter of 2011.

We formed a wholly-owned subsidiary in the United Kingdom, BioMimetic Therapeutics Limited, in October 2005 to facilitate our EU regulatory filings. There can be no assurance 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 procedural code, covering inpatient facility surgical procedures, a Current Procedural Terminology (''CPT'') code, which covers facility and medical professional outpatient, ambulatory surgical center, and office-based procedures, and/or a Health Care Common Procedure Coding System (''HCPCS'') Level II code to identify products, supplies, and services not included in the CPT codes. These codes are used in the submission of claims to insurers for reimbursement for medical services. While there are currently no specific ICD-9, CPT, or HCPCS codes for our product candidates, the target procedures such as ankle fusions 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 educating third party payers on the reasonableness and necessity of providing patients access to treatment by covering the use of our products, when reported under the existing procedural 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 complications and/or morbidity related to the harvesting of the autologous bone graft. For certain other indications for our product candidates in the pipeline, pursuing new provider billing codes for reimbursement may be an appropriate business strategy to pursue independently or collaboratively with the appropriate specialty medical societies. We will seek to pursue these opportunities 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 under a capitation system, which puts the providers at financial risk for the services provided to their patients by paying these providers a pre-determined payment per member per month for the provision of a continuum of services, and consequently, may limit the willingness of these providers to use our products. Typically the providers that are paid under capitation systems are primary care physicians (e.g. family medicine, internal medicine, pediatrics, OB/GYN), and it is less common for specialist physicians (who we believe will be the primary customers for our products) to be compensated under such programs.

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, and to demonstrate the clinical and economic effectiveness of surgical, medical, and therapeutic interventions. 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 profitably. 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

The consolidated financial statements presented in this Annual Report on Form 10-K for the year ended December 31, 2010 reflect the operations of our Company and our wholly-owned subsidiaries, BioMimetic Therapeutics Limited in the United Kingdom, BioMimetic Therapeutics Pty Ltd. in Australia, and BioMimetic Therapeutics Canada, Inc. Inter-company balances and transactions are eliminated in consolidation. As of December 31, 2010, the subsidiaries in the United Kingdom and Australia have no employees and have no operating activities other than making and maintaining regulatory submissions for our product candidates in the European Union (''EU'') and Australia. Also as of December 31, 2010, the subsidiary in Canada had one employee and had incurred certain operational expenses.

Employees

As of December 31, 2010, we employed 95 people, of which 40 were employed in research and development, 22 in regulatory and quality assurance, seven in operations and 26 in general and administrative. Our Chief Executive Officer 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 SEC.

Additionally, from time to time, we provide notifications of material news including press releases and conferences on our website. Webcasts of presentations made by our company at certain conferences may also be available from time to time on our website to the extent the webcasts are available. The content of our website is not intended to be incorporated by reference into this report or in any other report or document we file and any references to our website are intended to be inactive textual references only.

Our website also includes printable versions of our Code of Business Conduct and Ethics and the charters for each of the Audit, Compensation and Nominating and Governance Committees of our Board of Directors. Each of these documents is also available in print to any shareholder who requests a copy by addressing a request to: BioMimetic Therapeutics, Inc.

389 Nichol Mill Lane
Franklin, Tennessee 37067
Attn: General Counsel

Effective January 3, 2011, our Company's securities are listed in the NASDAQ Global Select Market. The NASDAQ Global Select Market is a market classification within the NASDAQ Stock Market® for companies that satisfy the highest initial financial and liquidity qualifications.

Item 1A. RISK FACTORS

Risks Relating to Our Business

Current economic uncertainty could adversely affect our operations.

Our business, financial condition and operating results may in the future be adversely affected by the economic conditions in the countries in which we operate or seek to operate. 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. Accordingly, the impact of the economy on commercial opportunities, such as our anticipated product launch in the United States for Augment, remains uncertain. In addition, 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, more dilutive, or completely unavailable to us. We believe our existing cash and investments, which include approximately $45.0 million in net proceeds from our public stock offering in 2010, will be sufficient to meet our anticipated cash requirements at least through the second half of 2012. However, a second economic downturn or an increase in our anticipated 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 or commercialization 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, 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, Health Canada or any other foreign regulatory authority finds some or all of our product candidates ineffective or unsafe or that benefits of a product candidate do not outweigh risks associated with it;
- we do not receive necessary regulatory approvals in the United States, Canada, or elsewhere;
- we are unable to get some or all of our product candidates to market in the United States, Canada or elsewhere 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;
- the patient and physician community does not accept our product or product candidates; and
- we are unable to establish effective sales, marketing and distribution capabilities to facilitate the commercialization of our product candidates once they receive regulatory approval.

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, including changes in FDA decisions, Health Canada or other foreign regulatory authority, policies or procedures that make prior applicable FDA precedents less reliable as future predictors;
- failure to satisfy one or more requirements or restrictions imposed by the FDA, Health Canada or other foreign regulatory authority 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 or the anticipated approval and subsequent commercialization of Augment in the United States 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 found 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, which may have a material adverse effect on our business, financial condition and results of operations.

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 its product or product candidate reveal safety or fundamental efficacy issues, then the development of our product candidates may be impacted as well, which may have a material adverse effect on our business, financial condition and results of operations. 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 development and licensing agreements. These agreements provide us with rights to certain intellectual property created by the other party, 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 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 agreements could be terminated by the other party, 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.

Disputes may arise regarding the scope of our rights under any of these agreements. Additionally, the other parties under these agreements might breach the terms of their respective agreements or fail to prevent infringement of a licensed patent by third parties. Loss of any of these agreements for any reason could materially and adversely affect our business, 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-BB 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-BB. Our agreement with Novartis may be terminated under certain circumstances.

We have established certain relationships with ß-TCP suppliers and obtain matrix materials from Kensey Nash and Integra. We are also continuing to evaluate ß-TCP products and other matrices from other potential suppliers for use in orthopedic and sports medicine applications. There is a risk that we will not be able to secure adequate sources of rhPDGF-BB, ß-TCP, or other matrix materials to meet our clinical and commercial needs for our products and product candidates.

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 other product candidates that we are developing 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, if at all, and the production of our product and product candidates would be interrupted or cancelled, resulting in lost revenue and delays in or terminations of 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 various 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-BB. If we are not able to obtain rhPDGF-BB from Novartis, we may not be able to meet our supply obligations to Luitpold for rhPDGF-BB after our current inventory is depleted. Based on our current forecasts for our rhPDGF-BB needs, our planned clinical study programs for our product candidates and our anticipated pre-clinical studies, and sales forecasts of Augment, the rhPDGF-BB in our inventory, in addition to our minimum purchase commitments of rhPDGF-BB in 2011, should meet our needs for approximately the next 12 to 18 months. Under the terms of our supply agreement, Novartis is required to support our efforts to establish our continued production of rhPDGF-BB 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-BB, 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 warehouse and distribution facility in the same complex as our headquarters in Franklin, Tennessee. We also 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 of the warehouse and distribution facility will begin in 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 manufacturing facility will be approved for commercial operations within two years of our starting the manufacturing build out. There can be no assurance, however, that 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). We are using at least three contract facilities to complete the manufacturing, packaging and final product testing for our Augment Injectable clinical study kits. We are using at least three contract facilities to complete the manufacturing, packaging and final product testing for our Augment Rotator Cuff 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 targets in the United States

if the FDA approves Augment) or produce sufficient quantities 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 for any one or more approved products, 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 will be materially and 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.

Although we are in the process of planning for a future sales network to represent Augment if approved in the United States, we currently 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 logistical support agreement with Joint Solutions, our Australian distribution agreement with Surgical Specialties, or other marketing, sales or distribution 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 materially and adversely affected.

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 working through a recently hired Canadian national sales manager, in addition to a logistical support agreement with a Canadian distributor, to progress Augment through the appropriate committees at the key accounts that we believe present the best opportunities for the product. There can be no assurance that any Canadian product evaluation committee 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 materially and adversely affected.

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

As a small company with 95 employees as of December 31, 2010, 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, such 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 $20.0 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 to maintain and enforce patent protection for the therapeutic uses of rhPDGF-BB. 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 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 two unexpired U.S. patents covering certain unique aspects of our product and product candidates. Other patents that covered our product and product candidates have expired. We do not believe, however, that such patent expirations have significantly affected our intellectual property position.

If any patent or other right which we own 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 to enforce our rights to use our 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.

We 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 and 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, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in these patent applications.

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 own and/or 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 claim 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, in-licensing opportunities 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 our business, financial condition and results of operations 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.

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.

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 suppliers are infringing their patents or are misappropriating their proprietary information. If there is a successful claim against us or our 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 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, which would have a material adverse effect on our business, financial condition and results of operations.

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 our business, financial condition and results of operations, 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, Health Canada's or other foreign regulatory authorities' approving or clearing, or the refusal of any regulatory authority to approve or clear, any 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 in the United States. 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. 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. For the current orthopedic indications, Augment and Augment Injectable are 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 and Augment Injectable require an approved PMA before they can be marketed in the United States.

We previously submitted a three-part modular PMA seeking approval of Augment which, after we complied with a request from the FDA for additional information, was accepted by the FDA for review and filed. There can be no assurance, however, that the review of our PMA by the FDA will not be delayed further, or that the additional data we submitted to the FDA will be sufficient for it to approve our PMA, or that the FDA will not require more data or place additional requirements on us before it will approve our PMA. If the FDA's review of our Augment PMA is delayed, or if the FDA ultimately denies our Augment PMA, it would have a material adverse effect on our business, financial condition and results of operations.

We previously filed an IDE application with the FDA seeking approval to initiate a pivotal trial evaluating the safety and effectiveness of Augment Injectable as a substitute for autograft in hindfoot fusion procedures (''Augment Injectable IDE''). In January 2011, the FDA conditionally approved the initiation of enrollment in our North American pivotal trial, and we expect to initiate patient enrollment in the United States in the first quarter of 2011. We may not be able to address the conditions the FDA has placed on the Augment Injectable IDE approval, or we may be required to revise this trial in a way that limits our ability to pool data from the trial with the ongoing Canadian Augment Injectable trial or our previous Augment pivotal study. If we are unable to address the FDA's conditions, we may be unable to complete the trial in a timely manner or the FDA may not accept the study as sufficient support for marketing approval, which would have a material adverse effect on our business, financial condition and results of operations.

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. For example, certain of our other product candidates may be reviewed by the FDA as drug products, which would require an approved new drug application (''NDA'') before they can be marketed. In response to a request for designation (''RFD'') we filed with the FDA for a product candidate designed to treat rotator cuff injuries, the FDA concluded that the rotator cuff product candidate should be reviewed as a drug, and not as a device. Although we continue to seek reclassification of our rotator cuff product candidate, there can be no assurance that the FDA will classify the product as anything other than a drug.

The process of obtaining FDA approval of a PMA or NDA is lengthy, expensive, and uncertain, and there can be no assurance 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 timely, or at all, our business and financial condition may be adversely affected.

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 there can be no assurance that the FDA will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. As part of our Augment PMA review and approval process, we anticipate that the FDA will conduct a pre-market inspection of our headquarters and of our suppliers and subcontractors prior to approval of our PMA. If the FDA identifies compliance issues during these inspections, then approval of our PMA could be significantly delayed or even denied. We may be required to make modifications to our manufacturing operations in response to these inspections which may require significant resources and may have material adverse effect upon our business, financial condition and results of operations.

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, financial condition and results of operations.

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 and drugs. 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, which would have a material adverse effect on our business, financial condition and results of operations.

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 seeking approval to initiate a 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, which would have a material adverse effect on our business, financial condition and results of operations.

The European Medicines Agency (''EMA'') previously determined that *GEMESIS* would be reviewed as a medicinal (i.e., a drug) product, and not as a medical device product, which is how the product was reviewed in the United States and Canada. In November 2010, however, our EU notified Body, BSi Group (''BSi''), confirmed their acceptance of the classification of *GEMESIS*, Augment and Augment Injectable as Class III medical devices under the European Medical Device Directives. BSi's classification determination was based in part on recent changes to the European Medical Device Directives that were made after EMA's previous determination. We will submit to BSi applications for CE Marks for *GEMESIS*, Augment, and Augment Injectable. A CE Mark is the approval by a European regulatory body, and the presence of a CE Mark is required before a medical device can be marketed in any country in the EU. We expect that the applications for *GEMESIS* and Augment will be submitted by the end of the first quarter 2011. There can be no assurance that the EMA will agree with BSi's classification of these products. If the EMA continues to take the position that *GEMESIS* should be reviewed as a medicinal combination product and/or determines that Augment and/or Augment Injectable should also be reviewed as medicinal combination products, we may face delays due to further discussions on classifications and/or the need to convert the submissions into drug applications (MAA's), and our right to continue to seek EU approval of *GEMESIS* could be terminated together with our right to receive a $10.0 million milestone payment from Luitpold upon approval of *GEMESIS*. Even if the EMA does not challenge BSi's classification of *GEMESIS*, if we are unable to gain EU regulatory approval for *GEMESIS* by May 12, 2012, we will be unable to earn the $10.0 million milestone payment from Luitpold. In addition, our other product candidates may encounter similar classification 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, which may have a material adverse effect on our business, financial condition and results of operations.

The FDA or its Advisory Committee may determine that the results of our clinical trials are insufficient for 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 discuss with and obtain guidance from regulatory authorities on certain of our clinical development activities. These discussions are not binding obligations on the part of regulatory authorities. Under certain circumstances, regulatory authorities may revise or retract previous guidance during the course of our clinical activities or after the completion of our clinical trials. The FDA may also disqualify a clinical trial in whole or in part from consideration in support of approval of a potential product for commercial sale or otherwise deny approval of that product. Even if we obtain successful clinical safety and efficacy data, we may be required to conduct additional, expensive trials to obtain regulatory approval. Prior to regulatory approval, the FDA may elect to obtain advice from outside experts regarding scientific issues and/or marketing applications under FDA review. These outside experts are convened by an FDA Advisory Committee to form an advisory panel. The advisory panel will report to the FDA and may make recommendations or make certain determinations regarding the reasonable assurance of a product's safety and effectiveness or the benefit/risk profile of a product. The views of the advisory panel may differ from those of the FDA. Augment is tentatively scheduled to be reviewed by the FDA's Orthopedic and Rehabilitation Devices Panel (the ''panel'') on May 12, 2011, and we expect the vote of the panel to the FDA on Augment to be an important element in the FDA's review of our PMA for Augment. If the panel determines that Augment is not safe or effective, or determines that benefits of Augment do not outweigh risks associated with Augment or makes any other negative determinations with respect to Augment, the FDA may chose not to approve our PMA for Augment. Even if the panel votes in favor of Augment, the FDA may still deny our PMA and either elect not to adopt the panel's determinations, or identify an issue not addressed by the panel as a basis for its denial.

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 for medical devices and drug products. 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.

The adoption of healthcare reform in the United States may have a material adverse effect on our business, financial condition and results of operation.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively known as the ''PPACA'') became federal law in the United States. This law represents comprehensive health care reform. The PPACA includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. Specifically, the law imposes a 2.3% excise tax on U.S. sales of medical devices beginning in 2013. The PPACA also includes numerous provisions that limit Medicare spending through reductions in various fee schedule payments and by instituting more sweeping payment reforms, such as bundled payments for episodes of care and the establishment of ''accountable care organizations'' under which hospitals and physicians will be able to share savings that result from cost control efforts. Many of these provisions will be implemented through the regulatory process, and policy details have not yet been finalized. Various healthcare reform proposals have also emerged at the state level. We cannot

predict the impact that these federal and state healthcare reforms will have on us. However, if any one or more of our products are approved for sale in the United States, the PPACA and other reforms may lower reimbursements for the approved product, reduce medical procedure volumes relating to the approved product, impact demand for the product or the prices at which we may sell the product, and increase our cost of doing business. The impact of the PPACA and other reforms may have a material adverse effect on our business, financial condition and results of operations.

Reforms in the healthcare industry and the uncertainty associated with pharmaceutical and medical device pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products, if approved.

Increasing expenditures for healthcare have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. In addition to the PPACA, numerous proposals that would result in changes to the U.S. healthcare system have been introduced or proposed in the U.S. Congress and in certain state legislatures within the United States, including reductions in the pricing of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. For example, in 2003, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 became federal law in the United States. Although we cannot predict the full effect of the implementation of this legislation on our business, the new Medicare prescription drug benefit, which will be managed by private health insurers and other managed care organizations, may result in additional government reimbursement for prescription drugs, which may make some prescription drugs more affordable but may further exacerbate industry-wide pressure to reduce prescription drug prices. We believe that legislation that reduces reimbursement for our product candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our products, if approved. This may materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional licensees and market our products, if approved. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of medical devices and pharmaceutical products, which may adversely impact product sales, upon approval, if at all.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term ‘‘remuneration’’ is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. §1320a-7b, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or

service that was not provided as claimed or is false or fraudulent. The federal Anti-Kickback Statute is broad, and despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The ''qui tam'' provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of $5,500 to $11,000 for each separate false claim.

In addition, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations. If we are found to have violated any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring or our operations, all of which could have a material adverse effect on our business and the results of operations.

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.

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, which would have a material adverse effect on our business, financial condition and results of operations.

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.

We received orphan drug designation for rhPDGF-BB treatment of osteochondritis dissecans, but there can be no assurance that the product will be able to obtain orphan drug market exclusivity.

The FDA has granted orphan drug designation for rhPDGF-BB to be used in conjunction with autograft and/or commercially available osteochondral allograft for the treatment of osteochondritis dissecans (‘‘OCD’’) of the knee, elbow or ankle. Orphan drug status may be designated for a drug that has the potential to treat a

‘‘rare disease or condition,’’ which generally is a disease or condition that affects fewer than 200,000 individuals within the United States. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA may not approve any other application to market the same drug for the same indication, except in very limited circumstances, for a period of seven years. There can be no assurance that a product candidate that receives orphan drug designation will receive orphan drug marketing exclusivity. More than one drug can have orphan designation for the same indication. If the FDA grants orphan designation to more than one drug candidate for the same orphan indication, and if one of those other drugs is approved before our product candidate is approved for that indication, we would not receive orphan exclusivity and would be blocked for seven years from having our product candidate approved for that indication. In addition, neither orphan drug designation nor orphan drug exclusivity prevents competitors from developing or marketing different drugs for that indication. We may seek to develop additional products that incorporate drugs that have received orphan drug designations for specific indications. In each case, there can be no assurance that our product candidate will be the first to be approved by the FDA for a given indication or be granted orphan drug exclusivity. In each case, if our product candidate is not the first to be approved for a given indication, and another drug receives orphan drug exclusivity, we may be unable to access the target market in the United States, which would have a material adverse effect on our company, our results of operations and our financial condition.

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, 2010, we had an accumulated deficit of $127.5 million. We have ongoing pivotal clinical studies for the use of Augment and Augment Injectable for the treatment of foot and ankle fusions, in addition to a pilot clinical trial to assess the safety and clinical utility of Augment Rotator Cuff for the repair of large rotator cuff tears.

In January 2008, we sold to Luitpold our remaining orofacial therapeutic business, and granted Luitpold 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 in the United States.

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, 2010, we had federal net operating loss carryforwards totaling $96.5 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 business, financial condition and results of operations.

We may 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 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, 2010 balance of our cash and investments will be sufficient to meet our anticipated cash requirements at least through the second half of 2012.

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.

In 2009, we filed a shelf registration statement on Form S-3 with the SEC registering the offer and sale of up to $150.0 million of certain securities which has been declared effective. In 2010, under the shelf registration statement, we raised net proceeds of approximately $45.0 million in a public offering of common stock. 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 additional shares of common stock, preferred stock, debt securities or warrants to purchase our common stock or any combination of such securities in an amount equal to slightly more than $100.0 million. There can be no assurance 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 product or product candidates, if approved;
- unanticipated expenditures in the acquisition and defense of intellectual property rights;
- the failure to develop strategic alliances for the marketing of our product or product candidates, if approved;
- additional inventory builds to adequately support the launch of new products;
- unforeseen changes in healthcare reimbursement for procedures using our product or product candidates, if approved;
- inability to train a sufficient number of surgeons to create demand for our product or product candidates, if approved;
- 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 product or product candidates, if approved;
- 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 are impacted by the current economic uncertainty.

In addition, 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, and could distract management's attention from our current product development programs or the commercialization of Augment, or could require us to divert operational resources.

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, Augment Injectable, Augment Rotator Cuff 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 uncertainty as a whole.

If our future quarterly or annual operating results are below the expectations of securities analysts or investors, then 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, our June 2009 rights offering, and our July 2010 public 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 the 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. Shares held by our affiliates may also be tradable under Rule 144, subject to the volume restrictions

of that rule. Furthermore, as of December 31, 2010, 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 May 2006 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, 2010, there were options issued and outstanding to purchase 2,615,688 shares of our common stock with a weighted average exercise price of $10.59. Also at December 31, 2010, there were 2,137,777 options available for future 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, 2010, our executive officers, directors and their affiliates beneficially owned shares representing approximately 31.4% of our capital stock. This total includes 1,830,253 shares (6.6% 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 4,720,065 shares (16.9% 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 intend to utilize the new space as a good manufacturing practices (''GMP'') manufacturing facility and expect to move certain of our manufacturing, warehousing and distribution 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-BB production, ß-TCP cup filling, component and final kit sterilization and international distribution. The building shell was completed in late 2009, and we expect the build out of our warehouse and distribution center will be complete in 2011, and the build out for our manufacturing operations will begin in the next two years. 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 manufacturing facility will be approved for commercial operations within two years of our starting the manufacturing build out. We cannot be certain, however, whether the FDA will approve the manufacturing or warehouse facilities.

Item 3. LEGAL PROCEEDINGS

None.

Item 4. (REMOVED AND RESERVED)

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
2010		
First Quarter	$13.99	$11.14
Second Quarter	$14.20	$10.93
Third Quarter	$11.99	$ 7.96
Fourth Quarter	$13.00	$10.01

	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

Stockholders

As of March 4, 2011, there were 29 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, our 2005 Employee Stock Purchase Plan and our 401(k) Profit Sharing Plan & Trust at December 31, 2010. We have no equity compensation plans that were not approved by our security holders.

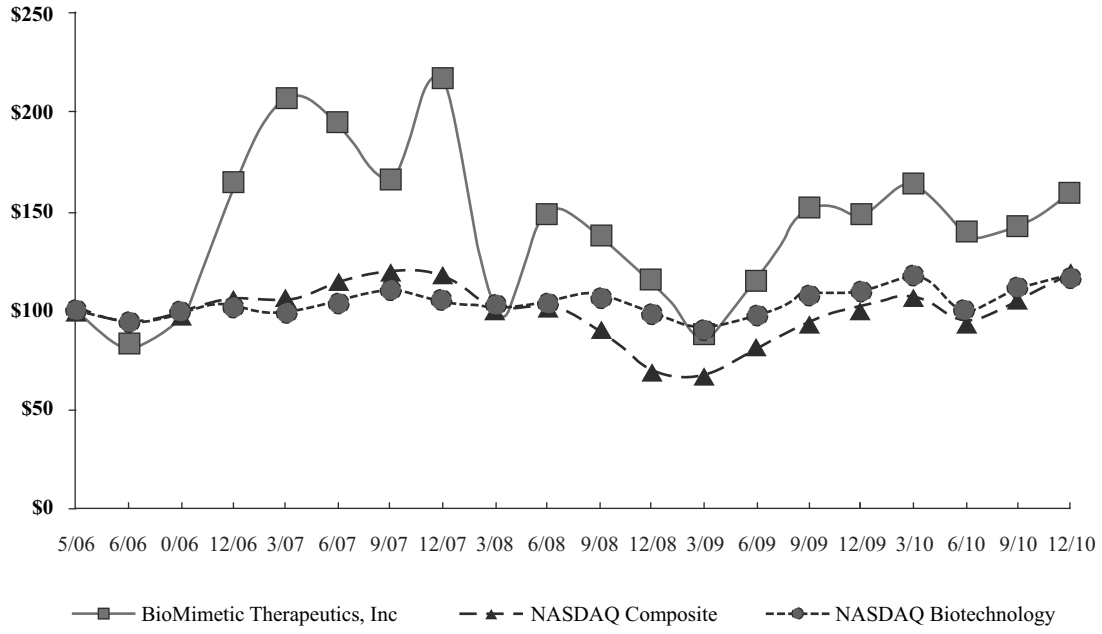
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
2001 Long-Term Stock Incentive Plan	2,615,688	$10.59	2,137,777
2005 Employee Stock Purchase Plan	N/A	N/A	111,243
Employee 401(k) Plan Company Match	N/A	N/A	41,344
Total	2,615,688	—	2,290,364

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 55 MONTH CUMULATIVE TOTAL RETURN*
Among BioMimetic Therapeutics, 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, 2010 and 2009 and the selected consolidated statements of operations data for each of the three years in the period ended December 31, 2010 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, 2008, 2007 and 2006 and the selected consolidated statements of operations data for the each of the two years ended December 31, 2007 have been derived from our audited consolidated financial statements which are not included in this Annual Report.

	Years Ended December 31,				
	2010	2009	2008	2007	2006[2]
	(In thousands, except share and per share information)				
Revenues[1]:					
Product sales	$ 15	$ 78	$ —	$ 5,040	$ 2,592
Royalty income	487	522	2,144	1,213	569
Sublicense fee income	971	971	974	741	710
Collaborative research and development	—	—	—	—	224
Other revenue	—	—	30	36	39
Total revenues	1,473	1,571	3,148	7,030	4,134
Costs and expenses[1]:					
Cost of sales	17	6	—	3,939	2,212
Research and development	17,967	21,095	24,561	19,218	11,676
General and administrative	15,161	11,511	11,253	8,829	6,516
Depreciation and capital lease amortization	1,234	1,333	1,423	1,130	842
Patent license fee amortization	1,658	2,569	2,663	2,234	2,116
Total costs and expenses	36,037	36,514	39,900	35,350	23,362
Loss from operations	(34,564)	(34,943)	(36,752)	(28,320)	(19,228)
Interest (expense) income, net	(3)	(308)	247	1,710	2,165
Investment income (loss), net	144	6,864	(10,797)	1,952	—
Other income from governmental grants	514	—	—	—	—
(Loss) gain on disposal of equipment and other	(28)	11	5	2	(1)
Gain on arbitration settlement	—	7,219	—	—	—
Gain on disposal of orofacial therapeutic business	—	—	39,292	—	—
Income tax benefit	—	—	—	74	—
Preferred stock accretion	—	—	—	—	(132)
Net loss	$ (33,937)	$ (21,157)	$ (8,005)	$ (24,582)	$ (17,196)
Basic and diluted net loss per share	$ (1.38)	$ (1.03)	$ (0.43)	$ (1.37)	$ (1.62)
Weighted average shares used to compute basic and diluted net loss per share	24,626,170	20,510,132	18,529,068	17,951,147	10,589,969
Cash dividends declared	$ —	$ —	$ —	$ —	$ —

	As of December 31,				
	2010	2009	2008	2007	2006[2]
			(In thousands)		
Balance Sheet Information:					
Cash and cash equivalents	$ 11,628	$ 21,543	$ 17,535	$ 25,483	$ 47,065
Investments – short term	65,751	47,002	33,218	—	—
Investments – long term	15,002	6,514	46,624	41,800	—
Total assets	105,555	88,912	125,120	89,618	65,395
Long-term capital lease obligations	216	175	35	53	49
Note payable	—	—	39,100	—	—
Total liabilities	22,433	21,861	66,066	27,166	20,394
Redeemable, convertible preferred stock	—	—	—	—	—
Accumulated deficit	(127,457)	(93,520)	(72,363)	(64,358)	(39,776)
Total stockholders' equity	83,122	67,052	59,054	62,452	45,001

(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.

Additionally, in January 2008, we sold our orofacial therapeutic business (*GEM 21S*) to Luitpold, recording a $39.3 million net gain on the transaction in 2008. 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, 2009 nor 2010.

(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 specializing in the development and commercialization of innovative products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, sports medicine and spine applications. Our product and product candidates use rhPDGF-BB, one of the principal wound healing and tissue repair stimulators in the body, in combination with tissue specific matrices when appropriate, as our primary technology platform for promoting tissue healing and regeneration. The matrices are synthetic or natural scaffold materials, such as ß-TCP, which have a history of demonstrated safety and efficacy in previous uses. This platform regenerative technology may offer physicians advanced biological solutions to actively stimulate the body's natural tissue regenerative process. We believe that our product candidates, if approved by the appropriate regulatory authorities, may offer new, effective and less invasive treatment options to improve the quality of life for millions of patients suffering injuries or deterioration of bones, ligaments, tendons and cartilage. Through the commercialization of this technology, we seek to become the leading company in the field of orthopedic regenerative medicine.

We have already demonstrated that our technology is safe and effective in stimulating bone regeneration with the U.S. and Canadian regulatory approvals of *GEM 21S*, our first periodontal product, and with the Canadian regulatory approval of Augment, our first orthopedic product. We are currently developing a number of other product candidates, including Augment Injectable, an orthopedic product candidate, and Augment Rotator Cuff, a sports medicine product candidate.

A key priority is obtaining FDA marketing approval of Augment in the United States. We received regulatory approval from Health Canada to market Augment in Canada in late 2009. To date, our product sales revenues have been limited. However, now that the FDA panel meeting has been tentatively scheduled for May 12, 2011 to review our PMA application for Augment, we believe that we are nearing regulatory approval of Augment in the United States. We anticipate approval of Augment by the FDA within three to six months after the panel meeting if the panel determines that there is a reasonable assurance that Augment is safe and effective and that Augment's benefits outweigh any potential risks. Therefore, we anticipate product sales revenues to commence from sales of Augment in the United States when, and if, approved. In addition, we have been incurring expenses in connection with our preparation for an anticipated U.S. commercial launch of Augment, and we expect those expenses to increase over the next few quarters as we plan to increase our staffing, particularly in the area of sales and marketing, and accelerate certain activities relating to the build-out of our warehouse, distribution and manufacturing facility.

We also remain focused on the commercial adoption of Augment in Canada, which was approved by Health Canada in the fourth quarter of 2009. We have now completed our transition from a single exclusive distributor to a network of independent sales agents who are more closely managed by us through our Canadian National Sales Manager. We now have over 30 independent sales representatives representing Augment throughout Canada. We have supplemented these efforts with three additional Regional Product Specialists based in the United States, providing technical product support to sales representatives, surgeons and hospital administration. Although we now expect to see an increase in sales as a result of our restructured distribution, the Canadian market for Augment is limited and we do not anticipate significant revenues from sales of Augment in Canada.

We expect that our efforts to develop our other product candidates, which include numerous ongoing clinical and non-clinical studies, will also start to increase our costs over the next few quarters as a result of continuing costs associated with the ongoing Augment Injectable clinical trial in Canada, the initiation of a rotator cuff pilot clinical study in Canada, which occurred in the fourth quarter of 2010, and the initiation of patient enrollment in a North American pivotal trial for Augment Injectable, which is expected to occur in the first quarter of 2011.

Various milestone payments were required under our agreements with Luitpold, Kensey Nash, and Novartis, as well as our intellectual property license agreements with ZymoGenetics and Harvard. Luitpold may be required to make certain milestone payments to us, and we may be required to make certain milestone

payments to Kensey Nash based on the occurrence of certain events. These milestone payments relate to the achievement of certain clinical developments, regulatory filings, approvals and sales levels for Augment Injectable.

Since our inception in 1999, we have incurred losses from operations each year. As of December 31, 2010, our accumulated deficit was $127.5 million. Our limited revenues, which at $1.5 million for the year ended December 31, 2010 consist of product sales, royalty income and sublicense fee income. 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 several years as we continue to fund our research and development activities, clinical trials, and regulatory and commercialization efforts.

In view of our limited revenue at this time, we continue to closely monitor our cash and investments balance and manage expenses. The continuing volatile business and economic environment, including the ensuing market instability and uncertainty, as well as uncertainty surrounding the potential FDA approval of Augment, may continue to impact our general business strategy and may adversely affect our business, financial condition and results of operation. For example, the economy may impact the demand for elective medical procedures that we are targeting with certain of our product candidates, or may impact the pricing that we may set for our products, if approved. Accordingly, the impact of the economy on commercial opportunities, such as our anticipated commercial launch of Augment in the United States, remains uncertain. We have responded to the current economic uncertainty by raising capital through the sale of common stock, by investing our cash and investments conservatively, and by employing cost control measures to conserve cash and manage expenses, such as limiting growth in staff, controlling expenditures and postponing certain product development activities where appropriate.

Financial Operations Overview

From our inception in 1999 through December 31, 2010, we have funded our operations with proceeds from the sale of capital stock, from the licensing and sale of our orofacial therapeutic business, and from research and development agreements, grants, product sales and royalties. The remaining proceeds of these activities are reflected in the balance of cash and investments totaling $92.4 million as of December 31, 2010, which includes $11.6 million in cash and cash equivalents and $80.8 million in short-term and long-term investments in U.S. government sponsored enterprise (“GSE”) securities and corporate bonds that are classified as available-for-sale.

Revenues

Our recent revenues have been limited and are comprised primarily of product sales, royalty income and sublicense fee income.

We received regulatory approval from Health Canada to market Augment in Canada in late 2009. To date, our product sales revenues have been limited. We expect product sales revenues to commence in the United States from the sales of Augment when, and if, the FDA approves the commercialization of Augment.

Royalty income for the year ended December 31, 2010 was $0.5 million, and is based on net sales of *GEM 21S* as reported to us by Luitpold, who owns the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. As part of the 2008 agreement to sell our orofacial therapeutic business, including *GEM 21S*, to Luitpold, we expect to continue to receive ongoing royalty payments at least through 2026 based on Luitpold’s net sales of *GEM 21S*.

Sublicense fee income for the year ended December 31, 2010 was $1.0 million, and is based on the straight-line amortization of certain milestone payments previously received from Luitpold.

Other Income and Expense

Other income and expense as reflected in our consolidated statements of operations include interest income and expense, investment income and losses, grant income and various gains or losses resulting from one-time or unusual transactions.

We received three government cash grants totaling $0.5 million during 2010, which were recognized when awarded as other income in our consolidated statement of operations for the year ended December 31,

2010. There are no unfulfilled conditions nor any contingent liability for repayment related to either the IWT program or the QTPD program cash grants received by us.

Research and Development Expenses

Our largest expenditures related to our research and development activities, which were $18.0 million for the year ended December 31, 2010.

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 Injectable, Augment Rotator Cuff 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 start to increase over the next few quarters as a result of continuing costs associated with the Canadian Augment Injectable trial, the initiation of a rotator cuff pilot clinical study in Canada, which occurred in the fourth quarter of 2010, and the initiation of patient enrollment in a North American pivotal trial for Augment Injectable, which is expected to occur in the first quarter of 2011.

Direct external costs represent significant expenses paid to third parties that specifically relate to the clinical development of our product candidates, 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.

The following table summarizes our research and development expenses for the five years ended December 31, 2010:

	Research and Development Expenses				
	Years Ended December 31,				
Market	**2010**	**2009**	**2008**	**2007**	**2006**
Direct external:					
Periodontal	$ 34,311	$ 251,306	$ 1,061,533	$ 1,789,290	$ 1,434,571
Orthopedic	4,995,835	7,611,308	10,638,241	7,143,764	5,180,996
Sports medicine	1,327,412	984,969	491,825	716,125	325,170
	6,357,558	8,847,583	12,191,599	9,649,179	6,940,737
Internal:					
Periodontal	454,133	688,420	590,330	2,400,252	2,049,165
Orthopedic	8,274,842	9,595,711	9,999,420	5,878,196	2,438,251
Sports medicine	2,880,383	1,963,715	1,779,626	1,290,751	247,729
	11,609,358	12,247,846	12,369,376	9,569,199	4,735,145
Total	$17,966,916	$21,095,429	$24,560,975	$19,218,378	$11,675,882

General and Administrative Expenses

We anticipate that our general and administrative expenses, which were $15.2 million for the year ended December 31, 2010, will continue to increase as we expand our sales and marketing networks to represent our products, as well as our manufacturing operations, facilities and other administrative activities related to our efforts to bring our product candidates into commercialization.

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 cope with the current economic volatility and uncertainty.

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.''

Milestone Payments

Various milestone payments were required under our agreements with Luitpold, Kensey Nash, and Novartis, as well as our intellectual property license agreements with ZymoGenetics and Harvard. Luitpold may be required to make certain milestone payments to us, and we may be required to make certain milestone payments to Kensey Nash based on the occurrence of certain events. These milestone payments relate to the achievement of certain clinical developments, regulatory filings, approvals and sales levels for Augment Injectable.

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 certain 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.

In November 2010, we executed three agreements that amended agreements that were part of our 2008 transaction to sell our orofacial therapeutic business, including *GEM 21S*, to Luitpold: (1) Amendment No. 1 to Amended and Restated Exclusive Sublicense Agreement, (2) Amendment No. 1 to Asset Purchase Agreement, and (3) Amendment No. 1 to Agreement Terminating Research, Development and Marketing Agreement. The agreement amendments are effective as of November 1, 2010. Under these amendments, we continue to have the right to seek European regulatory approval for *GEMESIS*, and are still entitled to receive a $10.0 million milestone payment from Luitpold upon obtaining such approval and providing Luitpold with the documentation necessary to transfer such approval to them. We, however, were required to obtain a reclassification of *GEMESIS* from a drug product to a medical device prior to March 31, 2011. Such reclassification was obtained on November 12, 2010. We are now permitted to continue to seek European approval of *GEMESIS* for a period of 18 months following the date of the reclassification until May 12, 2012. If we are unsuccessful with obtaining European approval by May 12, 2012, we will lose our right to seek

European approval of *GEMESIS* and forfeit the $10.0 million milestone payment. In addition, if we successfully resolve all European regulatory issues necessary for *GEMESIS* product approval by May 12, 2012 except for quality and/or manufacturing issues relating solely to Luitpold's quality and/or manufacturing operations, we will be deemed to have obtained constructive European approval, and will be entitled to receive 90% of the $10.0 million milestone payment. Thereafter, we and Luitpold will work together to obtain the final European approval at which time we would be entitled to receive the remainder of the $10.0 million milestone payment. In order to trigger a milestone payment, any European approval or constructive approval of *GEMESIS* must contain the same dosing as currently approved in the United States and Canada, include approved indications for the use of *GEMESIS* in the treatment of periodontal and gingival defects as a stand-alone product, and permit Luitpold to market *GEMESIS* as currently manufactured by Luitpold at its facility. Because of uncertainties in the regulatory review process, we have excluded this milestone payment from our financial guidance for 2011.

In addition, 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. Further, 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. In September 2010, we amended the agreement with Kensey Nash to amend a development plan, as well as material and product specifications, pricing and conformance, for our Augment Injectable product candidate and to provide for certain milestone payments from us to Kensey Nash for the accomplishment of certain development milestones such as the initiation of certain clinical trials, regulatory filings, product approvals, and/or commercial launch of Augment Injectable. In addition, there are certain time-based milestone payments, triggered by such events, payable to Kensey Nash.

Many of the events triggering a milestone 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* prior to May 12, 2012. Excluding this Luitpold payment, and assuming that all future contingencies are met and all payments are made (not taking into account any expiration of the relevant agreements before such contingencies are met), we anticipate that the milestone payments that we are required to make will result in a net payment by us of approximately $3.3 million in the near term (from 2011 to 2012) and approximately $7.1 million in the long term (from 2013 to 2015).

We have licensed a number of U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. As a part of the licensing agreement relating to such patents, we agreed to pay royalties based on net sales of licensed products under the agreement on a country-by-country basis during the term of the agreement. In accordance with such agreement, we are required to make minimum royalty payments for sales of an orthopedic product as follows: $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. Based upon the 2009 Canadian regulatory approval of Augment, we shipped our first order of Augment to a Canadian distributor in December 2009. Accordingly, we recorded $1.0 million in royalty expense on our consolidated statement of operations for the year ended December 31, 2010.

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.

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, income taxes, valuation of any losses on purchase commitments, and fair valuation of investments, inventory and stock-based compensation. 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 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. 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 on a quarterly basis, when the sales information is received from the sublicensor. Any amounts received in advance of performance are recorded as deferred revenue until earned. Government grants received in cash are recognized as other income when awarded in accordance with the accounting guidance for government grants as addressed by International Financial Reporting Standards (''IFRS'') in International Accounting Standards No. 20, *Accounting for Government Grants and Disclosure of Government Assistance*, as accounting for government grants is not specifically addressed in U.S. generally accepted accounting principles.

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 the clinical development of our product candidates, including Augment, Augment Injectable and Augment Rotator Cuff, consisting of 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 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, 2010, 2009 and 2008.

Inventory Valuation

We value our inventory at the lower of our actual cost (first-in, first-out) or 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.

Raw materials inventory consists of bulk drug substances, labeling materials, cup trays, cup lids, and other packaging materials used in the manufacturing of our orthopedic product candidates. Work in progress inventory consists of production runs of cups and vials that are not yet approved and finalized for packaging. Finished goods inventory consists of finished cups and vials ready for packaging, as well as packed kits of Augment ready for sale. Shipping and handling costs are included in the cost of sales of the product. Reserves for obsolescence, shrinkage, expired inventory and potential scrapping of product batches that may not be released for sale are included in inventory, if appropriate.

Cost of sales is also 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. The cost of sales will vary in direct correlation to the volume of product sales of Augment kits.

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, 2010, 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 milestone expenses, 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 awards of 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 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 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 grantee meets specific holding requirements. If the grantee 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. Upon 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 the three years ended December 31, 2010 for share-based compensation arrangements as we do not believe that we will recognize any deferred tax assets from such compensation costs recognized in the current period.

In general, stock option awards granted under the option plan vest 25% per year over a four-year period. The option plan currently provides 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 an 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.

Effective January 1, 2006, we adopted ASC 505, *Equity-Based Payments to Non-Employees* (''ASC 505''), and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*) (ASC 718''), using the modified prospective method of transition. Under that transition method, compensation expense recognized in the three years ended December 31, 2010 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 the following weighted average assumptions amortized to expense over the options' vesting periods for the year ended December 31, 2010: risk-free interest rate of 2.19%, expected dividend yield of 0%, volatility factor of the expected market price of our common stock ranged from 76% to 77%, forfeiture rate of 8.9% and weighted average expected life of the option ranged from 4.4 to 8.0 years. Since there is a limited trading history for our common stock, 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 expected to be outstanding, and are derived from the contractual terms of the options granted and adjusted for historical experience. 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.

During the year ended December 31, 2010, we granted stock options to our employees, members of the board of directors, and consultants to purchase an aggregate of 729,741 shares of our common stock at a weighted average exercise price of $11.79. Our net loss for the years ended December 31, 2010, 2009 and 2008 includes compensation costs of $4.0 million, $3.9 million and $3.4 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, 2010, 2009 and 2008.

Investments

Effective January 1, 2008, we adopted ASC 820-10, *Fair Value Measurements* (originally issued as SFAS No. 157, *Fair Value Measurements*) (''ASC 820-10''), 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 820-10 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.

As of January 1, 2010, we adopted ASU 2010-06, *Fair Value Measurements and Disclosures — Topic 855* (''ASU 2010-06''). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. In addition, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques.

In accordance with ASC 820-10, as amended by ASU 2010-06, we evaluate 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 for our management to make significant judgments.

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

Results of Operations

Years Ended December 31, 2010 and 2009

Net loss for the year ended December 31, 2010 was $33.9 million, or $1.38 per diluted share, compared to net loss of $21.2 million, or $1.03 per diluted share, for the same period in 2009. The net loss in 2009 included a $5.8 million realized gain and a $7.2 million settlement payment related to our previous investments in ARS, neither of which was repeated in 2010.

We anticipate that our operating losses, which are only partially offset by sales, revenues from royalty income, sublicense fee income, grant 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 Revenue

Although in 2009 we received regulatory approval from Health Canada for sales of Augment in Canada, our product sales revenues have been limited. We expect product sales revenues to commence in the United States from the sales of Augment when, and if, the FDA approves the commercialization of Augment.

In November 2010, we changed our distribution strategy in Canada, and have completed a transition from a single exclusive distributor to a network of independent sales agents who are more closely managed by us through our Canadian national sales manager. We now have over 30 independent sales representatives representing Augment throughout Canada. Although we have now begun to see an increase in sales as a result of our restructured distribution, the Canadian market for Augment is limited and we do not anticipate significant revenues from sales of Augment in Canada.

Cost of Sales

Cost of sales for the year ended December 31, 2010 was less than $0.1 million. 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. The cost of sales will vary in direct correlation to the volume of product sales of Augment kits. Certain raw materials were purchased during fiscal years that preceded the completion of the Phase III clinical trials. As a result, we expensed the pre-launch inventory used for clinical trials as research and development expense recorded on our consolidated statements of operations.

Royalty and Sublicense Fee Income

Royalty income for the year ended December 31, 2010 was $0.5 million, compared to $0.5 million for the same period in 2009. As part of a 2008 agreement to sell our orofacial therapeutic business, including *GEM 21S*, to Luitpold, we expect to continue to receive ongoing royalty payments at least through 2026 based on Luitpold's net sales of *GEM 21S*. In the years ended December 31, 2010 and 2009, Luitpold's net sales of *GEM 21S* as reported to us were $4.8 million and $5.2 million, respectively.

Sublicense fee income for the year ended December 31, 2010 was $1.0 million, which is comparable to $1.0 million for the same period in 2009. Sublicense fee income is based on the straight-line amortization of certain milestone payments previously received from Luitpold.

Research and Development Expenses

Research and development expenses relate to new and ongoing clinical trials of our product candidates in the United States, Canada, Australia and the European Union, as well as continuing expenses associated with pre-clinical studies and regulatory filings. These expenses for the year ended December 31, 2010 were $18.0 million, compared to $21.1 million for the same period in 2009. The $3.1 million decrease resulted in part from:

- a decrease of $2.7 million in professional services for clinical costs as certain orthopedic clinical trials came to a close in 2009;
- an increase of $0.2 million in contract manufacturing costs, milestones, and expenses for validation consulting, regulatory and outside R&D costs; and
- a decrease of $0.6 million in salaries, benefits, payroll taxes, stock compensation costs, recruiting & relocation, freight, small equipment and in general activities of the R&D program.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2010 were $15.2 million, compared to $11.5 million for the same period in 2009. The $3.7 million increase resulted in part from:

- an increase of $1.2 million in salaries, benefits, payroll taxes, and stock compensation costs,
- an increase of $0.4 million in professional fees, primarily driven by fees paid in preparation for future commercialization activities,
- an increase of $0.6 million in rent and utilities due to the late 2009 completion of a new building intended to house certain aspects of our manufacturing operations, and
- an increase of $0.8 million in charitable contributions, taxes and licenses, recruiting and relocation, travel and general G&A activities.
- an increase of $0.7 million in royalty expense due to a $1.0 million minimum royalty payment, as required in the first full year following the first commercial sale of an orthopedic product, as commercial sales of Augment in Canada commenced in December 2009.

Depreciation and Capital Lease Amortization

Depreciation and capital lease amortization for the year ended December 31, 2010 was $1.2 million, compared to $1.3 million for the same period in 2009. During the year ended December 31, 2010, we purchased equipment, computers and software totaling $0.5 million. In addition, during the year ended December 31, 2010, we incurred $0.2 million in engineering design and planning costs, for a cumulative total of $1.2 million recorded to construction in process as of December 31, 2010, related to a new building intended to house certain aspects of our manufacturing operations.

Patent License Fee Amortization

Patent license fee amortization for the year ended December 31, 2010 was $1.7 million, compared to $2.6 million for the same period in 2009. In 2010, we wrote-off certain capitalized costs totaling $12.4 million related to patents that had expired and were fully amortized as of December 31, 2010. Ongoing amortization expense is attributable to the capitalization of the remaining patent license fees, which amounted to a cumulative $1.9 million as of December 31, 2010.

Interest and Investment Income

Total net interest and investment income for the year ended December 31, 2010 was $0.1 million, compared to $6.6 million for the same period in 2009. Analysis of the decrease follows:

- The net interest and investment income for 2009 included a net realized gain of $5.8 million related to the sales, redemptions and partial redemptions certain ARS investments. Excluding this, total net interest and investment income for the year ended December 31, 2009 was $0.8 million.
- Interest expense on a note payable was $0.5 million for the year ended December 31, 2009. There was no such interest expense for the year ended December 31, 2010 because the note was paid in full as of December 2009.
- Interest rates earned on our cash and cash equivalents ranged from 0.01% to 0.18% during the year ended December 31, 2010, compared to same period in 2009 when interest rates ranged from 0.00% to 1.10%.

Other Income

In July 2010, we were awarded a cash grant of $25,000 under the Incumbent Worker Training (‘‘IWT’’) program. The IWT program was created by the Tennessee Department of Labor and Workforce Development — Workforce Development Division of the State of Tennessee to reimburse companies for certain qualifying training expenses.

In November 2010, we were awarded two cash grants totaling $0.5 million under the U.S. government’s Qualifying Therapeutic Discovery Project (‘‘QTDP’’) program. The QTDP program was created by the U.S. Congress as part of the Patient Protection and Affordable Care Act of 2010, and provides a tax credit or grant

equal to eligible costs and expenses for tax years 2009 and 2010. The QTDP program is aimed at creating and sustaining high-quality, high-paying jobs in the United States, while advancing the nation's competitiveness in life, biological and medical sciences. We submitted applications and received the awards based on our orthopedic and sports medicine programs.

Provision for Income Taxes

At December 31, 2010, we had federal net operating loss (''NOL'') carryforwards of $96.5 million, of which $2.3 million originated from the disqualifying disposition of stock options. The federal NOL carryforwards will begin to expire in 2022. State NOL carryforwards at December 31, 2010 totaled $84.1 million and will expire between 2013 and 2030. Foreign NOL carryforwards at December 31, 2010 totaled $0.2 million and will begin to expire 2030. To the extent NOL carryforwards, when realized, related to nonqualified stock option deductions, the resulting benefits will be credited to stockholders' equity.

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, 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 sale of our orofacial therapeutic business, offset in part by a $13.4 million impairment loss on our ARS investments.

Product Sales Revenues

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, freight 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 during fiscal years that preceded the completion of the Phase III clinical trials. As a result, we expensed the pre-launch inventory used for clinical trials as research and development expense recorded on our consolidated statements of operations.

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:

- 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, and
- a decrease of $0.3 million in salaries, payroll taxes, benefits, insurance, recruiting and relocation expenses, and general activities of the R&D programs.

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.

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. Analysis of the decrease follows:

- 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.

Liquidity and Capital Resources

Cash Flows

For the year ended December 31, 2010, net cash used in operating activities was $27.3 million, primarily consisting of salaries, clinical trials, research and development activities and general corporate operations. Net cash used in investing activities was $28.4 million for the year ended December 31, 2010 and consisted of net purchases of short-term and long-term investments, purchases of property and equipment and capitalized patent costs. Net cash provided by financing activities was $45.8 million for the year ended December 31, 2010 and consisted of net proceeds from issuance of common stock, including approximately $45.0 million pursuant to a July 2010 public stock offering.

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 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.

Capital Resources

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) Profit Sharing Plan & Trust (the ''401(k) plan'') for net proceeds of $16.6 million.

In July 2010, we sold 5,642,280 shares of common stock at a price of $8.50 per share, resulting in net proceeds of approximately $45.0 million after deducting underwriting discounts, commissions and expenses.

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*. In addition, under a separate agreement with Luitpold, we may be entitled to receive a $10.0 million milestone payment from Luitpold upon regulatory approval of *GEMESIS* in the EU.

Various other milestone payments may be required under our agreements with Luitpold and Kensey Nash. Refer to ''Financial Operations Overview — Milestone Payments'' for more information regarding these potential milestone payments.

Cash and Cash Equivalents and Investments

As of December 31, 2010, the remaining net proceeds from our capital offerings and sale of our orofacial therapeutic business, including *GEM 21S* (discussed above in ''Results of Operations'' and in ''Business — Divestiture of Orofacial Therapeutic Business''), have been invested conservatively in cash and cash equivalents and in short-term and long-term investments in GSE securities.

At December 31, 2010, we had $11.6 million in cash and cash equivalents held in three financial institutions. Our excess cash reserves are invested in overnight sweep accounts, operating accounts, money market accounts and a certificate of deposit. In addition to the balance of cash and cash equivalents at December 31, 2010, we had $65.8 million in short-term investments classified as available-for-sale consisting of GSE securities totaling $60.6 million and corporate bonds totaling $5.2 million. The short-term GSE securities have maturity dates ranging from January 2011 through November 2011, and the corporate bonds have maturity dates ranging from August 2011 through October 2011 and ratings ranging from ''A'' to ''AA.'' In addition, as of December 31, 2010, we had long-term investments of $15.0 million consisting of four GSE securities with maturity dates ranging from February 2012 through September 2012.

In 2008 and 2009, we had investments in certain auction rate securities (''ARS''). As of December 31, 2008, we had estimated the fair value to be $46.6 million, representing an ''other-than-temporary'' impairment loss of $13.4 million recorded in earnings in our consolidated statement of operations for 2008. As of December 31, 2009, all of our ARS investments had been sold at a discount or redeemed by the issuers at par, resulting in total cash proceeds of $52.4 million and a net realized gain of $5.8 million reclassified from unrealized gains and recorded in earnings in our consolidated statement of operations for 2009.

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, after finalizing the sale of all of the remaining securities at issue in that arbitration proceeding, we settled the arbitration claim and dismissed the case upon receipt of a $7.2 million payment from the respondent in the arbitration. The settlement payment is recorded as a gain on our consolidated statement of operations for the year ended December 31, 2009.

We believe that the December 31, 2010 balance of our cash and cash equivalents and investments, which includes net proceeds from the sale of our orofacial therapeutic business in 2008 and from additional capital resources secured in 2009 and 2010 as described above, will be sufficient to meet our anticipated cash requirements at least through the second half of 2012.

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*) (''ASC 220''), 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 three years ended December 31, 2010 are as follows (in millions):

	2010	2009	2008
Net loss	$(33.9)	$(21.2)	$(8.0)
Other comprehensive loss:			
Net unrealized gain on foreign currency translation	0.0	—	—
Net unrealized (loss) gain on investments classified as available for sale	(0.1)	(0.1)	0.1
Comprehensive loss	$(34.0)	$(21.3)	$(7.9)

Unaudited Quarterly Financial Information

The following table presents unaudited quarterly financial data (in millions, except per share data). Our quarterly results of operations for these periods are not necessarily indicative of future results.

	Revenue	Loss From Operations	Net Loss	Net Loss Per Share – Basic	Net Loss Per Share – Diluted
Year ended December 31, 2010					
1st Quarter	$0.3	$ (8.5)	$ (8.5)	$(0.39)	$(0.39)
2nd Quarter	0.4	(7.7)	(7.7)	(0.35)	(0.35)
3rd Quarter	0.4	(7.8)	(7.7)	(0.29)	(0.29)
4th Quarter	0.4	(10.6)	(10.0)	(0.36)	(0.36)
Year ended December 31, 2009					
1st Quarter	$0.4	$ (8.3)	$ (8.1)	$(0.43)	$(0.43)
2nd Quarter	0.4	(8.2)	(6.3)	(0.32)	(0.32)
3rd Quarter	0.4	(8.4)	(7.9)	(0.36)	(0.36)
4th Quarter	0.4	(10.0)	1.1	0.05	0.05

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, 2010:

	Payments due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1 – 3 years**	**3 – 5 years**	**More than 5 years**
Capital lease obligations	$ 305,776	$ 84,004	$ 175,222	$ 46,550	$ —
Operating lease obligations	12,249,611	1,472,438	3,078,720	3,266,215	4,432,238
Purchase and supplier obligations – raw materials	5,770,681	2,801,711	2,968,970	—	—
Purchase and supplier obligations – equipment	930,558	847,558	83,000	—	—
Total	$19,256,626	$5,205,711	$6,305,912	$3,312,765	$4,432,238

Recent Accounting Pronouncements

Fair Value Measurements and Disclosures

In January 2010, the Financial Accounting Standards Board (''FASB'') issued Accounting Standards Update (''ASU'') 2010-06, *Fair Value Measurements and Disclosures — Topic 855* (''ASU 2010-06''). ASU 2010-06 provides amendments to Accounting Standards Codification (''ASC'') 820-10, *Fair Value Measurements* (''ASC 820-10''), which was originally issued as SFAS No. 157, *Fair Value Measurements*, and adopted by us as of January 1, 2008). ASC 820-10 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 820-10 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 three categories (level 1, level 2 or level 3). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. Furthermore, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures required by ASU 2010-06 are effective for interim and annual reporting periods beginning after December 31, 2009 (except for disclosures in the reconciliation of activity within level 3, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years). We adopted ASU 2010-06 as of January 1, 2010, and the adoption did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2010.

Subsequent Events

In February 2010, the FASB issued ASU 2010-09, *Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements* (''ASU 2010-09''), to amend ASC 855, *Subsequent Events* (''ASC 855''). 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, companies are not required to 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 evaluated subsequent events in accordance with ASU 2010-09, and the evaluation did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2010.

Revenue Recognition

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition — Milestone Method (Topic 605)* (''ASU 2010-17''). ASU 2010-17 provides guidance for defining a milestone and criteria for determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all the consideration is contingent upon milestone events, such as the successful completion of phases in a clinical study or achieving a specific result or regulatory approval. An entity often recognizes these milestone payments as revenue in their entirety upon achieving the related milestone, commonly referred to as the milestone method. Authoritative guidance on the use of the milestone method did not previously exist in the accounting literature. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Our adoption of ASU 2010-17 did not have a material impact on our consolidated financial statements as of and for the year ended December 31, 2010.

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 0.01% to 0.18% during the year ended December 31, 2010. We have not used derivative financial instruments for speculation or trading purposes.

At December 31, 2010, we had $11.6 million in cash and cash equivalents held in three financial institutions. Our excess cash reserves are invested in overnight sweep accounts, operating accounts, money market accounts and a certificate of deposit. In addition to the balance of cash and cash equivalents at December 31, 2010, we had $65.8 million in short-term investments in GSE securities and corporate bonds classified as available-for-sale. Also at December 31, 2010, we had $15.0 million in long-term investments in GSE securities. The GSE securities have maturity dates ranging from January 2011 through September 2012, and the corporate bonds have maturity dates ranging from August 2011 through October 2011 and ratings ranging from ''A'' to ''AA.''

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required for each of the three years ended December 31, 2010 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. 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, 2010. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as defined in Rule 13a-15(f) promulgated under the Exchange Act, that occurred during the quarter ended December 31, 2010 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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) promulgated under the Exchange Act, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Management assessed our internal control over financial reporting as of December 31, 2010, the end of our fiscal year. 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. Management's assessment included evaluation of elements such as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies and our overall control environment.

Based on our assessment, management has concluded that our internal control over financial reporting was effective. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Inherent Limitations on Effectiveness of Controls

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.

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, 2010, 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, 2010, 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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010 of BioMimetic Therapeutics, Inc., and our report dated March 10, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 10, 2011

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 2011 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2010.

Item 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2011 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2010.

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 2011 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2010.

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 2011 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2010.

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 2011 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2010.

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.

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BIOMIMETIC THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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, 2010, 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 10, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 10, 2011

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,628,329	$ 21,543,347
Investments – short term	65,751,039	47,001,504
Receivables – trade	8,050	78,000
Receivables – other	468,380	612,020
Inventory	2,258,193	1,044,305
Prepaid expenses	588,063	647,156
Total current assets	80,702,054	70,926,332
Investments – long term	15,001,765	6,513,975
Prepaid expenses – long term	5,252	5,418
Property and equipment, net	7,592,820	8,156,842
Capitalized patent license fees, net	1,867,937	2,924,614
Deposits	385,000	385,000
Total assets	$ 105,554,828	$ 88,912,181
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,670,830	$ 2,255,748
Accrued payroll, employee benefits and payroll taxes	2,590,126	2,299,237
Other accrued expenses	1,908,680	135,070
Current portion of capital lease obligations	78,665	56,520
Deferred revenue	971,188	971,188
Total current liabilities	7,219,489	5,717,763
Accrued rent – related party	419,465	418,305
Capital lease obligations	215,644	174,818
Deferred revenue	14,578,490	15,549,678
Total liabilities	22,433,088	21,860,564
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized; no shares issued and outstanding as of December 31, 2010 and 2009	—	—
Common stock, $0.001 par value; 37,500,000 shares authorized; 27,925,984 shares issued and outstanding as of December 31, 2010; 21,825,028 shares issued and outstanding as of December 31, 2009	27,926	21,825
Additional paid-in capital	210,553,647	160,532,625
Accumulated other comprehensive income	(2,462)	17,387
Accumulated deficit	(127,457,371)	(93,520,220)
Total stockholders' equity	83,121,740	67,051,617
Total liabilities and stockholders' equity	$ 105,554,828	$ 88,912,181

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2010	2009	2008
Revenues:			
Product sales	$ 14,742	$ 78,000	$ —
Royalty income	487,595	522,038	2,144,234
Sublicense fee income	971,188	971,188	973,849
Other revenue	—	—	30,301
Total revenues	1,473,525	1,571,226	3,148,384
Costs and expenses:			
Cost of sales (exclusive of depreciation and amortization shown separately below)	17,250	5,666	—
Research and development[(a)]	17,966,916	21,095,429	24,560,975
General and administrative[(b)]	15,160,468	11,511,619	11,252,445
Depreciation and capital lease amortization	1,234,335	1,332,881	1,423,341
Patent license fee amortization	1,658,104	2,569,159	2,663,299
Total costs and expenses	36,037,073	36,514,754	39,900,060
Loss from operations	(34,563,548)	(34,943,528)	(36,751,676)
Interest (expense) income, net	(3,602)	(308,127)	247,134
Investment income (loss), net	143,720	6,863,834	(10,796,893)
Other income from governmental grants	513,959	—	—
(Loss) gain on disposal of equipment and other	(27,680)	11,137	5,025
Gain on arbitration settlement	—	7,219,270	—
Gain on disposal of orofacial therapeutic business	—	—	39,291,413
Loss before income taxes	(33,937,151)	(21,157,414)	(8,004,997)
Income taxes	—	—	—
Net loss	$(33,937,151)	$(21,157,414)	$ (8,004,997)
Basic and diluted net loss per share	$ (1.38)	$ (1.03)	$ (0.43)
Weighted average shares used to compute basic and diluted net loss per share	24,626,170	20,510,132	18,529,068

Related party disclosures:

(a) Research and development includes professional fees to related parties	$ 14,875	$ 9,000	$ 10,000
(b) General and administrative includes rent and operating expenses to related parties	$ 1,898,668	$ 1,271,243	$ 1,044,856

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2010, 2009 and 2008

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Comprehensive loss:						
Net loss	—	—	—	—	(33,937,151)	(33,937,151)
Other comprehensive loss:						
Net unrealized gain on foreign currency translation				111	—	111
Net unrealized loss on investments				(19,960)	—	(19,960)
Total comprehensive loss				(19,849)	(33,937,151)	(33,957,000)
Issuance of common stock	458,676	459	1,113,950	—	—	1,114,409
Public offering of common stock, net	5,642,280	5,642	44,923,405	—	—	44,929,047
Compensation expense relating to common stock options granted	—	—	3,983,667	—	—	3,983,667
Balance at December 31, 2010	27,925,984	$27,926	$210,553,647	$ (2,462)	$(127,457,371)	$ 83,121,740

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2010	2009	2008
Cash flows from operating activities			
Net loss	$ (33,937,151)	$(21,157,414)	$ (8,004,997)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and capital lease amortization expense	1,234,335	1,332,881	1,423,341
Patent license fee amortization	1,658,104	2,569,159	2,663,299
(Loss) gain on investments	—	(5,800,550)	13,375,960
Loss (gain) on disposal of equipment	200	32,074	(5,025)
Gain on foreign currency translation	111	—	—
Non-cash stock-based compensation expense	3,983,667	3,892,895	3,409,915
Non-cash issuance of common stock	283,188	374,211	—
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	213,590	1,164,527	1,533,526
Inventory	(1,213,888)	217,682	(474,855)
Prepaid expenses	(14,101)	(17,509)	119,484
Accounts payable, accrued payroll and other accrued expenses	1,480,741	(4,313,055)	2,042,006
Deferred liability	—	—	(1,250,000)
Deferred revenue	(971,188)	(971,188)	(973,850)
Net cash used in operating activities	(27,282,392)	(22,893,972)	(25,739,632)
Cash flows from investing activities			
Capitalized patent license fees	(601,427)	(510,044)	(1,643,707)
Proceeds from disposal of equipment	—	—	7,887
Purchases of property and equipment	(534,097)	(2,310,910)	(2,880,534)
Equipment deposits	—	1,899,608	194,215
Purchases of investments	(126,807,284)	(58,370,400)	(61,882,691)
Sales of investments	99,550,000	90,379,590	10,600,000
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 (used in) provided by investing activities	(28,392,808)	41,087,844	(22,351,798)
Cash flows from financing activities			
Payments on capital lease obligations	(73,445)	(18,187)	(17,351)
Issuance of common stock under compensation plans	831,221	432,085	1,061,157
Net proceeds from issuance of common stock	45,002,406	24,500,614	—
Net proceeds from drawdown of note payable	—	—	39,100,000
Payments on note payable	—	(39,100,000)	—
Net cash provided by (used in) financing activities	45,760,182	(14,185,488)	40,143,806
Net (decrease) increase in cash and cash equivalents	(9,915,018)	4,008,384	(7,947,624)
Cash and cash equivalents, beginning of period	21,543,347	17,534,963	25,482,587
Cash and cash equivalents, end of period	$ 11,628,329	$ 21,543,347	$ 17,534,963
Supplemental disclosures of cash flow information			
Interest paid	$ 4,479	$ 529,265	$ 265,982
Supplemental non-cash disclosures			
Acquisition of property and equipment through capital leases	$ 136,416	$ 196,625	$ —

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 specializing in the development and commercialization of regenerative protein therapeutic 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, sports injury and spine applications.

The Company's first periodontal product, *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), received marketing approval from the U.S. Food and Drug Administration (''FDA'') in November 2005. The Company's first orthopedic product, Augment™ Bone Graft (''Augment''), received marketing approval from Health Canada in November 2009. The Company continues to seek FDA approval for the marketing of Augment in the United States.

The Company recorded product sales revenue from sales of *GEM 21S* until January 2008, at which time the Company sold its orofacial therapeutic business, including *GEM 21S*, to Luitpold Pharmaceuticals, Inc. (''Luitpold''). Product sales revenues from sales of Augment in Canada were first recorded in December 2009. The Company is focusing its expertise and development efforts on its orthopedic, sports medicine and spine product candidates, including its lead product candidates Augment, Augment™ Injectable Bone Graft (''Augment Injectable'') and Augment™ Rotator Cuff Graft (''Augment Rotator Cuff''), 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, clinical trials and regulatory activities in the United States, Canada, the European Union (''EU'') and Australia.

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, BioMimetic Therapeutics Pty Ltd. in Australia, and BioMimetic Therapeutics Canada, Inc. Inter-company balances and transactions are eliminated in consolidation. As of December 31, 2010, the subsidiaries in the United Kingdom and Australia have no employees and have no operating activities other than making and maintaining regulatory submissions for the Company's product candidates in the European Union (''EU'') and Australia. The subsidiary in Canada was established in 2010 to facilitate sales activities in Canada for Augment, which received regulatory approval from Health Canada in the fourth quarter of 2009. As of December 31, 2010, the Canadian subsidiary had one employee and had incurred certain operational expenses.

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, 2010 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. Interest earned on cash and cash equivalents are included in interest income in the accompanying consolidated statements of operations.

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 accumulated other comprehensive income in the accompanying consolidated balance sheets and consolidated statements of stockholders' equity. 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 product sales of Augment in Canada. An allowance of $8,050 has been recorded as of December 31, 2010 to recognize management's estimate of uncollectible accounts. Management's determination of the collectability of trade receivables requires significant judgments to be made. This determination includes an evaluation based on historical trends in aging of receivables, customer payment history, and analysis of certain risks on a customer specific basis.

Receivables — Other

Receivables from others consist of the following: (1) royalty income, (2) interest and investment income receivable, and (3) other receivables in the normal course of business transactions.

Inventory

Inventories are carried at the lower of actual cost (first-in, first-out) or current net realizable value. The Company regularly reviews 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 the Company's historical usage and anticipated future usage. If appropriate, reserves for such obsolescence, shrinkage, expiration, and potential scrapping of product batches that may not be released for sale are included in inventory. Although the Company's management makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated change in demand or technological developments could have a significant impact on the value of the Company's inventory and reported operating results.

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, 2010, no reserves have been recorded associated with these future purchase commitments.

2. Summary of Significant Accounting Policies – (continued)

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.

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 remaining patent life, and to write-off fully amortized costs upon expiration. The termination dates of the patents range from June 2025 to January 2026.

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, 2010, 2009 and 2008.

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.

2. Summary of Significant Accounting Policies – (continued)

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

Product sales revenue is recognized upon delivery of the product to the customer. The Company generated its first revenues in December 2005 from the sale of *GEM 21S* to Luitpold after receiving FDA approval in November 2005. In January 2008, the Company sold to Luitpold its remaining orofacial therapeutic business, including the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. As such, no product sales revenue from sales of *GEM 21S* has been recorded for the years ended December 31, 2010, 2009 or 2008. See Note 5.

In November 2009, the Company received approval from Health Canada for the marketing and commercialization of Augment in Canada. Based upon this approval, in December 2009, the Company shipped its first order of Augment to a Canadian distributor, Joint Solutions, a sales and distribution company for orthopedic products headquartered in Burlington, Ontario, Canada. Thus, product sales revenue from sales of Augment in Canada has been recorded for the years ended December 31, 2010 and 2009.

Royalty income

Royalty revenues are received from a sublicensor in arrears based on sales by the sublicensor. 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 sales information is received from Luitpold.

Sublicense fee income

Non-refundable license fees under agreements where the Company has 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.

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.

2. Summary of Significant Accounting Policies – (continued)

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, were recognized monthly as other revenue as the related payments were due and/or invoiced.

Other income and expense

Other income and expense as reflected in the accompanying consolidated statements of operations include interest income and expense, investment income and losses, grant income and various gains or losses resulting from one-time or unusual transactions.

In July 2010, the Company was awarded a cash grant of $25,000 under the Incumbent Worker Training (''IWT'') program. The IWT program was created by the Tennessee Department of Labor and Workforce Development — Workforce Development Division of the State of Tennessee to reimburse companies for certain qualifying training expenses. There are no unfulfilled conditions nor any contingent liability for repayment related to the IWT program cash grant.

In November 2010, the Company was awarded two cash grants totaling $488,959 under the U.S. government's Qualifying Therapeutic Discovery Project (''QTDP'') program. The QTDP program was created by the U.S. Congress as part of the Patient Protection and Affordable Care Act of 2010, and provides a tax credit or grant equal to eligible costs and expenses for tax years 2009 and 2010. The QTDP program is aimed at creating and sustaining high-quality, high-paying jobs in the United States, while advancing the nation's competitiveness in life, biological and medical sciences. There are no unfulfilled conditions nor any contingent liability for repayment related to the QTPD program cash grant.

As accounting for government grants is not specifically addressed in U.S. generally accepted accounting principles, the Company follows the accounting guidance for government grants as addressed by International Financial Reporting Standards (''IFRS'') in International Accounting Standards No. 20, *Accounting for Government Grants and Disclosure of Government Assistance*. The three resulting government cash grants received by the Company during the year ended December 31, 2010 were recognized as other income when awarded.

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, stock-based compensation costs 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

2. Summary of Significant Accounting Policies – (continued)

differences are 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.

The Company accounts for uncertain tax positions in accordance with 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'')). 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 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, 2010 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, the Company adopted ASC 505, *Equity-Based Payments to Non-Employees* (''ASC 505''), and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*) (''ASC 718''), using the modified prospective method of transition. Under that transition method, compensation expense recognized in the three years ended December 31, 2010 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. These assumptions include the risk free interest rate, expected dividend yield, volatility factor of the expected market price of the Company's common stock, 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 are derived from the contractual terms of the options granted and adjusted for historical experience. The Company amortizes the fair value of each option over each

2. Summary of Significant Accounting Policies – (continued)

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.

Comprehensive Loss

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 and long-term investments, accounts receivable, accounts payable, accrued expenses and capital lease obligations.

For information on the fair value of the Company's investments, see Note 11.

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, 2010, the Company had short-term investments of $65,751,039 classified as available-for-sale consisting of U.S. government sponsored enterprise (''GSE'') securities totaling $60,585,169 and corporate bonds totaling $5,165,870. The GSE securities have maturity dates ranging from January 2011 through November 2011. The corporate bonds have maturity dates ranging from August 2011 through October 2011 and ratings ranging from ''A'' to ''AA.'' In addition, as of December 31, 2010, the Company had long-term investments of $15,001,765, consisting of four GSE securities with maturity dates ranging from February 2012 through September 2012.

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.

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.

2. Summary of Significant Accounting Policies – (continued)

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

Fair Value Measurements and Disclosures

In January 2010, the Financial Accounting Standards Board (''FASB'') issued Accounting Standards Update (''ASU'') 2010-06, *Fair Value Measurements and Disclosures — Topic 855* (''ASU 2010-06''). ASU 2010-06 provides amendments to Accounting Standards Codification (''ASC'') 820-10, *Fair Value Measurements* (''ASC 820-10''), which was originally issued as SFAS No. 157, *Fair Value Measurements*, and adopted by the Company as of January 1, 2008). ASC 820-10 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 820-10 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 three categories (level 1, level 2 or level 3). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. Furthermore, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques. The new disclosures and clarifications of existing disclosures required by ASU 2010-06 are effective for interim and annual reporting periods beginning after December 31, 2009 (except for disclosures in the reconciliation of activity within level 3, which are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years). The Company adopted ASU 2010-06 as of January 1, 2010, and the adoption did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2010. See Note 11.

Subsequent Events

In February 2010, the FASB issued ASU 2010-09, *Subsequent Events (Topic 855): Amendments to Certain Recognition and Disclosure Requirements* (''ASU 2010-09''), to amend ASC 855, *Subsequent Events* (''ASC 855''). 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, companies are not required to 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, and the evaluation did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2010.

Revenue Recognition

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition — Milestone Method (Topic 605)* (''ASU 2010-17''). ASU 2010-17 provides guidance for defining a milestone and criteria for determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Research or development arrangements frequently include payment provisions whereby a portion or all the consideration is contingent upon milestone events, such as the successful completion of phases in a clinical study or achieving a specific result or regulatory approval. An entity often recognizes these milestone payments as revenue in their entirety upon achieving the related milestone, commonly referred to as the

2. Summary of Significant Accounting Policies – (continued)

milestone method. Authoritative guidance on the use of the milestone method did not previously exist in the accounting literature. ASU 2010-17 is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. The Company's adoption of ASU 2010-17 did not have a material impact on the Company's consolidated financial statements as of and for the year ended December 31, 2010.

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*) (''ASC 260''). Under the provisions of ASC 260, basic net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is computed by dividing the net loss for the period 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 2,615,688, 2,543,235 and 2,117,392 shares as of December 31, 2010, 2009 and 2008, 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. Comprehensive Loss

ASC 220, *Comprehensive Income* (formerly SFAS No. 130) (''ASC 220''), establishes standards for reporting and display of comprehensive loss and its components in the condensed 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.

The components of the Company's comprehensive loss are as follows:

	Years Ended December 31,		
	2010	2009	2008
Net loss	$(33,937,151)	$(21,157,414)	$(8,004,997)
Other comprehensive loss:			
Net unrealized gain on foreign currency translation	111	—	—
Net unrealized (loss) gain on investments classified as available for sale	(19,960)	(118,155)	135,542
Comprehensive loss	$(33,957,000)	$(21,275,569)	$(7,869,455)

5. Royalty Income, Royalty Expense and Sublicense Fee Income

Royalty Income

The Company has certain agreements with Luitpold that cover an exclusive worldwide sublicense and license, trademark license, concurrent use, supply and royalty income relationship. In 2003, the Company entered into an exclusive sublicense agreement with Luitpold, pursuant to which the Company licensed to Luitpold the rights to the exclusive worldwide marketing, distribution and sales of *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''). In consideration for the license, Luitpold was obligated to pay royalties to the Company based on Luitpold's net sales of *GEM 21S*. Luitpold was required to report its sales and remit royalties to the Company on a quarterly basis.

5. Royalty Income, Royalty Expense and Sublicense Fee Income – (continued)

In January 2008, the Company sold its remaining orofacial therapeutic business to Luitpold, including the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. The Company recorded a $39,291,413 net gain in 2008, and received a total of $39,816,121 in cash from the sale transaction and $3,436,911 in cash from the sale of existing inventory. Of the total cash received, $10,000,000 was received subsequently in 2009, and accordingly, 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. The Company expects to continue to receive ongoing royalty payments based on net sales of *GEM 21S* by Luitpold at least through 2026.

The royalty income earned by the Company from Luitpold's sales of *GEM 21S* is classified as revenue on the Company's consolidated statements of operations in accordance with the accounting guidance of ASC 605, *Revenue Recognition*.

Royalty Expense

The Company co-owns certain U.S. patents with Harvard University (''Harvard''). In 2001, the Company entered into a license agreement with Harvard that provides it with the exclusive worldwide license to these patents, which are directed towards the use of recombinant platelet derived growth factor (''rhPDGF'') and other growth factors for the healing and restoration of bone and other tissue defects. Under the license agreement, the Company is obligated to make certain royalty and milestone payments to Harvard.

The Company has licensed a number of U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. As a part of the licensing agreement relating to such patents, the Company agreed to pay royalties based on net sales of licensed products under the agreement on a country-by-country basis during the term of the agreement. In accordance with such agreement, the Company is required to make minimum royalty payments for sales of an orthopedic product as follows: $1,000,000 in the first full year following the first commercial sale, and $1,500,000 and $2,500,000 in the second and third years, respectively. Based upon the 2009 Canadian regulatory approval of Augment, the Company shipped its first order of Augment to a Canadian distributor in December 2009. Accordingly, the Company recorded $1,000,000 in royalty expense on its consolidated statement of operations for the year ended December 31, 2010.

The royalty expense incurred by the Company is classified as a general and administrative expense on the Company's consolidated statements of operations in accordance with the accounting guidance of ASC 605-45-45, *Principal Agent Considerations*, and ASC 705, *Cost of Sales and Services*.

Sublicense Fee Income

Sublicense fee revenue represents the current amortization of the milestone payments the Company previously received from Luitpold. The U.S. Food and Drug Administration (''FDA'') approved the marketing of *GEM 21S* on November 18, 2005. As a result, the Company received an initial milestone payment of $15,000,000 pursuant to the terms of the Company's 2003 sublicense agreement with Luitpold. In December 2007, the Company received an additional $5,000,000 milestone payment from Luitpold in connection with 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 income represents the current amortization of the $20,000,000 proceeds from these two milestones.

6. Inventory

Inventory at December 31 is summarized as follows:

	2010	2009
Raw materials	$1,413,306	$ 814,925
Work in progress	902,550	—
Finished goods	234,206	229,380
	2,550,062	1,044,305
Reserve for obsolescence	(291,869)	—
	$2,258,193	$1,044,305

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. Work in progress inventory consists of production runs of cups and vials that are not yet approved and finalized for packaging. Finished goods inventory consists of finished cups and vials ready for packaging, as well as packed kits of Augment™ Bone Graft (''Augment'') ready for sale. Shipping and handling costs are included in the cost of sales of the product. An allowance has been recorded as of December 31, 2010 for obsolescence, shrinkage and potential scrapping of product batches that may not be released for sale.

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. The cost of sales will vary in direct correlation to the volume of product sales of Augment kits. Certain raw materials were purchased during fiscal years that preceded the completion of the Phase III clinical trials. As a result, the Company expensed the pre-launch inventory used for clinical trials as research and development expense recorded on its consolidated statements of operations.

7. Property and Equipment

Property and equipment at December 31 is summarized as follows:

	2010	2009
Equipment, IT hardware and purchased software	$ 3,236,367	$ 3,061,623
Furniture and fixtures	735,892	722,920
Leased equipment	190,208	188,963
Construction in process	1,160,301	993,457
Leasehold improvements	4,049,917	4,047,159
Equipment, IT hardware, purchased software, furniture and fixtures and leased equipment, not place in service	4,342,143	4,182,898
	13,714,828	13,197,020
Less accumulated depreciation and amortization	(6,122,008)	(5,040,178)
	$ 7,592,820	$ 8,156,842

In May 2007, the Company entered into a lease agreement for approximately 32,000 square feet of office space at the Company's headquarters in Franklin, Tennessee. This lease replaced in its entirety the Company's previous lease dated April 2004, as amended in July 2005. The Company has made leasehold improvements to this facility, and amortizes such costs over the life of the lease, which continues until December 31, 2016.

In August 2007, the Company entered into a lease agreement for approximately 30,000 square feet of space in a new building located at the Company's headquarters 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 when completed.

7. Property and Equipment – (continued)

Construction in process consists of engineering design and planning costs related to the new manufacturing facility that have been incurred as of the balance sheet date.

The Company has purchased equipment, IT hardware, purchased software, furniture and fixtures, and leased equipment which has not yet been placed into service. These purchases include $4,202,197 in equipment that the Company intends to use in the new manufacturing facility and $125,834 in IT network servers as of December 31, 2010. In addition, under agreements with various equipment suppliers for the manufacture of the equipment for the new manufacturing facility, as of December 31, 2010, the Company has estimated purchase commitments of $930,558 remaining to be paid through the year 2012.

See Note 14 for additional information regarding the Company's operating lease agreements, leased equipment, and purchase commitments.

8. 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.

9. Capitalized Patent License Fees

As of December 31, 2010, the Company owned or co-owned approximately five non-expired U.S. patents, approximately one U.S. patent which is a non-expired patent due to a patent term extension, a number of non-expired foreign patents, and numerous pending U.S. and foreign patent applications. The Company has exclusively licensed approximately four non-expired U.S. patents and a number of non-expired foreign patents.

The Company has incurred, and continues to incur, costs related to patent license fees and patent applications for Augment, Augment Injectable, Augment Rotator Cuff and the Company's other product candidates in the pipeline. These payments have been capitalized as patent license fees and will be amortized over their remaining patent life. The termination dates of the patents range from June 2025 to January 2026. In 2010, the Company wrote-off certain capitalized costs totaling $12,378,492 related to patents that had expired and were fully amortized as of December 31, 2010. As of December 31, 2010 and 2009, the Company had remaining capitalized costs totaling $1,893,633 and $12,532,346, respectively, related to the acquisition of its patent licenses.

Based on agreements in place and payments made as of December 31, 2010, amortization expense related to capitalized patent license fees is expected to be $27,136 for each of the five years ended December 31, 2015.

10. Investments

As of December 31, 2010, the Company had short-term investments of $65,751,039 classified as available-for-sale consisting of U.S. government sponsored enterprise (''GSE'') securities totaling $60,585,169 and corporate bonds totaling $5,165,870. The short-term GSE securities have maturity dates ranging from January 2011 through November 2011, and the corporate bonds have maturity dates ranging from August 2011 through October 2011 and ratings ranging from ''A'' to ''AA.'' In addition, as of December 31, 2010, the Company had long-term investments of $15,001,765, consisting of four GSE securities with maturity dates ranging from February 2012 through September 2012.

10. Investments – (continued)

In 2008 and 2009, the Company had investments in certain auction rate securities (''ARS''). As of December 31, 2008, the Company had estimated the fair value to be $46,624,040, representing an ''other-than-temporary'' impairment loss of $13,375,960 recorded in investment income (loss) in its consolidated statement of operations for the year ended December 31, 2008. 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 and a net realized gain of $5,800,550 reclassified from unrealized gains and recorded in investment income (loss) in its consolidated statement of operations for the year ended December 31, 2009. Additionally, 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. The settlement payment is recorded as a gain in the Company's consolidated statement of operations for the year ended December 31, 2009.

In 2010, there were no declines in market value of investments judged by the Company to be other-than-temporary. Realized gains and losses on investments in marketable securities sold are included in investment income (loss) in the accompanying consolidated statements of operations for the year ended December 31, 2010.

11. Fair Value Measurements

As of January 1, 2008, the Company adopted ASC 820-10, *Fair Value Measurements* (originally issued as SFAS No. 157, *Fair Value Measurements*) (''ASC 820-10''), 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 820-10 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.

As of January 1, 2010, the Company adopted ASU 2010-06, *Fair Value Measurements and Disclosures — Topic 855* (''ASU 2010-06''). ASU 2010-06 provides amendments to ASC 820-10 to require new disclosures for transfers in and out of levels 1 and 2, as well as a reconciliation of activity within level 3. In addition, ASU 2010-06 provides amendments that clarify existing disclosures regarding levels of disaggregation and inputs and valuation techniques.

In accordance with ASC 820-10, as amended by ASU 2010-06, 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.

11. Fair Value Measurements – (continued)

As of December 31, 2010, financial assets and liabilities subject to fair value measurements were as follows:

Assets	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$11,628,329	$—	$—	$11,628,329
Short-term investments (GSE and corporate bonds)	65,751,039	—	—	65,751,039
Long-term investments (GSE securities)	15,001,765	—	—	15,001,765
Total cash and investments	$92,381,133	$—	$—	$92,381,133

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 consist of GSE securities and corporate bonds classified as available for sale. The Company's long-term investments consist of four GSE securities with maturity dates ranging from February 2012 through September 2012. The carrying amounts reported in the consolidated balance sheets approximate the fair value of the Company's short-term and long-term investments.

12. Other Accrued Expenses

Other accrued expenses at December 31 are summarized as follows:

	2010	2009
Royalties payable	$1,007,916	$ 89,954
Professional fees	728,956	5,000
Taxes and licenses	87,834	30,817
Patent costs	56,273	—
Facilities & utilities	21,262	—
Other	6,439	9,299
	$1,908,680	$135,070

13. Capital Shares

Public Offering of Common Stock

In July 2010, the Company sold 5,642,280 shares of common stock at a price of $8.50 per share, resulting in net proceeds of approximately $45.0 million after deducting underwriting discounts, commissions and expenses.

14. Commitments and Contingencies

Operating Leases

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

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 2010 the Company paid Noblegene monthly rent of $53,642, as adjusted, plus additional proportionate operating and insurance costs

14. Commitments and Contingencies – (continued)

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. 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 sheets.

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 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. Under the terms of the January 2009 amended lease, in 2010 the Company paid Noblegene monthly rent of $66,950, as adjusted.

14. Commitments and Contingencies – (continued)

The Company recognized rent expense of $1,435,036, $839,875 and $641,371 for the operating leases with Noblegene associated with the office space and new manufacturing space for the years ended December 31, 2010, 2009 and 2008, respectively. The future commitments as of December 31, 2010 under these operating lease agreements are as follows:

2011	$ 1,472,438
2012	1,516,611
2013	1,562,109
2014	1,608,973
2015	1,657,242
Thereafter	4,432,238
Total	$12,249,611

In addition to rent expense, the Company recognized expenses for common area maintenance, taxes, and certain insurance associated with the office space and new manufacturing space of $303,324, $312,374 and $239,604 for the years ended December 31, 2010, 2009 and 2008, respectively.

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 accumulated amortization of such equipment at December 31, 2010 and 2009 totaled $36,983 and $9,338, respectively. The net book value of such equipment at December 31, 2010 and 2009 totaled $279,058 and $179,625, respectively.

The future commitments as of December 31, 2010 under these capital lease agreements are as follows:

	Principal	Interest	Total
2011	$ 78,665	$ 5,339	$ 84,004
2012	83,920	3,691	87,611
2013	85,668	1,943	87,611
2014	46,056	494	46,550
2015	—	—	—
Total	$294,309	$11,467	$305,776

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, 2010, the Company has paid a total of $4,202,197 for the equipment, which is classified as equipment not placed in service (see Note 7). In addition, under these agreements, the Company has estimated remaining purchase commitments of $847,558 for 2011 and $83,000 for 2012.

Litigation

In the ordinary course of business, the Company is subject to legal claims and assessments. However, there are no such claims or assessments that currently exist that in the opinion of management are expected to have a material impact on the financial condition or operating results of the Company.

Employment Agreements

The Company has employment contracts with several individuals, which provide for base salaries, potential annual cash bonuses and long-term equity incentives. 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.

14. Commitments and Contingencies – (continued)

Supply Agreements

The Company has executed supply agreements with Novartis Vaccines and Diagnostics and with Cam Bioceramics BV. Under these agreements, the Company has agreed to certain minimum purchase commitments and/or binding orders of which there are commitments and binding orders of $2,801,711 for 2011 and estimated commitments and binding orders of $2,968,970 for 2012.

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 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 stock options granted by the Company to employees are generally structured to qualify as ''incentive stock options'' (''ISOs'') and stock options granted to non-employees, such as directors and consultants, are structured as ''non-qualified stock options'' (''NQSO''). 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 receives a tax deduction for the exercise of NQSOs. The Company has not recognized any income tax benefit for the three years ended December 31, 2010 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.

In general, stock option awards granted under the option plan vest 25% per year over a four-year period. The option plan currently provides 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 an 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.

Effective January 1, 2006, the Company adopted ASC 505, *Equity-Based Payments to Non-Employees* (''ASC 505''), and ASC 718, *Compensation — Stock Compensation* (formerly SFAS No. 123(R), *Share-Based Payment*) (''ASC 718''), using the modified prospective method of transition. Under that transition method, compensation expense recognized in the three years ended December 31, 2010 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.

15. Stock-Based Compensation – (continued)

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, 2010 as follows:

	2010	2009	2008
Risk free interest rate	2.19%	2.11%	2.85%
Expected dividend yield	—	—	—
Volatility factor of the expected market price	76% – 77%	77% – 79%	79%
Forfeiture rate	8.9%	6.9%	6.2%
Weighted average expected life of the option	4.4 to 8.0 years	4.2 to 8.0 years	4.3 to 8.0 years

Since there is a limited trading history for the Company's common stock, the expected volatility and forfeiture rates are based on historical data from three companies similar in size and value to the Company. The expected life 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 and adjusted for historical experience. The resulting weighted average expected life of the options granted to employees and non-employees is represented as a range. The Company's historical experience has shown that employees tend to exercise stock options as the options vest or upon termination, represented by the lower end of the range, whereas non-employee directors and/or consultants tend to hold the stock options longer term, represented by the higher end of the range. 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.

As of December 31, 2010, a total of 6,019,723 shares of common stock have been authorized by the board of directors for issuance under the option plan. In addition, as of December 31, 2010, a total of 2,615,688 options to purchase shares of common stock were issued and outstanding and a total of 1,266,258 shares of common stock had been issued upon the exercise of outstanding options, leaving a total of 2,137,777 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.

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, 2008	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		
Granted	729,741	$11.79		
Exercised	(419,747)	$ 3.77		
Forfeited, tendered or expired	(237,541)	$ 8.12		
Options at December 31, 2010	2,615,688	$10.59	9.0 years	$21.6
Options exercisable at December 31, 2010	1,091,271	$ 9.17	7.9 years	$ 2.2

15. Stock-Based Compensation – (continued)

The weighted-average grant-date fair value of options granted during the years ended December 31, 2010, 2009 and 2008 was $11.78, $8.70 and $13.31, respectively. The total intrinsic value of options exercised during the years ended December 31, 2010, 2009 and 2008 was $4,712,084, $955,904 and $2,293,814, respectively.

The total fair value of options vested during the years ended December 31, 2010, 2009 and 2008 was $5,141,862, $3,968,981 and $3,068,462, respectively. The fair value of vested and non-vested options 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 non-vested shares of stock options at December 31, 2010, and changes during the year ended December 31, 2010, is as follows:

	Shares	Weighted Average Grant-Date Fair Value
Non-vested at January 1, 2010	1,408,249	$11.20
Granted	729,741	$11.78
Vested	(474,497)	$10.84
Forfeited or expired (net of tenders)	(139,076)	$11.09
Non-vested at December 31, 2010	1,524,417	$11.60

Based on the Company's stock option grants outstanding at December 31, 2010, the Company has estimated the remaining unrecognized stock-based compensation expense to be $6,378,741 with a weighted average remaining amortization period of 2.5 years.

In accordance with the provisions of ASC 718, the Company recorded stock-based compensation expense in connection with the option plan totaling $3,983,667, $3,892,895 and $3,409,915 for the years ended December 31, 2010, 2009 and 2008, respectively. During the year ended December 31, 2010, the Company modified the terms of certain stock option awards for one employee to accelerate vesting by 12 months upon the employee's termination. The incremental stock-based compensation expense resulting from this modification totaled $125,775, and is included in the Company's net loss for the year ended December 31, 2010. No income tax benefit related to the Company's stock-based compensation arrangements is included in its net loss.

2005 Employee Stock Purchase Plan

In 2005, the Company's board of directors adopted the 2005 Employee Stock Purchase Plan (the ''purchase plan''). The 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 shares of common stock 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, 2010, a total of 111,243 shares of common stock remain 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 $48,771, $34,260 and $33,380 during the years ended December 31, 2010, 2009 and 2008, respectively.

15. Stock-Based Compensation – (continued)

401(k) Profit Sharing Plan

Effective January 1, 2004, the Company began sponsoring the 401(k) Profit Sharing Plan & Trust (the ''401(k) plan''), which is a defined contribution retirement plan covering substantially all the Company's employees, subject to certain minimum age and service requirements. Participation in the 401(k) plan is optional. The Company provides matching contributions at the discretion of the Company's board of directors, and generally consists of matching contributions in shares of the Company's common stock valued at up to 4% of eligible employee compensation. Such matching contributions, if approved, are generally awarded during the first quarter of each calendar year, but cover the previous calendar year just ended resulting in compensation expense recorded in that previous calendar year.

In September 2010, the Company's board of directors approved an amendment to the 401(k) plan that will make the Company's match for the 2011 fiscal year non-discretionary. In addition, the matching shares will vest immediately. These changes were made in order to convert the Company's plan to a safe harbor plan, which will eliminate the need for annual discrimination testing.

As of December 31, 2010, there were 41,344 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 $234,416, $339,950 and $0 for the years ended December 31, 2010, 2009 and 2008, respectively.

16. 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 $0, $46,127 and $74,882 for the years ended December 31, 2010, 2009 and 2008, respectively.

Section 223 Health Savings Account Plan

Effective January 1, 2010, the Company began offering employees the benefit of participating in a Section 223 Health Savings Account Plan, whereas the Company and the employee may make contributions to a Health Savings Account (''HSA'') under section 223 of the Internal Revenue Code if the employee is covered by a high deductible health plan (''HDHP''). The Company made contributions of $345,353 for the year ended December 31, 2010.

17. Income Taxes

At December 31, 2010, the Company had federal net operating loss (''NOL'') carryforwards of $96,491,551, of which $2,280,554 originated from the disqualifying disposition of stock options. The federal NOL carryforwards will begin to expire in 2022. State NOL carryforwards at December 31, 2010 totaled $84,115,388 and will expire between 2013 and 2030. Foreign NOL carryforwards at December 31, 2010 totaled $173,938 and will begin to expire 2030. To the extent NOL carryforwards, when realized, related to the stock option deductions for disqualifying dispositions, the resulting benefits will be credited to stockholders' equity. 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), the Company's management believes that there is not sufficient evidence at December 31, 2010 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2010. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including loss carryforwards.

17. Income Taxes – (continued)

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.

The Company incurred net operating losses, and no income tax expense has been recorded, for the three years ended December 31, 2010.

The Company files income tax returns in the U.S. federal jurisdiction and various state and foreign 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 2006.

Effective January 1, 2007, the Company adopted a provision of ASC 740 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, 2010.

The benefit for income taxes consists of the following amounts:

	Years Ended December 31,		
	2010	2009	2008
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current	—	—	—
Deferred:			
Federal	(11,282,566)	(6,575,611)	(2,349,485)
State	(489,727)	(284,703)	(95,857)
Total deferred	(11,772,293)	(6,860,314)	(2,445,342)
Total benefit, before valuation allowance	(11,772,293)	(6,860,314)	(2,445,342)
Change in valuation allowance	11,772,293	6,860,314	2,445,342
Total benefit, after valuation allowance	$ —	$ —	$ —

17. Income Taxes – (continued)

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

	2010	2009
Deferred tax assets (liabilities) – current:		
Inventory reserve	$ 111,377	$ —
Deferred revenue	370,605	370,509
Accrued salaries and paid time off	795,558	811,380
Other	9,998	10,654
Subtotal deferred tax assets – current	1,287,538	1,192,543
Deferred revenue – *GEM 21S*	—	(9,528)
Subtotal deferred tax liabilities – current	—	(9,528)
Total net deferred tax assets (liabilities) – current	$ 1,287,538	$ 1,183,015
Deferred tax assets (liabilities) – noncurrent:		
Net operating loss carryforwards	$ 35,711,032	$ 23,744,004
Fixed assets (tax basis difference)	948,954	760,538
Intangibles (tax basis difference)	—	261,978
Deferred revenue	5,563,152	5,932,202
Deferred compensation on stock options	329,082	247,231
Unrealized loss on investments	982	2,895
Other	347,266	283,850
Total deferred tax assets (liabilities) – noncurrent	42,900,468	31,232,698
Net deferred tax assets (liabilities)	44,188,006	32,415,713
Valuation allowance	(44,188,006)	(32,415,713)
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:

	2010	2009	2008
Federal income tax benefit at U.S. statutory rates	$(11,538,476)	$(7,193,521)	$(2,721,699)
State income taxes, net of federal benefit	(1,261,703)	(737,533)	(218,690)
Permanent differences	1,226,479	1,151,082	824,902
Change in valuation allowance	11,772,293	6,860,314	2,445,342
Other	(198,593)	(80,342)	(329,855)
Total income tax benefit for continuing operations	$ —	$ —	$ —

18. Related Party Transactions

All related party transactions are reviewed and approved by the audit committee, as required by the audit committee charter.

18. Related Party Transactions – (continued)

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, 2010, Harvard paid $34,284 to Dr. Lynch, for a cumulative total of $974,637 as of December 31, 2010, 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 its 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 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, 2010, 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, 2010, 2009 and 2008, the Company paid Dr. Friedlaender $10,000, $5,000 and $5,000, respectively, for consulting services performed pursuant to the consulting agreements.

18. Related Party Transactions – (continued)

Consulting Agreement with a Relative of a Member of the Board of Directors

In December 2009, the Company entered into a one-year consulting agreement with Dr. Michael Ehrlich for consulting services relating to the development of products in the orthopedic market. The 2009 agreement extends the consulting relationship that the Company had with Dr. Ehrlich pursuant to a December 2006 consulting agreement. In October 2004, the Company appointed Dr. Michael Ehrlich's son, Chris Ehrlich, as a member of its board of directors. For the years ended December 31, 2010, 2009 and 2008, the Company paid Dr. Michael Ehrlich $4,875, $4,000 and $5,000, 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.

	Revenue	Loss From Operations	Net Loss	Net Loss Per Share – Basic	Net Loss Per Share – Diluted
Year ended December 31, 2010					
1st Quarter	$352,329	$ (8,524,540)	$ (8,522,241)	$(0.39)	$(0.39)
2nd Quarter	374,564	(7,683,575)	(7,655,085)	(0.35)	(0.35)
3rd Quarter	353,139	(7,812,468)	(7,751,360)	(0.29)	(0.29)
4th Quarter	393,493	(10,542,965)	(10,008,465)	(0.36)	(0.36)

	Revenue	Loss From Operations	Net Income (Loss)	Net Income (Loss) Per Share – Basic	Net Income (Loss) Per Share – Diluted
Year ended December 31, 2009					
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

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 10, 2011

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 10, 2011
/s/ Larry Bullock Larry Bullock	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2011
/s/ Larry W. Papasan Larry W. Papasan	Chairman of the Board of Directors	March 10, 2011
/s/ Thorkil K. Christensen Thorkil K. Christensen	Director	March 10, 2011
/s/ Chris Ehrlich Chris Ehrlich	Director	March 10, 2011
/s/ Charles Federico Charles Federico	Director	March 10, 2011
/s/ Gary E. Friedlaender, M.D. Gary E. Friedlaender, M.D.	Director	March 10, 2011
/s/ James G. Murphy James G. Murphy	Director	March 10, 2011
/s/ Douglas Watson Douglas Watson	Director	March 10, 2011

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).

Exhibit No.	Description
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).
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).

Exhibit No.	Description
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).
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 from registrant to Deutsche Bank AG, Cayman Islands Branch, 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 between registrant and Deutsche Bank AG, Cayman Islands Branch, 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).

Exhibit No.	Description
10.46	Securities Account Control Agreement between registrant and Deutsche Bank AG, Cayman Islands Branch, 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 from Deutsche Bank AG, Cayman Islands Branch, to registrant 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).
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**	Release and Settlement Agreement, effective as of December 21, 2009, between the registrant and Deutsche Bank Securities, Inc. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009).
10.57**	Amended and Restated Manufacturing and Supply Agreement, effective as of December 1, 2009, between the registrant and Novartis Vaccines and Diagnostics, Inc. (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2009).
10.58**	First Amendment to Development, Manufacturing and Supply Agreement, effective August 15, 2006, between the registrant and Kensey Nash Corporation (Incorporated by reference to the registrant's Annual Report on Form 10-K/A for the year ended December 31, 2009).
10.59**	Second Amendment to Development, Manufacturing and Supply Agreement, effective November 1, 2006, between the registrant and Kensey Nash Corporation (Incorporated by reference to the registrant's Annual Report on Form 10-K/A for the year ended December 31, 2009).
10.60**	Third Amendment to Development, Manufacturing and Supply Agreement, effective April 2, 2008, between the registrant and Kensey Nash Corporation (Incorporated by reference to the registrant's Annual Report on Form 10-K/A for the year ended December 31, 2009).
10.61	Separation Agreement and Full Release between the registrant and Steven Hirsch dated September 29, 2010 (Incorporated by reference to the registrant's Form 8-K filed on September 30, 2010).

Exhibit No.	Description
10.62**	Fourth Amendment to Development, Manufacturing and Supply Agreement, effective September 30, 2010, between the registrant and Kensey Nash Corporation.
10.63	Amendment No. 1 to Amended and Restated Exclusive Sublicense Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated November 1, 2010 (Incorporated by reference to the registrant's Form 8-K filed on November 19, 2010).
10.64	Amendment No. 1 to Asset Purchase Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated November 1, 2010 (Incorporated by reference to the registrant's Form 8-K filed on November 19, 2010).
10.65	Amendment No. 1 to Agreement Terminating Research, Development and Marketing Agreement between the registrant and Luitpold Pharmaceuticals, Inc. dated November 1, 2010 (Incorporated by reference to the registrant's Form 8-K filed on November 19, 2010).
10.66**	Logistical Support Agreement between the registrant and Joint Solutions Alliance Corporation dated November 3, 2010.
10.67**	Supply Agreement between the registrant and Integra LifeSciences Corporation dated July 17, 2010.
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 for the period ended December 31, 2010 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 10, 2011

/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 for the period ended December 31, 2010 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 10, 2011

/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, 2010 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, Part I, 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.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 10, 2011

/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, 2010 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, Part I, 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.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 10, 2011

/s/ Larry Bullock

Larry Bullock
Chief Financial Officer

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Directors and Senior Management

Directors

Larry W. Papasan[2]
Chairman of the Board of Directors
Past President, Smith & Nephew Orthopedics

Thorkil K. Christensen
Chief Financial Officer of Novo A/S

Chris Ehrlich
Partner, InterWest Partners

Charles Federico[1][2]
Past President and Chief Executive Officer,
Orthofix International N.V.

Gary E. Friedlaender, M.D.[1][3]
Professor and Chair, Orthopaedics and
Rehabilitation, Yale School of Medicine;
Chief of the Department of Orthopaedics and
Rehabilitation, Yale New Haven Hospital

Samuel E. Lynch, D.M.D., D.M.Sc.
President and Chief Executive Officer,
BioMimetic Therapeutics, Inc.

James G. Murphy[2][3]
Vice President of Finance,
NMS Labs

Douglas Watson[1][3]
Past President and Chief Executive Officer,
Novartis Corporation, the US Subsidiary
of Novartis AG

(1) Member of the Compensation Committee
(2) Member of the Audit Committee
(3) Member of the Nominating and
Governance Committee

Senior Management

Samuel E. Lynch, D.M.D., D.M.Sc.[1]
President and Chief Executive Officer

Larry Bullock[1]
Chief Financial Officer

Earl M. Douglas[1]
Vice President and General Counsel

Bill Beasley
Vice President, Clinical Research

Hans Kestler
Vice President, Orthopedics and
Sports Medicine

R. Scott Ludecker
Vice President, Global Sales and Marketing

John McKay
Vice President, Quality and
Environmental, Health, Safety

James A. Monsor
Senior Vice President, Operations

Russ Pagano, Ph.D.[1]
Vice President of Regulatory and
Clinical Affairs

Leo Snel
Senior Vice President of Research &
Development, Protein Biochemistry

(1) Executive Officers

Corporate Headquarters
389 Nichol Mill Lane, Franklin, TN 37067
(615) 844-1280 | www.biomimetics.com

Annual Meeting
The annual meeting of stockholders will be held on Tuesday, June 14, 2011, at 8:00 a.m. CDT at the Company's headquarters.

Transfer Agent & Registrar
American Stock Transfer & Trust Company
59 Maiden Lane, New York, NY 10038
(800) 937-5449 | www.amstock.com

Independent Registered Public Accountants
Ernst & Young LLP
Nashville, TN

Legal Counsel
Morrison & Foerster LLP
New York, NY

Harwell Howard Hyne Gabbert & Manner, P.C.
Nashville, TN

Form 10-K/Investor Contact
A copy of the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission, may be obtained from the Company at no charge or can be accessed on our website or at www.sec.gov. Requests for the Annual Report on Form 10-K and other investor information should be directed to Kearstin Patterson, director of corporate communications, at the Company's corporate office, at www.biomimetics.com or by email to: info@biomimetics.com.

Stock Listing
The Company's common stock is traded on the NASDAQ Global Market under the symbol BMTI.

Cautionary Note Regarding Forward-Looking Statements
This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on the current intent and expectations of the management of BioMimetic. These statements are not guarantees of future performance and involve risks and uncertainties that are difficult to predict. There are many important factors that could cause actual results to differ materially from those indicated in the forward-looking statements. BioMimetic's actual results and the timing and outcome of events may differ materially from those expressed in or implied by the forward-looking statements because of risks associated with the marketing of BioMimetic's product and product candidates, unproven preclinical and clinical development activities, regulatory oversight, and other risks detailed in the Company's filings with the Securities and Exchange Commission. Except as required by law, BioMimetic undertakes no responsibility for updating the information contained in this report beyond the published date, whether as a result of new information, future events or otherwise.

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BioMimetic Therapeutics, Inc.
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615.844.1280 | www.biomimetics.com