2011
Annual Report

BioMimetic Therapeutics

BIOMIMETIC™

REJECT ORDINARY

Dear Fellow Shareholder:

2011 was a year of challenge and change for BioMimetic, its employees and its shareholders. The delays in the U.S. approval process for Augment® Bone Graft required us to take decisive steps to refocus our resources and re-evaluate our priorities. It has been a difficult period for the Company, but fortunately our team was prepared for the challenge, and we look forward to the significant milestones ahead of us.

Our near-term success is dependent on accomplishing three goals; approval of Augment Bone Graft in the United States, pursuing product approvals around the world and a successful U.S. launch of our new product offering, Augmatrix™ Biocomposite Bone Graft.

In early 2012, we began taking the necessary steps toward the advancement of these goals. We expect to submit our PMA amendment for Augment Bone Graft by mid-2012 with a final approvability decision anticipated between April 2013 and January 2014. In anticipation of approval, we are continuing to build out the commercial infrastructure necessary for market launch in the U.S. Augment Bone Graft was approved in Australia and New Zealand in the fourth quarter of 2011, and we anticipate approvals in several additional countries during 2012 and 2013.

We also recently began commercializing a new bone graft substitute product line in the U.S. called Augmatrix Biocomposite Bone Graft. The Augmatrix product line complements our existing orthobiologic portfolio and will enable us to establish a near-term commercial presence with surgeons and hospitals, while providing solutions to enhance the healing of injuries for which Augment Bone Graft will not initially be indicated.

As we reflect on the successes of our organization and the progress we continue to make, we are reminded of how fortunate we are to have a strong financial base, a promising product pipeline, and, most importantly, a group of talented and committed employees who believe that good science, good technology and perseverance will prevail.

At BioMimetic, it is our passion to develop and commercialize products that improve patient care, thereby improving the quality of life for orthopedic and periodontal patients around the world. We are proud of the lives we have been able to improve so far and remain dedicated to bringing safe, efficacious and cost effective products to market that improve the healing of musculoskeletal injuries. In short, we remain enthusiastic about the future of BioMimetic.

I look forward to reporting our progress on the achievement of these goals throughout 2012.

Sincerely,

Samuel E. Lynch

President and Chief Executive Officer

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

Annual Meeting
The annual meeting of stockholders will be held on Thursday, June 7, 2012, 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
Ropes & Gray LLP
Boston, MA

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, led 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, senior director of corporate communications, at the Company's corporate o ce, at 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

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, 2011

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, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was $102.2 million.

As of March 9, 2012, a total of 28,128,280 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 2012 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, 2011. 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.

Table of Contents

		Page
	PART I	
Item 1.	Business	1
Item 1A.	Risk Factors	31
Item 1B.	Unresolved Staff Comments	55
Item 2.	Properties	55
Item 3.	Legal Proceedings	56
Item 4.	Mine Safety Disclosures	56
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	57
Item 6.	Selected Financial Data	59
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operation	61
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	80
Item 8.	Financial Statements and Supplementary Data	81
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	81
Item 9A.	Controls and Procedures	81
Item 9B.	Other Information	84
	PART III	
Item 10.	Directors, Executive Officers and Corporate Governance	84
Item 11.	Executive Compensation	84
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	84
Item 13.	Certain Relationships and Related Transactions, and Director Independence	84
Item 14.	Principal Accountant Fees and Services	84
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	84

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’’ (Item 1), ‘‘Risk Factors’’ (Item 1A) and ‘‘Management’s Discussion and Analysis of Financial Condition and Results of Operations’’ (Item 7) contains ‘‘forward-looking statements.’’ Statements in this Annual Report on Form 10-K 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 of 1933, as amended (the ‘‘Securities Act’’) and Section 21E of the Exchange Act of 1934, as amended (the ‘‘Exchange Act’’). 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,’’ ‘‘seek’’ 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:

- timing, advancement and results of regulatory filings, clinical trials, and non-clinical studies, as well as potential regulatory approval of our product candidates in various countries around the world, including the regulatory approval of Augment® Bone Graft (‘‘*Augment*’’) in the United States and the European Union, and Augment® Injectable Bone Graft (‘‘*Augment Injectable*’’) in the United States, Canada, Australia, and the European Union;
- market acceptance of and demand for *Augment* or Augmatrix™ Biocomposite Bone Graft (‘‘*Augmatrix*’’) in any market and for our product candidates generally, including reimbursement prospects and the economic conditions that could adversely affect the level of demand for *Augment*, *Augmatrix* or our other product candidates;
- the potential expansion of our platform PDGF technology to a broad array of musculoskeletal applications or its ability to address unmet medical needs;
- 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;
- our commercialization strategy and transition to a commercial entity;
- estimates regarding our capital requirements, and anticipated timing of the need for additional funds;
- estimates regarding milestone payments to us or by us;
- securities claims, derivative claims, product liability claims, other litigation or claims or regulatory inquiries that have been and may be brought against us and our officers and directors;
- financial markets;
- the competitive environment; and
- the current economic uncertainty.

Any or all of our forward-looking statements may turn out to be inaccurate. 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’’ (Item 1A) 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.

We qualify all of the forward-looking statements in this Annual Report on Form 10-K 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 do not 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.

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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 therapies for orthopedic, sports medicine and spine applications.

Our Augment® platform of product and product candidates include an engineered version of recombinant human platelet-derived growth factor BB (''rhPDGF-BB''), one of the principal wound healing and tissue repair stimulators in the body. Our platform regenerative technology for promoting tissue healing and regeneration combines rhPDGF-BB with tissue specific matrices, when appropriate. The matrices are engineered or natural scaffold materials, such as Beta Tri-Calcium Phosphate (''ß-TCP''), which have a history of demonstrated safety and efficacy in previous uses.

Our platform regenerative technology may offer physicians advanced biological solutions to actively stimulate the body's natural tissue regenerative process. We believe that our product and product candidates, if approved by the appropriate regulatory authorities, may offer new, effective and in some cases less invasive treatment options for the repair of bone, cartilage, tendons and ligaments, thus helping patients recover from their injuries and improving their quality of life.

Through the commercialization of this patented technology, we seek to become the leading company in the field of regenerative medicine with the product and product candidates we are developing, including the following lead product and product candidates:

- Augment® Bone Graft (''*Augment*'');
- Augment® Injectable Bone Graft (''*Augment* Injectable''); and
- Augment® Rotator Cuff Graft (''*Augment* Rotator Cuff'').

In addition, in February 2012, we began marketing Augmatrix™ Biocomposite Bone Graft (''*Augmatrix*'') in anticipation of an expected commercial launch in the second quarter of 2012. *Augmatrix* is a family of tissue specific grafting materials previously cleared by the U.S. Food and Drug Administration (''FDA''). *Augmatrix* is available in multiple forms to suit an array of bone grafting challenges, including fracture repair and general bone void filling procedures. Refer to ''Introduction of Augmatrix™ Biocomposite Bone Graft'' below for more information.

We have completed or continue to sponsor clinical trials with our three leading product candidates (*Augment*, *Augment* Injectable and *Augment* Rotator Cuff) for use in multiple orthopedic and sports medicine indications including the treatment of foot and ankle fusions, the stimulation of wrist fracture healing, and the surgical treatment of rotator cuff tears.

We believe we have demonstrated that our technology is safe and effective in stimulating bone regeneration with various regulatory approvals of our initial product candidates, including:

- *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*'') — We developed *GEM 21S* as our first periodontal product. *GEM 21S* was approved by the U.S. Food and Drug Administration (''FDA'') in the United States in 2005 and Health Canada (''HC'') in Canada in 2006. In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the European Union (''EU''); however, we have since been informed that the EU regulatory authorities are re-evaluating the CE Mark. We sold *GEM 21S* to Luitpold Pharmaceuticals, Inc. (''Luitpold'') in early 2008; and
- *Augment* — We are developing *Augment* as our first orthopedic product. In 2009, *Augment* was approved by HC for commercialization in Canada. In 2011, *Augment* was listed by the Australian Therapeutics Goods Administration (''TGA'') in Australia and by the New Zealand Medicines and Medical Devices Safety Authority (''Medsafe'') in New Zealand, clearing the way for commercialization of *Augment* in Australia and New Zealand, respectively. We are currently

pursuing additional regulatory approvals in the United States as well as several markets located outside of the United States (''OUS''). Refer to ''Regulatory and Commercialization Activities Outside of the United States'' below for more information on our OUS activities.

FDA Review of Pre-Market Approval Application for Augment Bone Graft

A key business objective is obtaining FDA marketing approval of *Augment* for use as an alternative to autograft in hindfoot and ankle fusion procedures in the United States. Significant recent events related to this endeavor are described below.

FDA Advisory Panel Meeting

In May 2011, the FDA's Medical Devices Advisory Committee conducted a meeting of its Orthopaedic and Rehabilitation Devices Panel (the ''panel'') to discuss, make recommendations, and vote on information related to our Pre-Market Approval (''PMA'') application for *Augment* for the treatment of hindfoot and ankle fusions in the United States. The FDA's advisory committees provide independent expert advice to the agency on a range of issues, including questions related to the development and evaluation of products regulated by FDA, such as assessment of a product's benefit-risk profile. The FDA is not bound by or limited to the advisory panel's recommendations. The panel voted in favor of *Augment* on each of the three voting questions posed by FDA, voting:

- 12 to 6 in support of the safety of *Augment* for use as an alternative to autograft in hindfoot and ankle fusion procedures;
- 10 to 8 in support of the efficacy of *Augment* for use as an alternative to autograft in hindfoot and ankle fusion procedures; and
- 10 to 8 that *Augment* demonstrates a reasonable benefit to risk profile for the same indication.

Augment received strong support among clinicians on the panel with nine of 12 voting in favor of a reasonable risk to benefit profile and unanimous favorable recommendations on all three votes from the three foot and ankle specialists and two oncologists. Also during the panel meeting, the FDA presented the panel with a number of non-voting questions that sought the panel's input with respect to various issues.

FDA Post-Panel Response Letter

In January 2012, we announced the receipt of a comprehensive post-panel response letter (the ''letter'') from the FDA related to our PMA application for *Augment*. The FDA acknowledged that the panel voted in favor of a reasonable assurance of safety, effectiveness and a positive benefit to risk ratio; however, the FDA stated that ''notwithstanding the Advisory Panel's recommendation, the PMA, without additional information, must be considered not approvable and that... to place the Company's PMA in approvable form, the Company must amend it to include the following...'' The letter listed the information that we would need to submit, and the FDA to find acceptable, for the PMA application to be approvable. The letter outlined a pathway that could potentially lead to approval without additional clinical trials to support the safety and effectiveness of *Augment*.

In the letter, the FDA requests that we submit additional information from the *Augment* pivotal study as it relates to the product's safety and effectiveness, as well as additional information relating to antibody safety and reproductive issues. The FDA also requested that we submit additional information relating to post-approval studies to monitor the cancer safety of the product and further evaluate its pharmacokinetic (''PK'') profile in humans.

Based on our assessment of the letter, the FDA's key requests for additional information regarding the pivotal study are as follows:

- A re-reading of all 24-week CT scans by the original musculoskeletal radiologist, and at least one additional radiologist, and additional statistical analyses correlating the radiological outcomes to the clinical outcomes to allow FDA to evaluate the ''robustness'' of the data, given the differences in the outcome of the intent-to-treat and the modified-intent-to-treat patient population analyses;
- Further analysis of all serious study adverse events and re-categorization of all secondary surgeries as failures; and

- Stratification of results by various subgroup patient populations (e.g., patients with degenerative disease or patients with risk factors such as smoking, diabetes or obesity), and stratification of the subgroup data based on the amount of *Augment* or autograft used.

As part of our efforts to address the FDA's key requests for additional information required by the *Augment* PMA post-panel response letter, our independent radiologist is proceeding with re-reading all the 24-week CT scans. In addition, a new independent radiologist working through a contract research organization that specializes in image analysis will also read all the 24-week CT scans. Our original radiologist has explained and demonstrated to the new radiologist the methods he utilized in reading the original CT scans. From these new readings, we will provide the FDA with an intra-reader analysis (which demonstrates the consistency of the results from multiple readings by the same radiologist of the same CT scan) and inter-reader reliability analysis (which shows the consistency among different readers). We previously provided the FDA with an intra-reader analysis based on 53 patients and found an 85% concordance between the two readings. However, in the letter, the FDA has now requested this analysis for all treated patients. These analyses will consist of standard reliability statistics; for example, concordance, correlation and kappa.

Subsequent Discussions with FDA

In January 2012, we met with the FDA review team for our PMA application for *Augment*. After that meeting, we reiterated our previous guidance regarding the timing of our submission of an amendment to our PMA and the anticipated date of the final decision by the FDA on the approvability of the *Augment* PMA. Given our desire to focus our attention on addressing the FDA's issues related to the *Augment* PMA, and conserve resources until there is further clarity from the FDA regarding *Augment*, we have voluntarily suspended additional screening and enrollment of patients in our *Augment* Injectable clinical program.

Based on our discussions with the FDA in February 2012, we currently anticipate that information regarding the potential tumor promotion risk of PDGF in another product called Regranex® will be included in our labeling, but at this time we do not anticipate that such information will be required in the form of a black box warning. While we anticipate that our labeling will include information on Regranex (a topical cream containing PDGF that is indicated for the treatment of diabetic foot ulcers and owned by Healthpoint Biotherapeutics), we also anticipate it will include the differences between Regranex and *Augment* particularly as it pertains to dosage and frequency of use of the two products. In addition, we anticipate that the language in our labeling concerning potential carcinogenic risk will also include our pre-clinical data (e.g., long term carcinogenicity, long term toxicity, reproductive toxicity, and PK studies). We also discussed with the FDA possibly including in our labeling the results of the human PK study that we completed in December 2011. The study demonstrated no detectable change in circulating serum levels of rhPDGF-BB after *Augment* is applied in foot and ankle fusions. Although our expectations with regard to the *Augment* labeling are based on discussions with the FDA, we have not received any formal written communication from the FDA providing definitive decisions with respect to these issues. In addition, during our discussions the FDA emphasized that they may change their position at any time as warranted by further analyses or clinical findings.

Next Steps

We currently anticipate that by the middle of 2012 we will submit an amendment to the *Augment* PMA that will include the requested additional information. If the submission is timely and satisfactorily addresses the FDA's issues, product approval could occur between April 2013 and January 2014. Although we are confident that we can compile and submit the additional information requested by the FDA, there can be no assurance that the FDA will be satisfied with our response. The FDA noted throughout the letter that if we cannot provide the requested additional information, or if the additional information does not address FDA's issues or it raises new concerns, then a new clinical trial may be required. We continue, however, to believe in the safety and effectiveness of *Augment* and remain optimistic about obtaining FDA approval of the product candidate.

As we work through this process, we continue to carefully manage expenses as well as our cash and investments in order to be in a position to quickly respond to these requests from the FDA and be in a position to begin commercialization of *Augment* in the United States.

Regulatory and Commercialization Activities Outside of the United States

We are currently pursuing additional regulatory approvals in the United States as well as several OUS markets. Outside of the United States, our current focus is on near-term approvals where we can access the market within the next 12 to 15 months, or less. In addition to our efforts for the commercial adoption of *Augment* in Canada, Australia and New Zealand, the additional potential OUS markets we are pursuing include countries in Europe, the Middle East, Asia and Latin America.

Canada

We remain focused on the commercial adoption of *Augment* in Canada, which was approved by HC in the fourth quarter of 2009. We recorded product sales revenues of approximately $0.3 million for the year ended December 31, 2011. In September 2011, we contracted with a new distribution partner with extensive experience in Orthopaedic sales in the Canadian marketplace. Our new distribution partner has developed a network of independent sales agencies, and currently utilizes over 30 sales representatives covering all of Canada. We have supplemented these efforts with the assistance of our U.S. based Area Sales Directors who are providing technical product support and training to sales representatives, surgeons and hospital administration. We do not anticipate significant revenues from sales of *Augment* in Canada in the near term.

In February 2012, we announced results of our 30-patient Canadian *Augment* Rotator Cuff pilot clinical trial. *Augment* Rotator Cuff achieved its primary safety endpoint, which was evaluated by a comparison of adverse events between the two treatment groups, and no device-related serious adverse events (''SAE'') were reported. Refer to ''Clinical Trials and Product Development Programs'' for more information.

Australia and New Zealand

Another key business objective is the successful commercial launch of *Augment* in Australia and New Zealand. In October 2011, the TGA cleared our medical device application for *Augment*, which was subsequently listed on the Australian Register of Therapeutic Goods (''ARTG''), clearing the way for commercialization of the product in Australia. In December 2011, Medsafe listed *Augment* on the Web Assisted Notification of Devices (''WAND''), clearing the way for commercialization of the product in New Zealand.

We will sell *Augment* through an exclusive medical device distributor in Australia and New Zealand. This distributor is a sales organization with a 30 person sales team throughout Australia and New Zealand. Reimbursement for patients in Australia's Private Health Insurance setting is established biannually, which should lead to reimbursement for *Augment* in the second half of 2012 or early 2013, enabling a full launch in Australia at that time. However, we do not anticipate significant revenues from sales of *Augment* in Australia and New Zealand.

Europe

In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. We believe this CE Mark, obtained on behalf of Luitpold, triggers a $10.0 million final milestone payment due to us from Luitpold pursuant to the terms of our sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified us that it is evaluating whether the milestone conditions have been satisfied. We are considering our options in the event Luitpold does not make the payment.

We are seeking approval for *Augment* in Europe as a medical device under the CE Mark procedure, which is designed to provide a single marketing approval for all countries included in the EU. Accordingly, we submitted a device application to a Notified Body in Europe for the approval of *Augment*. As a result of Luitpold's request for a re-evaluation of the CE Mark for *GEM 21S*, the EU regulatory authorities have postponed their review of our *Augment* CE Mark application until their re-evaluation of the CE Mark for *GEM 21S* is completed. Therefore, approval of the *Augment* CE Mark will be delayed. We are not able to provide updated guidance on the timing for potential receipt of the *Augment* CE Mark until the *GEM 21S* re-evaluation is complete.

Introduction of Augmatrix™ Biocomposite Bone Graft

In February 2012, we introduced *Augmatrix*, a new bone graft substitute product line. The *Augmatrix* product line is comprised of carbonate-apatite (calcium phosphate) and bovine Type I collagen and is designed to be combined with bone marrow aspirate (''BMA''). The products are available in multiple forms to suit an array of bone grafting challenges, including fracture repair and general bone void filling procedures. The product line has been FDA cleared for use in orthopedic indications and is ready for sale in the United States. Aggregate sales of bone graft substitutes in the United States are estimated to reach $1.7 billion in 2012, according to Millennium Research.

We entered into a supply agreement with Collagen Matrix, Inc. (''CMI'') under which CMI will supply their Matrix product to us for resale as part of our *Augmatrix* product line. The agreement provides that we shall have the exclusive right to purchase the Matrix product from CMI and the exclusive right to sell the Matrix product in all countries where it is approved for marketing or sale by the applicable regulatory authority.

We believe the addition of the *Augmatrix* product line will provide surgeons with a range of bone grafting solutions to procedures for which our rhPDGF-BB based offerings will not initially be indicated. The *Augmatrix* bone graft substitute platform complements our existing orthobiologic portfolio and will allow us to penetrate the large bone graft substitutes market earlier than anticipated. We expect to add offerings to the *Augmatrix* product line with the goal of expanding the sales of these products through a portion of our current distribution network, while establishing a commercial presence with surgeons and hospitals.

Industry Overview, Economic Outlook and Market Opportunities

According to industry data, the worldwide orthopedic market was estimated at $40 billion in 2011. This includes joint fusion and replacement, fracture repair, sports injury and spinal procedures. Growth in the worldwide orthopedic market is expected, driven by a potentially recovering economy, 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 expected 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, such as the bone graft substitutes described above, currently represents a meaningful proportion of revenue within the orthopedic and sports medicine market segments. 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.

Current Therapies Used by the Competition

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, the patient's general health and an evaluation of the risk factors. 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, which is the process of harvesting a patient's own tissues, is the leading procedure for replacing or supplementing lost bone matter. Using autologous 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 usually 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 mitigate 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 is very low to non-existent and therefore may be insufficient to assist the healing process.

Given the limitations associated with autografts, allografts and xenografts, synthetic bone grafts have become popular in the 2000's. 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 very small 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.

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 ‘‘Products and 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. Improved handling characteristics. 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 quantity and quality. Requires scaffold. Technique dependent. Concentrates inflammatory proteins. Unpredictable outcome.
BMPs	Stimulates bone growth. Bio-active osteoinductive proteins. Does not require painful graft harvesting.	Limited indications approved. High cost. Limited or no effect on softtissue healing. Potential for inappropriate bone formation and other serious complications. Neutralizing antibodies seen, indicating a potential immune system response. Requires refrigeration.
***Augment* and other BioMimetic 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. Predictable outcome.	Higher cost than currently available synthetics. Requires refrigeration. Limited initial indications.

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. Platelet rich plasma (''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, xenograft or allograft tissues.

Products and 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.

Ultimately, our goal is to commercialize our product and 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 ''Clinical Trials and Product Development Programs'' below for details regarding our previously completed or ongoing clinical studies.

The table below summarizes our current products and 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.
	Augmatrix Biocomposite Bone Graft	Fracture repair and general bone void filling procedures.
Sports Injury	*Augment* Rotator Cuff Graft	Rotator cuff tendon to bone repair.
	Augment Tendinopathy Injection	Injuries due to tendon overuse.

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 have evaluated *Augment* in several open clinical applications, including foot and ankle fusions and distal radius fractures. We believe we have demonstrated that our technology is safe and effective in stimulating bone regeneration with the Canadian regulatory approval of *Augment* in 2009 and the Australian and New Zealand regulatory clearance of *Augment* in 2011.

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. In May 2011, the FDA's Medical Devices Advisory Committee conducted a meeting of its Orthopedic and Rehabilitation Devices Panel (the ''panel'') to discuss, make recommendations, and vote on information related to our PMA application for *Augment*. The panel voted in favor of the safety of *Augment* (12 to 6), the efficacy of *Augment* (10 to 8), and that *Augment* demonstrates a reasonable benefit to risk profile (10 to 8). In January 2012, we announced the receipt of a comprehensive post-panel response letter (the ''letter'') from the FDA related to our PMA application for *Augment*. The letter stated that *Augment* was not approvable until certain additional requests from FDA were satisfied, and if those requests could not be satisfied with the data from the existing pivotal trial, a new study might be necessary. Based on our assessment of the letter, the FDA's key requests for additional information regarding the pivotal study include a re-reading of all 24-week CT scans, further analysis of all study adverse events, re-categorization of secondary surgeries as failures, and stratification of results by various subgroups. We currently anticipate that by the middle of 2012 we will submit an amendment to the *Augment* PMA that will include the requested additional information. If the submission is timely and satisfactorily addresses the FDA's issues, product approval could occur between April 2013 and January 2014.

Building on the successful approval of *GEM 21S* in the United States, Canada and the EU, as well as the approval of *Augment* in Canada, Australia and New Zealand, 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 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 regenerative 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*, *Augment* and our other product candidates. Although human studies to demonstrate rhPDGF-BB'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 bio-synthetic version of PDGF-BB produced using recombinant DNA technology.

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.

Summary of Clinical Trials and 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.

We currently have several clinical trials for orthopedic clinical development indications that are currently ongoing, which seek to establish the safety, clinical utility and/or effectiveness of *Augment*, *Augment* Injectable and *Augment* Rotator Cuff. In particular, the following studies are currently in progress:

Augment Bone Graft

(1) 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.

In October 2009, we announced top-line results from our *Augment* pivotal study, and in March 2010, we announced additional data on secondary end points included in the study. In July 2010, we announced the one-year results from the study.

We pursued a modular approach for filing our 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 May 2011, the FDA's Medical Devices Advisory Committee conducted a meeting of its Orthopedic and Rehabilitation Devices Panel (the ''panel'') to discuss, make recommendations, and vote on information related to our PMA application for *Augment*. The panel voted narrowly in favor of the safety, efficacy, and benefit-risk profile of *Augment*.

In January 2012, we announced the receipt of a comprehensive post-panel response letter (the ''letter'') from the FDA indicating our PMA application for *Augment* was not approvable. The letter outlined certain additional information needed to address the FDA's concerns. Based on our assessment of the letter, the FDA's key requests for additional information regarding the pivotal study include a re-reading of all 24-week CT scans, further analysis of all study adverse events, re-categorization of secondary surgeries as failures, and stratification of results by various subgroups. We currently anticipate that by the middle of 2012 we will submit an amendment to the *Augment* PMA that will include all of the requested additional information. If the submission is timely and satisfactorily addresses the FDA's issues, product approval could occur between April 2013 and January 2014.

(2) EU Augment Registration 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 was an open label trial, and has been, 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 used the data in conjunction with data from the North American pivotal trial and other trials to apply for product registration approval in the EU.

In 2011, we submitted a device application to a European Notified Body for the approval of *Augment*. We are seeking approval in Europe under the CE Mark procedure, which is designed to provide a single marketing approval for all countries included in the EU. Luitpold has requested a re-evaluation of the CE Mark for *GEM 21S*, and as a result, the EU regulatory authorities have postponed their review of our *Augment* CE Mark application until their re-evaluation of the CE Mark for *GEM 21S* is completed. Therefore, approval of the *Augment* CE Mark will be delayed. We are not able to provide updated guidance on the timing for potential receipt of the *Augment* CE Mark until the *GEM 21S* re-evaluation is complete.

Augment Injectable Bone Graft

(3) 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* 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* Injectable to autograft. The primary endpoint of the study is non-inferiority of *Augment* Injectable 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 expect to file the DLA for approval of *Augment* Injectable in Canada, and release top-line data from our 75-patient Canadian registration study, around the middle of 2012.

(4) 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 April 2011, we initiated patient enrollment in a North American pivotal trial evaluating *Augment* Injectable in hindfoot fusion indications. The study was initially approved by the FDA to enroll 201 patients at 25 clinical centers with the intent to pool patients from previous clinical trials. We continue to have discussions with the FDA in an effort to finalize the study design and sample size, and given certain comments made during the May 2011 panel meeting for *Augment*, we proposed to increase the sample size to 300 patients in order to minimize potential future concerns by the FDA regarding the statistical analysis of the study results. To date, the trial has been initiated at over 20 hospitals and 105 patients have been enrolled. After receipt of the *Augment* post-panel response letter, and based on our desire to focus our attention on addressing the FDA's issues related to the *Augment* PMA and to conserve resources until there is further clarity from the FDA regarding *Augment*, we re-engaged discussions with the FDA regarding the current *Augment* Injectable study design and have voluntarily suspended additional screening and enrollment of patients in the study. Once we have more clarity on a study design that we believe will be acceptable to the FDA, we may decide to restart enrollment at that time. It is important to note that our decision to temporarily suspend additional screening and enrollment was not based on any safety concerns with *Augment* Injectable.

Augment Rotator Cuff Graft

(5) 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 as compared to standard surgical repair (suture alone). *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 medical device study and enrolled 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. The study results indicated improvement in the clinical outcome assessments on DASH and WORC index scores. We conducted MRI assessments, but they were subject to a large degree of variability and did not prove a reliable determinant of clinical healing in this study. *Augment* Rotator Cuff was found to be user-friendly for the surgeons and required no additional operating room or anesthesia time over the current standard of care. A sample size calculation based on the clinical functional scores suggested a sample size between 100 and 300 patients would be required to demonstrate statistical superiority of *Augment* Rotator Cuff to the current standard of care of suture repair alone. We are evaluating potential next steps, if any, in the development of this product candidate, which will be regulated as a drug in the United States and as a medical device in Canada.

In February 2012, we announced results of our 30-patient Canadian *Augment* Rotator Cuff pilot clinical trial. This study's objective is to determine the safety and performance of *Augment* Rotator Cuff for primary surgical treatment of full thickness rotator cuff tears as compared to standard surgical repair (suture alone). *Augment* Rotator Cuff achieved its primary safety endpoint, which was evaluated by a comparison of adverse events between the two treatment groups, and no device-related serious adverse events (''SAE'') were reported. Although not powered to achieve statistical significance, the results also indicated improvement in the clinical outcome assessments on DASH and WORC index scores. Additionally, *Augment* Rotator Cuff was found to be user-friendly for the surgeons and required no additional operating room or anesthesia time over the current standard of care.

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 and marketing 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 in excess of 300 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 in the process of assembling a network of distributors to market *Augment* in selected high potential markets. We may also choose to support these markets with an International Commercial Director, and if this investment makes good business sense, we may potentially add product specialists to support distributor and surgeon training and drive adoption of our products.

In November 2009, we announced that we received approval from Health Canada to begin marketing *Augment* in Canada as an alternative to the use of autograft in foot and ankle fusion indications, and in January 2010, we commercially launched *Augment* in Canada. In September 2011, we contracted with a new distribution partner with extensive experience in Orthopaedic sales in the Canadian marketplace. Our new distribution partner has developed a network of independent sales agencies, and currently utilizes over 30 sales representatives covering all of Canada. We have supplemented these efforts with the assistance of our U.S. based Area Sales Directors who are providing technical product support and training to sales representatives, surgeons and hospital administration.

We will sell *Augment* through an exclusive medical device distributor in Australia and New Zealand. This distributor is a sales organization with a 30 person sales team throughout Australia and New Zealand. Reimbursement for patients in Australia's Private Health Insurance setting is established biannually, which should lead to reimbursement for *Augment* in the second half of 2012 or early 2013, enabling a full launch in Australia at that time. However, we do not anticipate significant revenues from sales of *Augment* in Australia and New Zealand.

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* and *Augmatrix*.

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 expected to be 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 and commercial orthopedic product and product candidate kits.

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 Item 2 ''Properties'' for details regarding the lease agreements. We also lease approximately 30,000 square feet of space in a second building on the same site. The building shell of the second building was completed in late 2009. In order to reduce expenses and in view of the delay in our *Augment* development program and a recent reduction in our work force, we are currently seeking to sublease certain amounts of space in the first building, and in the second building if appropriate, and will consolidate our operations in the remaining space.

We have completed the build out, qualification, and approval of a warehouse and distribution center in the second building, and we expect to begin distribution of *Augmatrix* from that facility in the first half of 2012. We had intended to also utilize the space in the second building as a good manufacturing practices (''GMP'') manufacturing facility and had expected to move certain of our manufacturing operations to that space. In view of the delay in our *Augment* development program, however, we have postponed those plans and will continue to utilize third party suppliers for our manufacturing operation for the near future. Depending upon the timing of FDA approval of the *Augment* PMA, the build out for our manufacturing operations could 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 facilities.

Suppliers

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, Cam Bioceramics BV (''Cam Bioceramics''), Integra, CMI and others as follows:

Novartis Vaccines and Diagnostics, Inc.

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 Novartis' 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.

In February 2012, we amended the agreement with Novartis to modify the timing of certain minimum purchase obligations for rhPDGF-BB, to permit Novartis to supply us with rhPDGF-BB product having a shorter shelf-life than required under the original agreement, and to amend compensation terms.

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 Corporation

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 scaffold formulation, packaging and sterilization 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 original agreement had provided that it would terminate if the first commercial sale of a product developed under the agreement did not occur within seven years of the effective date of the agreement. In March 2012, the parties entered into an agreement amendment that changes this provision from seven years to eleven years after 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 BV

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 *Augment* and our 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.

Collagen Matrix, Inc.

In February 2012, we entered into a supply agreement with Collagen Matrix, Inc. (''CMI'') under which CMI will supply their Matrix product to us for resale to unrelated third parties as part of our *Augmatrix* product line. The agreement provides that we shall have the exclusive right to purchase the Matrix product from CMI and the exclusive right to sell the Matrix product in all countries where it is approved for marketing or sale by the applicable regulatory authority. The agreement also provides that CMI shall be the exclusive manufacturer and supplier of the Matrix product to us. The agreement includes certain milestone payments that we are obligated to pay CMI that are either time-based or based on certain cumulative sales thresholds. In addition, we are obligated to meet annual minimum purchase commitments. The agreement also provides for certain termination penalties, including: (1) a $750,000 termination fee if we terminate the agreement within the first year, (2) additional minimum purchase obligations if we terminate the agreement in the first or second years, and (3) a $1.5 million termination fee if the agreement is terminated by a third party that acquires us.

Equipment

We 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, 2011, we paid a cumulative total of $4.2 million for certain equipment that has been finished but not yet placed in service. We continually assess 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. As a result of the uncertainty regarding the FDA's review of our PMA application for *Augment*, and the timing of the related build-out construction and ultimately manufacturing operations, we recorded a $2.9 million impairment loss on the equipment intended to be used in the new manufacturing facility. Accordingly, as of December 31, 2011, the balance of the manufacturing equipment not placed in service, net of impairment loss, is $1.3 million on our consolidated financial statements.

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. In addition, we have estimated no remaining purchase commitments remaining to be paid under these agreements.

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 University (''Harvard''); and (4) licensing rights acquired from ZymoGenetics, Inc. (''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 four U.S. patents, each of which covers our current orthopedic product candidates (*Augment* and/or *Augment* Injectable), and is based on technology that we developed internally. In addition, these patents provide protection of *GEM 21S* and may provide protection for additional product candidates under development depending on the final formulations for those products. The following is a summary of these key patents:

Patent No.	Issued	Expiration	Title	General Scope
7,473,678	January 2009	June 2025	Platelet-derived growth factor compositions and methods of use thereof	Certain PDGF compositions including *Augment*, *Augment* Injectable and *GEM 21S*
7,799,754	September 2010	June 2026	Compositions and methods for treating bone	Certain methods of treating an impaired bone by applying certain PDGF compositions including *Augment*, *Augment* Injectable and *GEM 21S*
8,106,008	January 2012	November 2027	Compositions and methods for arthrodetic procedures	Certain methods of performing an arthrodetic surgical procedure (i.e. bone fusion) involving applying certain PDGF compositions including *Augment* and *Augment* Injectable
8,114,841	February 2012	August 2028	Maxillofacial bone augmentation using rhPDGF-BB and a biocompatible matrix	Certain methods of enhancing bone augmentation by applying certain PDGF compositions including *Augment* Injectable

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. We are aware that a third party has developed a product that, like *GEM 21S*, is intended for use in periodontal bone regeneration and is based on rhPDGF-BB and β-TCP. We believe that, if commercialized, this product may infringe on our patents related to *GEM 21S* and/or our other products and product candidates. We are currently considering our options to protect our proprietary rights.

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*, *Augment* Injectable and *GEM 21S* are protected in Canada by a patent licensed from ZymoGenetics, which expires in 2015.

In addition to the patents and patent applications discussed above that cover or seek to cover our lead product candidates *Augment* and *Augment* Injectable, we own a number of pending patent applications that seek to cover our sports medicine product candidates. We also own and/or license numerous additional patents or patent applications that cover or seek to cover various growth factor technology, and which primary focus on various PDGF applications, compositions, and manufacturing techniques.

The Harvard Exclusive License was entered into in 2001. In addition, we entered into two ZymoGenetics Exclusive License Agreements, including one in 2001 that covers periodontal and cranio-maxillofacial applications and a second in 2003 that covers orthopedic and sports medicine applications. With the exception of the ZymoGenetics' Canadian patent noted above that expires in 2015, all of the key patents under these agreements that covered our current product candidates have expired.

Trademarks

Augment®, Augmatrix™, *OsteoMimetic*™ and our stylized BioMimetic Therapeutics logo are our only trademarks. *Augment* is a registered trademark in Canada and the United States. *GEM 21S*®, *GEM 21A*™, and *GEM*® were transferred to Luitpold in connection with our divestiture of our orofacial therapeutic business.

Milestone and Royalty Payments

Various milestone payments were required under our agreements with Luitpold, Kensey Nash, Novartis, and CMI, discussed above, as well as our intellectual property license agreements with ZymoGenetics and Harvard as discussed in ''Intellectual Property'' above. Luitpold may be required to make certain milestone payments to us, and we may be required to make certain milestone payments to Kensey Nash and CMI 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*. 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, in January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. We believe this CE Mark, obtained on behalf of Luitpold, triggers a $10.0 million final milestone payment due to us from Luitpold pursuant to the terms of our sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified us that it is evaluating whether the milestone conditions have been satisfied. We are considering our options in the event Luitpold does not make the payment.

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. Also, the agreement with CMI includes certain time-based milestone payments that we are obligated to pay to CMI based on the execution date of the agreement, and we may be required to make additional milestone payments to CMI if certain *Augmatrix* sales targets are achieved.

All of the milestone payments under our agreements with ZymoGenetics and Harvard have been satisfied. With the exception of a $50,000 time-based milestone payment to CMI that is due six months after the execution of the agreement, the remaining milestone payments that we are required to pay to Kensey Nash and CMI remain contingent and have not yet occurred. Assuming that all future contingencies are met and all payments are made, we anticipate that the milestone payments that we are required to make will result in a total payment by us of approximately $0.4 million in the near term (from 2012 to 2013). Because of the uncertainty regarding the potential sales growth for *Augmatrix* and uncertainty regarding the timing associated with the *Augment Injectable* development program in view of our recent voluntary suspension of additional screening and enrollment of patients in the pivotal clinical study, we are unable to estimate the amount and timing of our remaining long-term (beyond 2013) milestone obligations.

We had licensed a number of other third-party U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. As a part of the licensing agreements with ZymoGenetics 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 were 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. As a result of our first shipment of *Augment* to a Canadian distributor in December 2009, we recognized a $1.0 million liability and royalty expense in our consolidated balance sheet and statement of operations, respectively, as of and for the year ended December 31, 2010.

In October 2010, Bristol-Myers Squibb Company (''BMS'') acquired ZymoGenetics and assumed ZymoGenetics' rights and responsibilities under the licensing agreements. In June 2011, we entered into an Amendment to Patent License Agreement (''BMS Amendment'') with BMS which converts our exclusive world-wide licenses to royalty-free, fully paid up, irrevocable licenses for intellectual property covering various formulations of rhPDGF and manufacturing processes for rhPDGF. The BMS Amendment provides for a one-time, final payment from us to BMS totaling $1.5 million, which was paid in July 2011. This payment satisfied the $1.0 million liability recognized as of December 31, 2010, and an additional $0.5 million was recognized as royalty expense in the consolidated statement of operations for the year ended December 31, 2011. No further payments of any kind (milestone, royalty, minimum royalty, sales bonus, nor sublicense fees) are due from the Company to BMS in accordance with the amendment.

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.

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. For instance, we are aware that a third party has developed a product that, like *GEM 21S*, is intended for use in periodontal bone regeneration and is based on rhPDGF-BB and β-TCP and is developing additional rhPDGF-BB based products for other applications, including wound healing and orthopedics. 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* line of product candidates, including *Augment*, *Augment* Injectable and *Augment* Rotator Cuff, 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, as well as xenograft based products including collagen mesh overlays.

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 PRP systems, while Wright Medical's Ignite system and Orthovita's Imbibe are systems designed to concentrate 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.

Two companies currently market recombinant protein therapeutics containing recombinant Bone Morphogenetic Proteins (''BMP'') in orthopedics. While these products, Medtronic's Infuse (rhBMP-2) and Olympus Biotech's OP-1 (Osteogenic Protein 1, or BMP-7) are primarily focused on spine and trauma. Should we elect to pursue these indications, we would directly compete with those products. Additionally, Infuse and OP-1 may be under review for additional indications which could compete with our products. Given these products contain recombinant proteins, any adverse events or regulatory/ clinical complications that arise and are attributed to these products could cause additional challenges for our recombinant protein platform technology both in terms of regulatory approvals and market acceptance.

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 Sanofi), tendon repair overlays as well as the commercially available PRP and BMA systems discussed above.

Regulatory Matters

U.S. Food and Drug Administration 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;
- product sales and distribution; and
- product post-market surveillance.

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

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 PMA application.

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

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

A PMA application must provide a demonstration of 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 (''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, the FDA may request input from an advisory committee on the safety, efficacy, or benefit-risk profile of the product that is the subject of the application. Although the FDA is not bound by any recommendations made by the advisory committees, it often adopts the panel's recommendations. If the FDA finds the information in the application 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.

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.

Some of our product candidates, such as *Augment* Rotator Cuff in the United States and *Augment* Tendinopathy Injection, are drugs and require FDA authorization prior to marketing by means of NDA approval.

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.

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, the FDA may request input from an advisory committee, on the safety, efficacy, or benefit-risk profile of the drug that is the subject of the application. 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 post-market testing and surveillance to monitor the drug's safety or efficacy.

Clinical Trials

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 ("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.

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 IRB 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.

Post-market Regulation

Augment and *Augment* Injectable are combination products and are therefore governed by aspects of both the drug and device post-market regulations, as applicable to the component.

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.

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 (''HC''). Likewise, in Australia the primary regulatory body is the Therapeutic Goods Administration (''TGA'') and in New Zealand the primary regulatory body is the New Zealand Medicines and Medical Devices Safety Authority (''Medsafe''). In addition to needing appropriate data to obtain market licensing in Canada, Australia and New Zealand, 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, Australia and New Zealand and to have the potential to gain approval of additional product candidates in these countries.

The primary regulatory environment in Europe is that of the EU, which consists of 27 member states and 42 competent authorities encompassing most of the major countries in Europe. The European Medicines Agency (''EMA'') previously determined that *GEM 21S* 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 the first quarter of 2011, however, our EU Notified Body, Polish Centre for Testing and Certification, confirmed their acceptance of the classification of *GEM 21S* and *Augment* as Class III medical devices under the European Medical Device Directives. Product classification determination was based in part on recent changes to the European Medical Device Directives that were made after EMA's previous determination. We submitted applications for CE Marking for *GEM 21S* in second quarter of 2011 and *Augment* in the third quarter of 2011to the Polish Centre for Testing and Certification. A CE Mark is the approval by a Notified Body, and the presence of a CE Mark is required before a medical device can be marketed in any country in the EU. In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. The submission for *Augment* is under review. In the EU, there can be no assurance that additional clinical trials will not be required to obtain CE Mark for *Augment*, or that such approval will be granted in a timely fashion, or at all.

We formed a wholly-owned subsidiary in the United Kingdom, BioMimetic Therapeutics Limited, in October 2005 to facilitate our EU regulatory filings.

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 believe that procedural coding will not be an issue. The challenge that we will likely 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, 2011 reflect our operations and those of our wholly-owned subsidiaries, BioMimetic Therapeutics Limited in the United Kingdom, BioMimetic Therapeutics Pty Ltd. in Australia, BioMimetic Therapeutics Canada, Inc., and BioMimetic Therapeutics USA, Inc. Inter-company balances and transactions are eliminated in consolidation. As of December 31, 2011, BioMimetic Therapeutics Limited and BioMimetic Therapeutics Pty Ltd. had no employees and had no operating activities other than making and maintaining regulatory submissions for our product candidates in the EU and Australia, respectively. BioMimetic Therapeutics Canada, Inc. was established in 2010 to facilitate sales activities in Canada for *Augment*, our first orthopedic product, which received regulatory approval from Health Canda in the fourth quarter of 2009. As of December 31, 2011, BioMimetic Therapeutics Canada, Inc. had no employees and had incurred certain operational expenses. BioMimetic Therapeutics USA, Inc., a Delaware corporation, was formed by us in 2011 to facilitate product sales activities in the United States.

Employees

As of December 31, 2011, we employed 75 people, of which 24 were employed in research and development, 14 in regulatory and quality assurance, eight in operations, eight in sales and marketing, and 21 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 six other 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, the public may read and copy materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, DC 20549. You may obtain information about the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website (*www.sec.gov*) where you can find our reports, proxies and other information.

Additionally, from time to time, we provide notifications of material news including press releases and conferences on our website. Webcasts of presentations we make 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.

Item 1A. RISK FACTORS

Risks Relating to Our Business

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 the associated risks;
- 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; or
- 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 decisions by the FDA, 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;
- insufficient financial resources;
- uncertainties regarding study designs and an inability to obtain clarity from regulators regarding study designs;
- 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, Australia and New Zealand or the anticipated approval and subsequent commercialization of *Augment* in the United States and the EU 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.

Current economic uncertainty could adversely affect our operations.

Our business, financial condition and operating results may 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 *Augmatrix*, and other anticipated future products, remains uncertain. In addition, given the current economic and regulatory environment, we are continuously assessing our expenses. Any necessary debt or equity financing may be difficult, costly, dilutive, or completely unavailable to us. From time to time, we may consider expense or other reductions. We believe our existing cash and investments will be sufficient to meet our anticipated cash requirements at least through 2013. Failure to secure 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 financial difficulties, which would directly affect our ability to attain our operating goals on schedule and on budget.

Current economic 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 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, and the commercialization of, 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 and commercialization 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 and obligations 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 and product candidates depends upon 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. We currently do not have an alternative source of rhPDGF-BB. With the production of *Augment* finished goods inventory in anticipation of product launch, we have depleted our current inventory 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, or manufacture commercial or clinical inventory of any product candidate that contains rhPDGF-BB, including our lead product candidates, *Augment*, *Augment* Injectable, and *Augment* Rotator Cuff. Our agreement with Novartis may be terminated under certain circumstances. 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.

Based on our current forecasts for our and Luitpold's rhPDGF-BB needs, our planned clinical study programs for our product candidates and our anticipated pre-clinical studies, sales forecasts of *Augment*, and finished goods currently in inventory, our minimum purchase commitments of rhPDGF-BB in 2012 should meet our needs for at least the next 24 months. 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. 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 we attempt to ensure the accuracy of our forecasts of future product demand, there can be no assurance that our purchase commitments would not exceed our forecasted future usage, potentially resulting in excess, expired, obsolete or scrapped inventory. In addition to any significant unanticipated change in demand or technological developments, such excess inventory could have a significant impact on the value of our inventory and reported operating results.

We have established certain relationships with β-TCP suppliers and obtain matrix materials from Kensey Nash and Integra. We are also continuing to evaluate β-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, β-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 and Australian markets 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 approval 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, Australia and New Zealand 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* and our other product candidates in Canada, Australia and New Zealand and other parts of the world. 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 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 have leased approximately 30,000 square feet of space in new building in the same complex as our headquarters in Franklin, Tennessee. 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. We have completed the build out, qualification, and approval of our warehouse and distribution center, and we expect to begin distribution from that facility in the first half of 2012. Depending upon the timing of FDA approval of the *Augment* PMA, the build out for our manufacturing operations could 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. There can be no assurance, however, whether the FDA will approve the manufacturing facility.

Currently we are utilizing at least two contract facilities to complete the manufacturing, packaging and final product testing for *Augment* (for our commercial product and for our clinical study kits). We are using at least four 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, Australia or New Zealand (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, the build-out of our 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.

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 and marketing management team, independent sales agents and company employed sales representatives and product specialists who will market the product to orthopedic surgeons and podiatric surgeons. Although we are in the process of planning for a commercial organization, 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. We have begun to develop our sales capabilities by hiring internal sales management and establishing contractual relationships with third-party sales representatives. However, delays in the FDA's approval of *Augment* may jeopardize those relationships. We may not be able to attract additional qualified personnel to serve in our sales and marketing organization, or retain those we have hired or with which we have contracted. 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.

The cost of establishing and maintaining a sales and marketing organization may exceed its cost effectiveness. If we fail to develop sales and marketing capabilities, if our sales efforts are not effective or if costs of developing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition would be materially adversely affected.

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, Australia or New Zealand, or any other product candidate that we may develop. Furthermore, as a result of 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 our current 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.

Although we have begun establishing contractual relationships with third-party sales representatives, those relationships are limited to the sale of *Augment*. We are currently attempting to expand those relationships to include *Augmatrix*. Most of these sales groups, however, already have relationships with other orthopedic products companies, some of which sell either 510k cleared synthetic bone substitute products or non-regulated tissue-based bone substitute products, both of which will compete with *Augmatrix*. Therefore, these sales groups may be unwilling or contractually unable to expand our existing contractual relationship to include *Augmatrix*. If we are unable to establish adequate sales and marketing capabilities for *Augmatrix*, we may not be able to generate sufficient revenue to maintain a net cash burn that enable us to reach FDA regulatory approval of *Augment* without the need to raise additional capital if available.

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 a company that is developing rhPDGF-BB based products for other applications, including wound healing and orthopedics, and other 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, Australia and New Zealand may not and *Augmatrix* in the United States 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 as well as our ability to successfully convince hospital administration on the value of our products. 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 and New Zealand, market acceptance is 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. However, there can be no assurance that any 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, our ability to generate revenue in such markets will be materially and adversely affected.

In reimbursed markets such as Australia, market acceptance is dependent upon *Augment* achieving adequate reimbursement. Reimbursement is contingent on several factors including providing tangible cost/benefit analysis as compared to local standard(s) of care, and providing clinical data that establishes the effectiveness of the product relative to the local standard(s) of care. If our clinical data is deemed insufficient, or our data/arguments on cost/benefit and comparative effectiveness are not able to meet local requirements, our ability to generate revenue in such markets will be materially and adversely affected.

For commercialization outside of the United States, we are in the process of assembling a network of distributors to market *Augment* in selected high potential markets. We may also choose to support these markets with an International Commercial Director, and if this investment makes good business sense, we may potentially add product specialists to support distributor and surgeon training and drive adoption of our products.

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

As a small company with 75 employees as of December 31, 2011, 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, Augmatrix 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 products may occur. 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 commercial regenerative protein therapeutic-device combination product in Canada, Australia and New Zealand. 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.

From time to time, we and/or our executive officers or directors may be named as defendants in lawsuits or involved in regulatory inquiries, which could result in substantial costs and divert management's attention.

Biotech companies with volatile stocks often are the subject of securities class actions and derivative lawsuits. Similarly, stock price volatility as well as the timing of disclosures relating to FDA or other regulatory developments may create interest on the part of self-regulatory organizations or the SEC. Recently, following various recent regulatory developments and a period of stock price volatility, we received regulatory inquiries to which we responded to in the ordinary course.

Also, two lawsuits have been filed against us. In July 2011, a complaint was filed in the United States District Court, Middle District of Tennessee, against us, and certain of our officers on behalf of certain purchasers of our common stock. The complaint alleges that we and certain of our officers violated federal securities laws by making materially false and misleading statements regarding our business, operations, management, future business prospects and the intrinsic value of our common stock, the safety and efficacy of *Augment*, its prospects for FDA approval and inadequacies in *Augment*'s clinical trials. The plaintiffs seek unspecified monetary damages and other relief.

In August 2011, a purported shareholder derivative complaint was filed in the United States District Court, Middle District of Tennessee, allegedly on behalf of and for the benefit of the Company, against all the members of the current Board of Directors of the Company, and names the Company as a nominal defendant. The shareholder derivative action makes factual allegations similar to the allegations in the class action lawsuit, and alleges breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets. The purported derivative action seeks modification of the Company's corporate governance policies and procedures, and also seeks monetary damages in an unspecified amount, including disgorgement of all profits, benefits and compensation obtained by the defendants, and plaintiff's costs and

disbursements associated with the lawsuit, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses, and such other relief as the court deems just and proper.

If we are not successful in our defense of such litigation, we could be forced to make significant payments to, or enter into other settlements with, our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results or financial condition. Additional lawsuits with similar claims may be filed by other parties against us and our officers and directors. Even if such claims are not successful, this litigation or other future similar actions, or other regulatory inquiries or investigations, may result in substantial costs, have a significant adverse impact on our reputation, and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Risks Relating to Intellectual Property

If we cannot protect our intellectual property, our ability to market our products in various markets around the world 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 if we are unable to successfully assert our patent rights against an infringer.

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 a number of 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 under 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 not 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, there can be no assurance 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, and may develop products similar to ours that are not covered by our patents. For instance, we are aware that a third party has developed a product that, like *GEM 21S*, is intended for use in periodontal bone regeneration and is based on rhPDGF-BB and β-TCP. We believe that, if commercialized, this product may infringe on our patents related to *GEM 21S* and/or our other products and product candidates. We are currently considering our options to protect our proprietary rights.

Although we believe that our patents and patent applications 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, Australia or New Zealand, 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 approval process by the FDA or other foreign regulatory body 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 approval or clearance by the FDA or other foreign regulatory authorities 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 application 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. The FDA's Medical Devices Advisory Committee conducted a meeting of its Orthopaedic and Rehabilitation Devices Panel (the ''panel'') on May 12, 2011 during which the panel reviewed *Augment*. The panel voted narrowly in support of the safety of *Augment* for use as an alternative to autograft in hindfoot and ankle fusion procedures; narrowly in support of the efficacy of *Augment* for use as an alternative to autograft in hindfoot and ankle fusion procedures; and narrowly in support of the finding that *Augment* demonstrates a reasonable benefit to risk profile for the same indication.

In January 2012, we announced the receipt of a comprehensive post-panel response letter (the ''letter'') from the FDA related to our PMA application for *Augment*. The FDA acknowledged that the panel voted in favor of a reasonable assurance of safety, effectiveness and a positive benefit to risk ratio; however, the FDA stated that ''notwithstanding the Advisory Panel's recommendation, the PMA, without additional information, must be considered not approvable and that...to place the Company's PMA in approvable form, the Company

must amend it to include the following...'' The letter listed the information that we would need to submit for the PMA application to be approvable, and outlined a pathway that could potentially lead to approval without additional clinical trials to support the safety and effectiveness of *Augment*. Based on our assessment of the letter, the FDA's key requests for additional information regarding the pivotal study include a re-reading of all 24-week CT scans, further analysis of all study adverse events, re-categorization of secondary surgeries as failures, and stratification of results by various subgroups. There can be no assurance as to the extent to which the re-reads of the 24-week CT scans will correlate with the original readings of those scans, and there is a risk that there could be little or no correlation. There is also a risk that an analysis of the *Augment* pivotal study data after re-categorization of secondary surgeries as failures may result in *Augment* not achieving statistical equivalence to autograft. If there is not an adequate correlation among the two re-reads and the original read, or if *Augment* does not achieve statistical equivalence to autograft upon re-categorization of secondary surgeries, the FDA may require a new clinical study before approving our *Augment* PMA. There is also a risk that if the FDA approves our *Augment* PMA, the FDA could significantly limit the scope of the approved indications based on its assessment of the requested subgroup analysis of the data. Any of these events would have a material, adverse effect on our business, financial condition and results of operations.

Even though the panel voted narrowly in favor of *Augment* and the FDA has followed up with a comprehensive post-panel response letter, the FDA has determined that our *Augment* PMA is not approvable until additional information is provided, which could include data from additional clinical or non-clinical studies. We may be unable to design studies that satisfactorily address certain issues raised by the FDA. Even if we are able to design adequate studies, such studies may be very time consuming and costly, and their results may be uncertain or negative. This could significantly delay or prevent the approval of *Augment*, or result in the FDA imposing labeling restrictions on any approval of *Augment* that would significantly reduce *Augment*'s potential market. Any of these events 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 initiated patient enrollment in the United States in the second quarter of 2011. The study was initially approved by the FDA to enroll 201 patients at 25 clinical centers with the intent to pool patients from previous clinical trials. We continue to have discussions with the FDA in an effort to finalize the study design and sample size, and given certain comments made during the May 2011 panel meeting for *Augment*, we proposed to increase the sample size to 300 patients in order to minimize potential future concerns by the FDA regarding the statistical analysis of the study results. To date, the trial has been initiated at over 20 hospitals and 105 patients have been enrolled. After receipt of the *Augment* post-panel response letter, and based on our desire to focus our attention on addressing the FDA's issues related to the *Augment* PMA and to conserve resources until there is further clarity from the FDA regarding *Augment*, we re-engaged discussions with the FDA regarding the current *Augment* Injectable study design and have voluntarily suspended additional screening and enrollment of patients in the study. Once we have more clarity on a study design that we believe will be acceptable to the FDA, we may decide to restart enrollment at that time. There is a risk, however, that the delay may cause investigators and/or clinical sites to drop out of the study, which would further delay completion of enrollment. An extended hold on enrollment may also negatively impact the data collection or require us to retrain the investigators and the sites before restarting enrollment. This could significantly increase the cost of completing the study.

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 further revise this trial. If we are unable to address the FDA's conditions, or if we fail to include a large enough sample size in the study, 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. The FDA may reject our proposed sample size and statistical plan, and require a significantly larger number of patients in the study, which would significantly increase the cost of the study and significantly further delay completion of the study. Also, if we are unable to expand the inclusion criteria for the study (e.g., inclusion of ankle surgeries), any FDA approved indications may be more limited, which would limit the potential market for the product and could have a material adverse effect on our business, financial condition and results of

operations. If we are unable to successfully finalize the study design for our *Augment* Injectable trial, or if the completion of the trial is delayed, or if the FDA ultimately determines that the results of the study do not provide sufficient support for marketing approval, it would have a material adverse effect on our business, financial condition and results of operations.

The FDA may select a different center 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 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.

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.

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 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* was reviewed by the FDA's Orthopedic and Rehabilitation Devices Panel (the ''panel'') on May 12, 2011. Even though the panel voted in favor of *Augment*, the FDA concluded that *Augment* is not approvable and that we will need to submit additional information for the application to be approvable.

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 have now completed the study. We intend to file a DLA for approval of *Augment* Injectable in Canada and release top-line data from the study around the middle of 2012. Although the *Augment* Injectable study is now complete, we may need to present additional data from other clinical trials or pool the data from the Canadian trial with data from other trials in order to obtain approval for *Augment* Injectable in Canada. We may not be able to pool this data with data from other trials. We ultimately may not obtain the approvals necessary to market *Augment* Injectable or our other product candidates in development in Canada, which would have a material adverse effect on our business, financial condition and results of operations.

The primary regulatory environment in Europe is that of the EU, which consists of 27 member states and 42 competent authorities encompassing most of the major countries in Europe. The European Medicines Agency (''EMA'') previously determined that *GEM 21S* 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 the first quarter of 2011, however, our EU Notified Body, Polish Centre for Testing and Certification, confirmed their acceptance of the classification of *GEM 21S* and *Augment* as Class III medical devices under the European Medical Device Directives. The product classification determination was based in part on recent changes to the European Medical Device Directives that were made after EMA's previous determination. We submitted applications for CE Marking for *GEM 21S* in second quarter of 2011 and *Augment* in the third quarter of 2011 to the Polish Centre for Testing and Certification. In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. A CE Mark is the approval by a Notified Body, and the presence of a CE Mark is required before a medical device can be marketed in any country in the EU. Although a CE Mark provides EU market access, reimbursement is decided by each individual country and some countries or providers may not provide reimbursement for *Augment*, which could significantly impact the product's market acceptance. The EU regulatory authorities may determine to rescind the CE Mark for *GEM 21S* and classify that product as a medicinal combination product. The EU regulatory authorities also may determine that *Augment* should be classified as a medicinal combination product, rather than a Class III medical device. The evaluation of the appropriate classification will delay the review process, and classification as medical combination products would result in further delay. If the EU regulatory authorities determine to review *GEM 21S* as a medicinal combination product, our right to continue to seek EU approval of *GEM 21S* could be terminated, and we expect that Luitpold will take the position that it is not obligated to make the $10.0 million milestone payment. We are considering our options in the event Luitpold does not make the payment. We may not collect the $10.0 million milestone payment from Luitpold.

Even though a drug or device may be approved for use in another jurisdiction, it may not be sold in Australia and New Zealand until approved by the applicable national regulatory agency. The manufacture, distribution and use of medical devices, drugs and equipment is regulated by the Therapeutic Goods Administration (''TGA'') in Australia and the New Zealand Medicines and Medical Devices Safety Authority (''Medsafe'') in New Zealand. In February 2010, we filed an application of Conformity Assessment with the Australian 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. In October 2011, the TGA approved our medical device application for *Augment*, which was subsequently listed on the Australian Register of Therapeutic Goods (''ARTG''), clearing the way for commercialization of the product in Australia. In December 2011, Medsafe listed *Augment* on the Web Assisted Notification of Devices (''WAND''), clearing the way for commercialization of the product in New Zealand. Although listed, there can be no assurance that any hospital's product evaluation committee will approve the use of *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 Australia

or New Zealand, and our ability to generate revenue from such sales will be materially and adversely affected, which may have a material adverse effect on our business, financial condition and results of operations.

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.

As we begin commercializing *Augmatrix* in the United States, our operations will 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 $5,000 to $10,000 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 and regulatory activities. As of December 31, 2011, we had an accumulated deficit of $160.6 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, 2011, we had federal net operating loss carryforwards totaling $124.6 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 inception and have funded our operations primarily from proceeds received from sales of our stock, the licensing and sale of our orofacial therapeutic business, sublicense fee income recorded from the receipt of certain milestones, and to a lesser extent, royalty income, investment income and product sales. We believe that the December 31, 2011 balance of our cash and investments will be sufficient to meet our anticipated cash requirements at least through 2013.

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. 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. Our current stock price is significantly depressed, which together with recent delays in our *Augment* development program and other

events may severely impair our ability to raise additional capital funds. There can be no assurance that any such funding will be available to us on favorable terms, or at all, or 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;
- the failure of our *Augment* PMA Amendment that we anticipate filing by the middle of 2012 to satisfactorily address the issues raised by the FDA in its post-panel response letter;
- the FDA determining that a new clinical trial will be required before our *Augment* PMA can be approved;
- unanticipated expenditures in research and development or manufacturing activities;
- legal expenses, including expenses associated with the securities class action and shareholder derivative lawsuits filed against us, and with other regulatory inquiries, and any settlement or damage payments associated with litigation;
- delayed market acceptance of our product or product candidates, if approved;
- increased expenses associated with the commercialization of *Augmatrix*;
- the failure to achieve sufficient sales of *Augmatrix* in order to adequately offset commercialization expenses;
- 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 qualified personnel or retaining key personnel to manage our business, including personnel to oversee our development programs and personnel to market and sell 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 (''Section 404'') 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 on Form 10-K, 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 on Form 10-K 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. Our stock has been and can be expected to continue to be highly volatile, particularly around the time of scheduled or expected announcements by us or regulatory agencies with respect to matters under regulatory review, such as, for example, announcements by us or the FDA regarding our *Augment* PMA. 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 Australia or any other approved product in the future;
- the status of litigation against us, our directors, and certain of our officers, or the status of regulatory inquiries brought against us and our officers and directors;
- 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 or any PDGF-containing product;
- changes in estimates of our revenue and operating results;
- variances in our cash flow, revenue or operating results from forecasts or projections;
- recommendations of securities analysts regarding investment in our stock;
- our ability to maintain 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 our officers, directors or existing stockholders could cause our stock price to decline.

The market price of our common stock may drop significantly if our officers, directors or 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. Our executive officers and directors may sell stock in

the future, either as part, or outside, of trading plans under SEC Rule 10b5-1 under the Exchange Act. 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, 2011, there were options issued and outstanding to purchase 2,748,331 shares of our common stock with a weighted average exercise price of $11.62. Also at December 31, 2011, there were 1,904,829 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, 2011, our executive officers, directors and their affiliates beneficially owned shares representing approximately 14.6% of our capital stock. This total includes 1,830,253 shares (6.5% 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. In addition, 4,720,065 shares (16.8% of our capital stock) are 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 of office space and approximately 30,000 square feet of space in a second building for a manufacturing, warehousing and distribution facility.

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 2011 we paid Noblegene monthly rent of $55,251, 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 second 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, which was June 2011; or (b) upon Noblegene obtaining a permanent mortgage on the new building, the timing of which is uncertain. 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 2011 we paid Noblegene monthly rent of $69,360, 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.

Item 3. LEGAL PROCEEDINGS

In July 2011, a complaint was filed in the United States District Court, Middle District of Tennessee, against us and certain of our officers on behalf of certain purchasers of our common stock. The complaint alleges that we and certain of our officers violated federal securities laws by making materially false and misleading statements regarding our business, operations, management, future business prospects and the intrinsic value of our common stock, the safety and efficacy of *Augment*, its prospects for FDA approval and inadequacies in *Augment's* clinical trials. The plaintiffs seek unspecified monetary damages and other relief.

In August 2011, a purported shareholder derivative complaint was filed in the United States District Court, Middle District of Tennessee, allegedly on behalf of and for the benefit of us, against all the members of our current Board of Directors, and names us as a nominal defendant. The shareholder derivative action makes factual allegations similar to the allegations in the class action lawsuit, and alleges breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets. The purported derivative action seeks modification of our corporate governance policies and procedures, and also seeks monetary damages in an unspecified amount, including disgorgement of all profits, benefits and compensation obtained by the defendants, and plaintiff's costs and disbursements associated with the lawsuit, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses, and such other relief as the court deems just and proper.

If we are not successful in our defense of the class action litigation and the derivative litigation, we could be forced to make significant payments to, or enter into other settlements with, our stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on our business, operating results and financial condition. Additional lawsuits with similar claims may be filed by other parties against us and our officers and directors. Even if such claims are not successful, these lawsuits or other future similar actions, or other regulatory inquiries or investigations, may result in substantial costs and have a significant adverse impact on our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

We plan to vigorously defend against the claims in both the class action litigation and the shareholder derivative litigation. The outcome of these matters is uncertain, however, and we cannot currently predict the manner and timing of the resolution of the lawsuits, or an estimate of a meaningful range of possible losses or any minimum loss that could result in the event of an adverse verdict in the lawsuits. However, there can be no assurance as to the ultimate outcome of these claims or whether our applicable insurance policies will provide sufficient coverage for these claims.

We are not a party to any other legal proceedings, claims or assessments that, in management's opinion, would have a material adverse effect on our business, financial condition and results of operations.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Select 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 Select Market, since our common stock commenced public trading:

	Price Range	
	High	Low
2011		
First Quarter	$14.80	$11.18
Second Quarter	$14.49	$ 4.99
Third Quarter	$ 5.17	$ 2.68
Fourth Quarter	$ 3.75	$ 2.70

	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

Stockholders

As of March 9, 2012, there were 27 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, 2011.

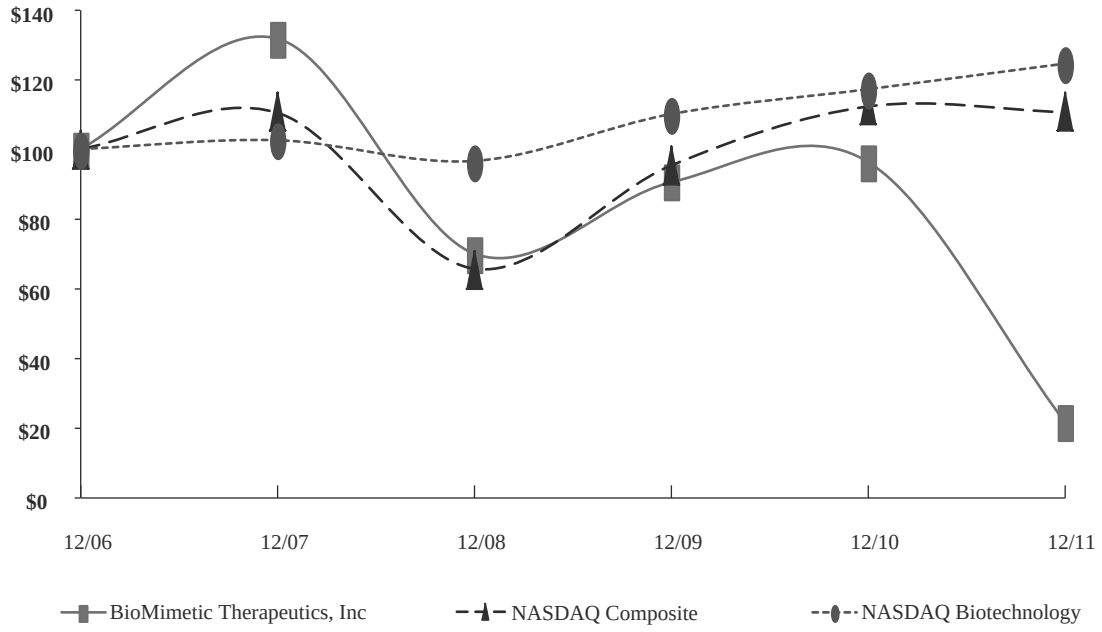
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
2001 Long-Term Stock Incentive Plan	2,748,331	$11.62	1,904,829
2005 Employee Stock Purchase Plan	N/A	N/A	50,596
Employee 401(k) Plan Company Match	N/A	N/A	—
Total	2,748,331	—	1,955,425

Performance Graph

The following graph compares the cumulative total stockholder return data for our common stock since December 31, 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 December 31, 2006, $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.

We have not declared or paid any cash dividends on our capital stock, and have 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 5 YEAR CUMULATIVE TOTAL RETURN*
Among BioMimetic Therapeutics, Inc. the NASDAQ Composite Index, and the NASDAQ Biotechnology Index



* $100 invested on 12/31/06 in stock or 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, 2011 and 2010 and the selected consolidated statements of operations data for each of the three years in the period ended December 31, 2011 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated balance sheet data as of December 31, 2009, 2008 and 2007 and the selected consolidated statements of operations data for the each of the two years ended December 31, 2008 have been derived from our audited consolidated financial statements which are not included in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2011	2010	2009	2008[1]	2007
	(In thousands, except share and per share information)				
Revenues:					
Product sales	$ 327	$ 15	$ 78	$ —	$ 5,040
Royalty income	427	487	522	2,144	1,213
Sublicense fee income	971	971	971	974	741
Other revenue	—	—	—	30	36
Total revenues	1,725	1,473	1,571	3,148	7,030
Costs and expenses:					
Cost of sales	53	17	6	—	3,939
Research and development	14,695	17,967	21,095	24,561	19,218
General and administrative	16,034	15,161	11,511	11,253	8,829
Depreciation and capital lease amortization	1,256	1,234	1,333	1,423	1,130
Patent license fee amortization	37	1,658	2,569	2,663	2,234
Total costs and expenses	32,075	36,037	36,514	39,900	35,350
Loss from operations	(30,350)	(34,564)	(34,943)	(36,752)	(28,320)
Interest (expense) income, net	(4)	(3)	(308)	247	1,710
Investment income (loss), net	113	144	6,864	(10,797)	1,952
Other income from governmental grants	—	514	—	—	—
Impairment loss on equipment	(2,940)	—	—	—	—
(Loss) gain on foreign currency translation and other transactions	(9)	(28)	11	5	2
Gain on arbitration settlement	—	—	7,219	—	—
Gain on disposal of orofacial therapeutic business	—	—	—	39,292	—
Income tax benefit	—	—	—	—	74
Net loss	$ (33,190)	$ (33,937)	$ (21,157)	$ (8,005)	$ (24,582)
Basic and diluted net loss per share	$ (1.19)	$ (1.38)	$ (1.03)	$ (0.43)	$ (1.37)
Weighted average shares used to compute basic and diluted net loss per share	28,002,185	24,626,170	20,510,132	18,529,068	17,951,147
Cash dividends declared	$ —	$ —	$ —	$ —	$ —

	As of December 31,				
	2011	2010	2009	2008	2007
			(In thousands)		
Balance Sheet Information:					
Cash and cash equivalents	$ 18,503	$ 11,628	$ 21,543	$ 17,535	$ 25,483
Investments − short term	42,950	65,751	47,002	33,218	—
Investments − long term	—	15,002	6,514	46,624	41,800
Total assets	74,887	105,555	88,912	125,120	89,618
Long-term capital lease obligations	132	216	175	35	53
Note payable	—	—	—	39,100	—
Total liabilities	20,875	22,433	21,861	66,066	27,166
Redeemable, convertible preferred stock	—	—	—	—	—
Accumulated deficit	(160,647)	(127,457)	(93,520)	(72,363)	(64,358)
Total stockholders' equity	54,012	83,122	67,052	59,054	62,452

(1) 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 subsequent to January 2008.

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 therapies for orthopedic, sports medicine and spine applications.

Our Augment® platform of product and product candidates include an engineered version of recombinant human platelet-derived growth factor BB (''rhPDGF-BB''), one of the principal wound healing and tissue repair stimulators in the body. Our platform regenerative technology for promoting tissue healing and regeneration combines rhPDGF-BB with tissue specific matrices, when appropriate. The matrices are engineered or natural scaffold materials, such as Beta Tri-Calcium Phosphate (''ß-TCP''), which have a history of demonstrated safety and efficacy in previous uses.

Our platform regenerative technology may offer physicians advanced biological solutions to actively stimulate the body's natural tissue regenerative process. We believe that our product and product candidates, if approved by the appropriate regulatory authorities, may offer new, effective and in some cases less invasive treatment options for the repair of bone, cartilage, tendons and ligaments, thus helping patients recover from their injuries and improving their quality of life.

Through the commercialization of this patented technology, we seek to become the leading company in the field of regenerative medicine with the product and product candidates we are developing, including the following lead product and product candidates:

- Augment® Bone Graft (''*Augment*'');
- Augment® Injectable Bone Graft (''*Augment* Injectable''); and
- Augment® Rotator Cuff Graft (''*Augment* Rotator Cuff'').

In addition, in February 2012, we began marketing Augmatrix™ Biocomposite Bone Graft (''*Augmatrix*'') in anticipation of an expected commercial launch in the second quarter of 2012. *Augmatrix* is a family of tissue specific grafting materials previously cleared by the U.S. Food and Drug Administration (''FDA''). *Augmatrix* is available in multiple forms to suit an array of bone grafting challenges, including fracture repair and general bone void filling procedures. Refer to ''Introduction of Augmatrix™ Biocomposite Bone Graft'' below for more information.

We have completed or continue to sponsor clinical trials with our three leading product candidates (*Augment*, *Augment* Injectable and *Augment* Rotator Cuff) for use in multiple orthopedic and sports medicine indications including the treatment of foot and ankle fusions, the stimulation of wrist fracture healing, and the surgical treatment of rotator cuff tears.

We believe we have demonstrated that our technology is safe and effective in stimulating bone regeneration with various regulatory approvals of our initial product candidates. *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), which we developed as our first periodontal product and later sold to Luitpold Pharmaceuticals, Inc. (''Luitpold''), was approved by the FDA in the United States in 2005 and by Health Canada (''HC'') in Canada in 2006. In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the European Union (''EU''); however, we have since been informed that the EU regulatory authorities are re-evaluating the CE Mark. In 2009, *Augment* was approved by HC for commercialization in Canada. In 2011, *Augment* was listed by the Australian Therapeutics Goods Administration (''TGA'') in Australia and by the New Zealand Medicines and Medical Devices Safety Authority (''Medsafe'') in New Zealand, clearing the way for commercialization of *Augment* in Australia and New Zealand, respectively.

The key business objectives for our company consist of our efforts to pursue regulatory approvals in the United States and in several markets located outside of the United States (''OUS''), preparing for and carrying out the commercial adoption of *Augment* in Canada, Australia and New Zealand, the continued development of our other product candidates, the introduction of new bone grafting products to complement our existing orthobiologic portfolio of product candidates, and managing our cash and investments.

Significant recent events related to these endeavors are as follows:

- *FDA Review of Pre-Market Approval ("PMA") Application for Augment* — 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. In May 2011, the FDA's Medical Devices Advisory Committee conducted a meeting of its Orthopedic and Rehabilitation Devices Panel (the ''panel'') to review our PMA application for *Augment*. The panel voted in favor of the safety of *Augment* (12 to 6), the efficacy of *Augment* (10 to 8), and that *Augment* demonstrates a reasonable benefit to risk profile (10 to 8). In January 2012, we announced the receipt of a comprehensive post-panel response letter (the ''letter'') from the FDA related to our PMA application for *Augment*. The letter stated that *Augment* was not approvable until certain additional requests from FDA were satisfied, and if those requests could not be satisfied with the data from the existing pivotal trial, a new study might be necessary. Based on our assessment of the letter, the FDA's key requests for additional information regarding the pivotal study include a re-reading of all 24-week CT scans, further analysis of all study adverse events, re-categorization of secondary surgeries as failures, and stratification of results by various subgroups. We currently anticipate that by the middle of 2012 we will submit an amendment to the *Augment* PMA that will include the requested additional information. If the submission is timely and satisfactorily addresses the FDA's issues, product approval could occur between April 2013 and January 2014.

- *Regulatory and Commercialization Activities Outside of the United States* — We are currently pursuing additional regulatory approvals in the United States as well as several OUS markets. Outside of the United States, our current focus is on near-term approvals where we can access the market within the next 12 to 15 months, or less. In addition to our efforts for the commercial adoption of *Augment* in Canada, Australia and New Zealand, the additional potential OUS markets we are pursuing include countries in Europe, the Middle East, Asia and Latin America.

- *Introduction of Augmatrix* — In February 2012, we began marketing *Augmatrix*, a new bone graft substitute product line, in anticipation of an expected commercial launch in the second quarter of 2012. The *Augmatrix* product line is comprised of carbonate-apatite (calcium phosphate) and bovine Type I collagen and is designed to be combined with bone marrow aspirate (''BMA''). The products are available in multiple forms to suit an array of bone grafting challenges, including fracture repair and general bone void filling procedures. The product line has been FDA cleared for use in orthopedic indications and is ready for sale in the United States. We believe the addition of the *Augmatrix* product line will provide surgeons with a range of bone grafting solutions to procedures for which our rhPDGF-BB based offerings will not initially be indicated, and will complement our existing orthobiologic portfolio allowing us to penetrate the large bone graft substitutes market earlier than anticipated.

- *Managing our cash and investments* — As of December 31, 2011, our balance of cash and investments totaled $61.5 million. We continue to carefully manage expenses as well as our cash and investments in order to be in a position to quickly respond to requests from the FDA and be in a position to begin commercialization of *Augment* in the United States. Given certain comments made during the May 2011 panel meeting for *Augment*, and our desire to focus our attention on addressing the FDA's issues related to the *Augment* PMA, we have determined it necessary to conserve resources until there is further clarity from the FDA regarding *Augment*. For example, we re-engaged discussions with the FDA regarding the current *Augment* Injectable study design and have voluntarily suspended additional screening and enrollment of patients in the study. Once we have more clarity on a study design that we believe will be acceptable to the FDA, we may decide to restart enrollment at that time. Also, in January 2012, we implemented a workforce reduction, reducing by approximately 25% of our total workforce. We believe that the reduction will permit us to conserve cash and dedicate our resources to obtaining a final decision from the FDA on our *Augment* PMA application.

Various milestone and royalty payments were required under certain of our agreements. In June 2011, we signed an Amendment to Patent License Agreements (''BMS Amendment'') with Bristol-Myers Squibb Company (''BMS''), who acquired ZymoGenetics and our License Agreements therewith. Under the BMS Amendment, we paid BMS a one-time payment of $1.5 million as final payment under our 2001 and 2003 Patent License Agreements with ZymoGenetics. No further payments of any kind (milestone, royalty, minimum royalty, sales bonus, nor sublicense fees) will be due under the ZymoGenetics agreements. See ''Milestone and Royalty Payments'' below for more information on these and other payments.

Since our inception in 1999, we have incurred losses from operations each year. As of December 31, 2011, our accumulated deficit was $160.6 million. We recorded revenues of $1.7 million for the year ended December 31, 2011, which consist of product sales, royalty income and sublicense fee income. In view of our limited revenue at this time, we continue to closely monitor our cash and investments balance and manage expenses. The uncertainty surrounding the FDA's review of our PMA application for *Augment* as described above, as well as the continuing volatile business and economic environment, including the ensuing market instability and uncertainty, may continue to impact our general business strategy and may adversely affect our business, financial condition and results of operation. Also, 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 FDA review process and the economy on commercial opportunities, such as our anticipated commercial launch of *Augment* in the United States, remains uncertain. Although the size and timing of our future operating losses are subject to this 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.

Financial Operations Overview

From our inception in 1999 through December 31, 2011, 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, royalties and product sales. As of December 31, 2011, our balance of cash and investments totaled $61.5 million, which includes $18.5 million in cash and cash equivalents and $43.0 million in investments classified as available-for-sale consisting of U.S. government sponsored enterprise (''GSE'') securities, corporate bonds, municipal bonds, bank bonds, and commercial paper.

Revenues

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

Product sales revenues for the three and twelve months ended December 31, 2011 were $0.1 million and $0.3 million, respectively, and were derived from sales of *Augment* in Canada. We will sell *Augment* through an exclusive medical device distributor in Australia and New Zealand. This distributor is an experienced sales organization with orthobiologic selling experience. However, we do not anticipate significant revenues from sales of *Augment* in Australia and New Zealand. Further, we expect product sales of *Augment* to commence in the United States when, and if, the FDA approves the commercialization of *Augment*.

Royalty income for the three and twelve months ended December 31, 2011 was $0.1 million and $0.4 million, respectively, and is based on net sales of *GEM 21S* as reported to us by Luitpold, who owns the rights to *GEM 21S* and markets it through its Osteohealth Company in the United States and Canada. We expect to continue to receive ongoing royalty payments at least through 2026 based on Luitpold's net sales of *GEM 21S* in accordance with the terms and conditions of our 2008 agreement to sell our orofacial therapeutic business, including *GEM 21S*, to Luitpold.

Sublicense fee income for the three and twelve months ended December 31, 2011 was $0.2 million and $1.0 million, respectively, and is based on the straight-line amortization of certain milestone payments previously received from Luitpold. In January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. We believe this CE Mark, obtained on behalf of Luitpold, triggers a $10.0 million final milestone payment due to us from Luitpold pursuant to the terms of our sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the

EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified us that it is evaluating whether the milestone conditions have been satisfied. We are considering our options in the event Luitpold does not make the payment. If we receive this milestone payment, it will be amortized and recorded to sublicense fee income.

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, foreign currency translation gains and losses, grant income and various gains or losses resulting from one-time or unusual transactions.

In 2011, we recorded a $2.9 million impairment loss on equipment intended to be used in our new manufacturing facility located on the same campus as our current office space in Franklin, Tennessee. We have not recognized any impairment losses on long-lived assets for the years ended December 31, 2010 and 2009.

In 2010, we received three government cash grants totaling $0.5 million, which were recognized when awarded as other income in our consolidated statement of operations. There are no unfulfilled conditions nor any contingent liability for repayment related to either the Incumbent Worker Training (''IWT'') program or the Qualifying Therapeutic Discovery Project (''QTDP'') program cash grants received by us.

In 2009, we recorded a gain on arbitration settlement of $7.2 million related to certain investments in auction rate securities.

Research and Development Expenses

A significant portion of our expenditures are incurred in connection with research and development activities. As we evaluate all development and commercialization plans, we have been seeking to curtail expenses, including those related to certain research and development activities, as we work with the FDA on an approval pathway for *Augment*.

We continue to incur research and development expenses related to our ongoing *Augment* Injectable pivotal clinical trial in Canada, *Augment* Rotator Cuff pilot clinical study in Canada, and North American pivotal trial for *Augment* Injectable. However, our efforts to curtail research and development expenses may result in our delaying potential increases in our staffing of research and development personnel and delaying certain development programs. We will make determinations as to which product candidates and development programs to advance and how much funding to direct to each on an ongoing basis in response to their scientific and clinical success.

Direct external costs represent significant expenses paid to third parties that specifically relate to the development and commercialization of our product and 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. Internal costs represent expenses for 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. 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, 2011:

	Research and Development Expenses				
	Years Ended December 31,				
Market	**2011**	**2010**	**2009**	**2008**	**2007**
Direct external:					
Periodontal	$ 120,543	$ 34,311	$ 251,306	$ 1,061,533	$ 1,789,290
Orthopedic	3,196,282	4,995,835	7,611,308	10,638,241	7,143,764
Sports medicine	992,526	1,327,412	984,969	491,825	716,125
	4,309,351	6,357,558	8,847,583	12,191,599	9,649,179
Internal:					
Periodontal	305,859	454,133	688,420	590,330	2,400,252
Orthopedic	7,414,708	8,274,842	9,595,711	9,999,420	5,878,196
Sports medicine	2,664,885	2,880,383	1,963,715	1,779,626	1,290,751
	10,385,452	11,609,358	12,247,846	12,369,376	9,569,199
Total	$14,694,803	$17,966,916	$21,095,429	$24,560,975	$19,218,378

General and Administrative Expenses

Our general and administrative expenses, which for the years ended December 31, 2011, 2010 and 2009 were $16.0 million, $15.2 million and $11.5 million, respectively, have increased as we expanded 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.

As we evaluate all development and commercialization plans, we have been seeking to control expenses as we work with the FDA on an approval pathway for *Augment*. Our efforts to control general and administrative expenses may result in our delaying further increases in our staffing of general and administrative personnel and postponing certain activities relating to the build-out of our warehouse, distribution and manufacturing facility.

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;
- the effects of competing technologies and market developments; and
- the industry demand and patient 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 and Royalty Payments

Various milestone and royalty payments were required under our agreements with Luitpold, Kensey Nash, Novartis, and Collagen Matrix, Inc. (''CMI'') 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 and CMI 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 (Kensey Nash) and *Augmatrix* (CMI).

Our first product, *GEM 21S*, was approved by 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 to Novartis and 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 were required to obtain a reclassification of *GEM 21S* from a drug product to a medical device prior to March 31, 2011. On November 12, 2010, we obtained such reclassification, and in January 2012, we announced receipt of the CE Mark for *GEM 21S* in the EU. We believe this CE Mark, obtained on behalf of Luitpold, triggers a $10.0 million final milestone payment due to us from Luitpold pursuant to the terms of our sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re- evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified us that it is evaluating whether the milestone conditions have been satisfied. We are considering our options in the event Luitpold does not make the payment.

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. Also, the agreement with CMI includes certain time-based milestone payments that we are obligated to pay CMI based on the execution date of the agreement, and we may be required to make additional milestone payments to CMI if certain *Augmatrix* sales targets are achieved.

All of the milestone payments under our agreements with ZymoGenetics and Harvard have been satisfied. With the exception of a $50,000 time-based milestone payment to CMI that is due six months after the execution of the agreement, the remaining milestone payments the we are required to pay to Kensey Nash and CMI remain contingent and have not yet occurred. Assuming that all future contingencies are met and all payments are made, we anticipate that the milestone payments that we are required to make will result in a total payment by us of approximately $0.4 million in the near term (from 2012 to 2013). Because of the

uncertainty regarding the potential sales growth for *Augmatrix* and uncertainty regarding the timing associated with the *Augment Injectable* development program in view of our recent voluntary suspension of additional screening and enrollment of patients in the pivotal clinical study, we are unable to estimate the amount and timing of our remaining long-term (beyond 2013) milestone obligations.

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 agreements with ZymoGenetics relating to such patents, we had 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 patent agreements, we were 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. As a result of our first shipment of *Augment* to a Canadian distributor in December 2009, we recognized a $1.0 million liability and royalty expense in our consolidated balance sheet and statement of operations, respectively, as of and for the year ended December 31, 2010.

In October 2010, Bristol-Myers Squibb Company (''BMS'') acquired ZymoGenetics and thereby assumed ZymoGenetics' rights and responsibilities under our licensing agreements therewith. In June 2011, we signed the BMS Amendment which converts our exclusive world-wide licenses to royalty-free, fully paid up, irrevocable licenses for intellectual property covering various formulations of rhPDGF and manufacturing processes for rhPDGF. The BMS Amendment provides for a one-time, final payment from us to BMS totaling $1.5 million, which was paid in July 2011. This payment satisfied the $1.0 million liability recognized as of December 31, 2010, and an additional $0.5 million was recognized as royalty expense in the consolidated statement of operations for the year ended December 31, 2011. No further payments of any kind (milestone, royalty, minimum royalty, sales bonus, or sublicense fees) will be due from us to BMS under the ZymoGenetics agreements.

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 on Form 10-K, 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 Accounting Standards Codification (''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 for sublicense fees, once received, are deferred and recognized as revenue on a straight-line basis over the remaining term of the sublicense. 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, 2011, 2010 and 2009.

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 and 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. 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.

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, 2011, 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

Our 2001 Long-Term Stock Incentive Plan (the ''2001 stock incentive plan'') provided that incentive stock options (''ISOs''), non-qualified stock options (''NQSOs''), stock appreciation rights (''SARs''), stock units, restricted stock, restricted stock units, performance units, performance shares awards and other equity-based interests could be granted to key personnel at an exercise price determined by our Compensation Committee, at the time the award was 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 2001 stock incentive plan was 10 years from the date of grant. The 2001 stock incentive plan expired in 2011 and no further options will be granted under this stock incentive plan. Our Board of Directors has approved the adoption of a new stock incentive plan subject to stockholder approval at our 2012 annual meeting of stockholders.

Historically, our long-term incentive compensation has consisted primarily of stock options. The stock options that we granted to employees were generally structured to qualify as ISOs or NQSOs, and stock options granted to non-employees, such as directors and consultants, were structured as NQSOs. 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 receive a tax deduction for the exercise of NQSOs. We have not recognized any income tax benefit for the three years ended December 31, 2011 for share-based compensation arrangements due to the fact that we do not believe that we will recognize any deferred tax assets from such compensation cost recognized in the current period.

In general, stock option awards granted under the 2001 stock incentive plan vest 25% per year over a four-year period. The 2001 stock incentive plan provides that upon a change in control all outstanding ISO awards held bya qualified employee may, under certain circumstances, be accelerated and exercisable immediately. Upon a change in control, the accelerated vesting percentage of a qualified 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. An employee will become a qualified employee following a change in control only upon the occurrence of certain events that impact the employee's employment.

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, 2011 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, 2011: risk-free interest rate of 2.27%, expected dividend yield of 0%, volatility factor of the expected market price of our common stock of 76%, forfeiture rate of 15.3% 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 is based on historical data from three companies similar in size and value to us. The expected dividend yield is based on our historical dividend experience, however, since our inception, we have not declared dividends. 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. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. We estimate pre-vesting forfeitures at the time of grant by analyzing historical data and revise those estimates in subsequent periods if actual forfeitures differ materially from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. 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. Our 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 or consultants tend to hold the stock options longer term, represented by the higher end of the range.

During the year ended December 31, 2011, we granted stock options to our employees, members of the board of directors, and consultants to purchase an aggregate of 727,830 shares of our common stock at a weighted average exercise price of $12.23. Our net loss for the years ended December 31, 2011, 2010 and 2009 includes compensation costs of $3.6 million, $4.0 million and $3.9 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.

Our ability to use our net operating loss (''NOL'') carryforwards could be limited and subject to annual limitations. In connection with future years, we may realize a ''more than 50% change in ownership'' which could further limit our ability to use our 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, we may not be able to take advantage of all or portions of our NOL carryforwards for federal income tax purposes.

We file income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. With few exceptions, we are no longer subject to U.S. federal examinations or state and local income tax examinations by tax authorities for years before 2007.

Effective January 1, 2007, we 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 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, 2011, 2010 and 2009.

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 — Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs that are not corroborated by market data, therefore requiring us to develop our own assumptions.

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, 2011 and 2010

Net loss for the year ended December 31, 2011 was $33.2 million, or $1.19 per diluted share, compared to net loss of $33.9 million, or $1.38 per diluted share, for the same period in 2010. We anticipate that our operating losses, which are only partially offset by product sales, royalty income, sublicense fee income and investment income, may continue over the next few years as we continue to fund our research and development activities and clinical trials and as we implement our sales and marketing network to represent our products.

Product Sales Revenue

We recorded product sales revenues of approximately $0.3 million for the year ended December 31, 2011 compared to $14,742 for the same period in 2010. In October 2011, we modified our sales channel in Canada. We are now selling *Augment* in Canada through an exclusive independent sales agent, who sells *Augment* through a sales force of independent distributors across Canada. We do not anticipate significant revenues from sales of *Augment* in Canada in the near term.

Also, pursuant to the TGA's approval of our medical device application for *Augment*, we will sell *Augment* through an exclusive distributor, who is an independent distributor of medical devices in the Australian and New Zealand orthobiologics space and has a team of experienced sales representatives who will sell our product. However, we do not anticipate significant revenues from sales of *Augment* in Australia and New Zealand.

We are currently seeking additional regulatory approvals of our products and product candidates in the United States, Europe, New Zealand, and certain other countries around the world. We expect product sales revenues to increase when, and if, these efforts materialize. Most significantly we expect product sales of *Augment* to commence in the United States when, and if, the FDA approves the commercialization of *Augment*.

Cost of Sales

Cost of sales for the year ended December 31, 2011 was $53,431 compared to $17,250 for the same period in 2010. 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 in our consolidated statements of operations.

Royalty and Sublicense Fee Income

Royalty income for the year ended December 31, 2011 was $0.4 million compared to $0.5 million for the same period in 2010. 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, 2011 and 2010, Luitpold's net sales of *GEM 21S* as reported to us were $4.2 and $4.8 million, respectively.

Sublicense fee income for the year ended December 31, 2011 was $1.0 million, which is comparable to $1.0 million for the same period in 2010. 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 include outside professional services expenses, as well as salaries, wages, benefits, payroll taxes and stock compensation expense for internal R&D personnel, and 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, 2011 were $14.7 million compared to $18.0 million for the same period in 2010. The $3.3 million decrease resulted from:

- a decrease of $2.0 million in professional fees and manufacturing activities as costs associated with the completed *Augment* clinical trials have slowed since 2010;
- a decrease of $1.0 million in salaries, benefits, payroll taxes and stock-based compensation expense due to a reduction in staffing in the research and development function; and
- a decrease of $0.3 million in general business activities in the research and development function, such as travel, insurance, lab supplies and telephone.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2011 were $16.0 million, compared to $15.2 million for the same period in 2010. Driven in part by our sales, marketing and customer service efforts, particularly in connection with our activities surrounding our preparation for commercial launch of *Augment*, the $0.8 million increase resulted from:

- an increase of $0.5 million in salaries, benefits, payroll taxes and stock-based compensation costs primarily driven by a net increase of five employees in the sales department;
- an increase of $0.3 million in travel and advertising driven primarily by our sales department's efforts to establish a sales network in anticipation of the commercialization of *Augment*;
- an increase of $0.4 million in rent and utilities; and
- a decrease of $0.4 million in royalty expense, as described further in ''Milestone and Royalty Payments'' above.

Depreciation and Capital Lease Amortization

Depreciation and capital lease amortization for the year ended December 31, 2011 was $1.3 million compared to $1.2 million for the same period in 2010. During 2011, we purchased equipment, computers and software totaling $0.9 million. In addition, leasehold improvements totaling $2.2 million relating to our new manufacturing and warehousing facility were capitalized during 2011.

Patent License Fee Amortization

Patent license fee amortization for the year ended December 31, 2011 was $36,793, compared to almost $1.7 million for the same period in 2010. In 2010, we wrote-off certain capitalized costs totaling $12.4 million related to patents that had expired and were fully amortized as of year-end 2010. Thus, ongoing amortization expense is attributable to the capitalization of the remaining patent license fees, which amounted to a cumulative $2.5 million as of December 31, 2011.

Interest and Investment Income

Total net interest and investment income for the year ended December 31, 2011 was $108,538 compared to $140,118 for the same period in 2010. Interest rates earned on our cash and cash equivalents averaged 0.01% during the year ended December 31, 2011, compared to same period in 2010 when interest rates ranged from 0.01% to 0.02%.

Other Income and Expense

In 2011, we recorded a $2.9 million impairment loss on equipment intended to be used in our new manufacturing facility located on the same campus as our current office space in Franklin, Tennessee. We have not recognized any impairment losses on long-lived assets for the year ended December 31, 2010.

In 2010, we were awarded three government grants totaling $0.5 million which were recorded as other income on our consolidated income statement for the year ended December 31, 2010. No such items were received in 2011. For more information, refer to "*Years Ended December 31, 2010 and 2009 — Other Income*" below.

Provision for Income Taxes

At December 31, 2011, we had federal NOL carryforwards of $124.6 million, of which $2.1 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, 2011 totaled $110.2 million and will expire between 2013 and 2031. 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, 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. Excluding these items, the Company's net loss for the twelve months ended December 31, 2009 would have been $34.2 million, or $1.67 per diluted share.

Product Sales Revenue

In 2010, our product sales revenue consisted of limited sales of *Augment* in Canada. In November 2010, we changed our distribution strategy in Canada, and completed a transition from a single exclusive distributor to a network of over 30 independent sales agents representing *Augment* throughout Canada. These sales representatives were closely managed by us through a Canadian national sales manager.

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 in 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;
- an increase of $0.8 million in charitable contributions, taxes and licenses, recruiting and relocation, travel and general G&A activities; and
- 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 auction rate security (“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 0.02% 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 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.

Liquidity and Capital Resources

Cash Flows

For the year ended December 31, 2011, net cash used in operating activities was $28.7 million. Sources of cash primarily consisted of product sales and royalty income. Uses of cash primarily consisted of salaries and benefits, clinical trials, research and development activities and general corporate operations.

Net cash provided by investing activities was $35.3 million for the year ended December 31, 2011 and consisted of net sales of investments, purchases of property and equipment and purchases of capitalized patent costs. We have incurred costs related to a new building intended to house certain aspects of our manufacturing and warehousing operations. For the year ended December 31, 2011, these costs have included $1.0 million in engineering design/planning and build-out construction costs (for a cumulative total of $2.2 million as of December 31, 2011), which have been capitalized as leasehold improvements, and $0.1 million in equipment that has not yet been placed into service (for a cumulative total of $4.2 million as of December 31, 2011).

Net cash provided by financing activities was $0.2 million for the year ended December 31, 2011 and consisted of payments on capital lease obligations and net proceeds from issuance of common stock under our stock-based compensation plans.

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, or for us to obtain approval from regulatory authorities and successfully commercialize our product candidates, if at all, 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.

In June 2011, at our 2011 annual meeting of stockholders, our stockholders approved an amendment to the Amended and Restated Certificate of Incorporation to increase the number of shares of our common stock, par value $0.001 per share, authorized for issuance from 37,500,000 to 100,000,000.

Royalties and Milestones

In January 2008, we sold our remaining orofacial therapeutic business to Luitpold, including the rights to the downstream formulation, fill, finish, manufacturing and kitting of *GEM 21S*. As a result of this transaction, we expect to continue to receive ongoing royalty payments based on net sales of *GEM 21S* by Luitpold at least through 2026. For the years ended December 31, 2011, 2010 and 2009, we recorded royalty income in our consolidated statements of operations of $0.4 million, $0.5 million and $0.5 million, respectively. In addition, we believe that upon receipt of the CE Mark in the EU for *GEM 21S*, obtained on behalf of Luitpold, we are entitled to a $10.0 million final milestone payment pursuant to the terms of our sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified us that it is evaluating whether the milestone conditions have been satisfied. We are considering our options in the event Luitpold does not make the payment.

We have licensed a number of U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. All of the licensed intellectual property covering our current product candidates has expired, and all of our financial obligations with respect to such licenses has ended. In accordance with an amendment to the Patent License Agreement with ZymoGenetics, we paid a $1.5 million royalty in July 2011 as final payment under that agreement. In addition, various other milestone and royalty payments may be required to be paid to us under our agreements with Luitpold or paid by us under our agreements with Kensey Nash and CMI. Refer to ‘‘Financial Operations Overview — Milestone and Royalty Payments’’ for more information regarding these royalty and milestone payments.

Cash and Cash Equivalents and Investments

As of December 31, 2011, the remaining net proceeds from our net cash flows, capital offerings, the 2008 sale of our orofacial therapeutic business, including *GEM 21S*, and our royalties and milestones have been invested conservatively in cash and cash equivalents and investments in GSE securities, corporate bonds, municipal bonds, bank bonds and commercial paper.

At December 31, 2011, we had $18.5 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, 2011, we had $43.0 million in short-term investments classified as available-for-sale consisting of $15.5 million in GSE securities, $10.1 million in corporate bonds, $2.9 million in municipal bonds, $3.0 million in bank bonds, and $11.5 million in commercial paper. The short-term GSE securities have maturity dates ranging from May 2012 to August 2012 with coupon rates ranging from 0.256% to 0.35%. The corporate bonds have maturity dates ranging from February 2012 to November 2012 with coupon rates ranging from 1.875% to 6.95%. The municipal bonds have maturity dates ranging from January 2012 to March 2012 with coupon rates ranging from 2.0% to 5.25%. The bank bond has a maturity date of January 2012 with a coupon rate of 0.26%. The commercial paper investments have maturity dates ranging from January 2012 to June 2012.

We believe that the December 31, 2011 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 2010 as described above will be sufficient to meet our anticipated cash requirements at least through 2013.

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

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, 2011 are as follows (in thousands):

	2011	2010	2009
Net loss	$(33,190)	$(33,937)	$(21,157)
Other comprehensive loss:			
Net unrealized (loss) gain on foreign currency translation	(2)	—	—
Net unrealized gain (loss) on investments classified as available for sale	9	(20)	(118)
Comprehensive loss	$(33,183)	$(33,957)	$(21,275)

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, 2011					
1st Quarter	$0.4	$ (8.0)	$ (8.0)	$(0.28)	$(0.28)
2nd Quarter	0.4	(8.3)	(8.2)	(0.29)	(0.29)
3rd Quarter	0.4	(7.1)	(7.1)	(0.25)	(0.25)
4th Quarter	0.5	(6.9)	(9.9)	(0.35)	(0.35)
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)

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, 2011:

	Payments due by period				
Contractual obligations	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Capital lease obligations	$ 221,772	$ 87,611	$ 134,161	$ —	$ —
Operating lease obligations	10,777,174	1,516,611	3,171,082	3,364,201	2,725,280
Purchase and supplier obligations – raw materials	17,069,725	3,957,021	8,913,482	4,199,222	—
Total	$28,068,671	$5,561,243	$12,218,725	$7,563,423	$2,725,280

Recent Accounting Pronouncements

Fair Value Measurements and Disclosures

In May 2011, the Financial Accounting Standards Board (‘‘FASB’’) issued Accounting Standards Update (‘‘ASU’’) No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (‘‘ASU 2011-04’’). The amendments in ASU 2011-04 generally represent a clarification of Topic 820, but also change certain fair value measurement principles and enhance the disclosure requirements particularly for level 3 fair value measurements. ASU 2011-04 also provides a consistent definition of fair value and ensures that the requirements for measuring fair value and for disclosing information about fair value measurements are similar in accordance with U.S. generally accepted accounting principles and International Financial Reporting Standards (‘‘IFRS’’). The amendments are effective for interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. Early application is not permitted. We do not expect the adoption of ASU 2011-04 to have a material impact on our consolidated financial statements.

Presentation of Comprehensive Income

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220) — Presentation of Comprehensive Income* (''ASU 2011-05''). ASU 2011-05 requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of equity, which is our current presentation, and also requires presentation of reclassification adjustments from other comprehensive income to net income on the face of the financial statements.

In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220)* (''ASU 2011-12''). ASU 2011-12 defers the requirement to present reclassification adjustments from other comprehensive income to net income on the face of the financial statements, pending further deliberation by the FASB.

These amendments are effective for interim and annual periods beginning after December 15, 2011 and are to be applied retrospectively. Early application is permitted, although we have not elected to adopt early. We do not expect the adoption of ASU 2011-05 and ASU 2011-12 to have a material impact on our consolidated financial statements, though it will change financial statement presentation once adopted in 2012.

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 averaging 0.01% during the year ended December 31, 2011. We have not used derivative financial instruments for speculation or trading purposes.

At December 31, 2011, we had $18.5 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, 2011, we had $43.0 million in short-term investments classified as available-for-sale and consisting of GSE securities, corporate bonds, municipal bonds, bank bonds and commercial paper. These investments have maturity dates ranging from January 2012 to November 2012 and coupon rates ranging from 0.256% to 6.95%.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required for each of the three years ended December 31, 2011 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 the period covered by this Annual Report on Form 10-K. 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 period covered by this Annual Report on Form 10-K 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, 2011, 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, 2011, 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, 2011, 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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011 of BioMimetic Therapeutics, Inc., and our report dated March 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 13, 2012

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 2012 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2011.

Item 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference from the definitive proxy statement for our 2012 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2011.

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 2012 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2011.

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 2012 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2011.

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 2012 annual meeting of stockholders, which will be filed no later than 120 days after December 31, 2011.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. All financial statements

Consolidated financial statements filed as part of this report are listed on Page F-1 of this Annual Report on Form 10-K.

2. Financial statement schedules

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

3. Exhibits

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

BIOMIMETIC THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Consolidated Financial Statements	
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2011 and 2010	F-3
Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2011, 2010 and 2009	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009	F-6
Notes to Consolidated Financial Statements	F-7

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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 13, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 13, 2012

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2011	December 31, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,503,061	$ 11,628,329
Investments − short term	42,950,397	65,751,039
Receivables − trade	85,759	8,050
Receivables − other	1,121,596	468,380
Inventory	3,528,771	2,258,193
Prepaid expenses	485,385	588,063
Total current assets	66,674,969	80,702,054
Investments − long term	0	15,001,765
Receivables − long term	73,801	0
Prepaid expenses − long term	4,577	5,252
Property and equipment, net	5,304,565	7,592,820
Capitalized patent license fees, net	2,443,590	1,867,937
Deposits	385,000	385,000
Total assets	$ 74,886,502	$ 105,554,828
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,392,910	$ 1,670,830
Accrued payroll, employee benefits and payroll taxes	2,430,701	2,590,126
Other accrued expenses	634,216	1,908,680
Current portion of capital lease obligations	83,921	78,665
Deferred revenue	973,849	971,188
Total current liabilities	6,515,597	7,219,489
Accrued rent − related party	622,950	419,465
Capital lease obligations	131,724	215,644
Deferred revenue	13,604,641	14,578,490
Total liabilities	20,874,912	22,433,088
Stockholders' equity:		
Preferred stock, $0.001 par value; 15,000,000 shares authorized; no shares issued and outstanding as of December 31, 2011 and 2010	0	0
Common stock, $0.001 par value; 100,000,000 shares authorized and 28,128,280 shares issued and outstanding as of December 31, 2011; 37,500,000 shares authorized and 27,925,984 shares issued and outstanding as of December 31, 2010	28,128	27,926
Additional paid-in capital	214,626,320	210,553,647
Accumulated other comprehensive income	4,490	(2,462)
Accumulated deficit	(160,647,348)	(127,457,371)
Total stockholders' equity	54,011,590	83,121,740
Total liabilities and stockholders' equity	$ 74,886,502	$ 105,554,828

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2011	2010	2009
Revenues:			
Product sales	$ 326,547	$ 14,742	$ 78,000
Royalty income	427,211	487,595	522,038
Sublicense fee income	971,188	971,188	971,188
Total revenues	1,724,946	1,473,525	1,571,226
Costs and expenses:			
Cost of sales (exclusive of depreciation and amortization shown separately below)	53,431	17,250	5,666
Research and development[(a)]	14,694,803	17,966,916	21,095,429
General and administrative[(b)]	16,033,714	15,160,468	11,511,619
Depreciation and capital lease amortization	1,256,552	1,234,335	1,332,881
Patent license fee amortization	36,793	1,658,104	2,569,159
Total costs and expenses	32,075,293	36,037,073	36,514,754
Loss from operations	(30,350,347)	(34,563,548)	(34,943,528)
Interest expense, net	(4,321)	(3,602)	(308,127)
Investment income, net	112,859	143,720	6,863,834
Impairment loss on equipment	(2,939,601)	0	0
Other income from governmental grants	0	513,959	0
Gain on arbitration settlement	0	0	7,219,270
(Loss) gain on foreign currency translation and other	(8,567)	(27,680)	11,137
Loss before income taxes	(33,189,977)	(33,937,151)	(21,157,414)
Income taxes	0	0	0
Net loss	$(33,189,977)	$(33,937,151)	$(21,157,414)
Basic and diluted net loss per share	$ (1.19)	$ (1.38)	$ (1.03)
Weighted average shares used to compute basic and diluted net loss per share	28,002,185	24,626,170	20,510,132
Related party disclosures:			
(a) − Research and development includes professional fees to related parties	$ 32,375	$ 14,875	$ 9,000
(b) − General and administrative includes rent and operating expenses to related parties	$ 2,099,043	$ 1,898,668	$ 1,271,243

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2011, 2010 and 2009

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	0	0	0	0	(21,157,414)	(21,157,414)
Other comprehensive income:						
Net unrealized loss on investments				(118,155)	0	(118,155)
Total comprehensive loss				(118,155)	(21,157,414)	(21,275,569)
Issuance of common stock	169,784	170	806,127	0	0	806,297
Private placement of common stock, net	941,177	941	7,982,638	0	0	7,983,579
Registration rights issuance of common stock, net	2,000,000	2,000	16,588,395	0	0	16,590,395
Compensation expense relating to common stock options granted	0	0	3,892,895	0	0	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	0	0	0	0	(33,937,151)	(33,937,151)
Other comprehensive loss:						
Net unrealized gain on foreign currency translation				111	0	111
Net unrealized loss on investments				(19,960)	0	(19,960)
Total comprehensive loss				(19,849)	(33,937,151)	(33,957,000)
Issuance of common stock	458,676	459	1,113,950	0	0	1,114,409
Public offering of common stock, net	5,642,280	5,642	44,923,405	0	0	44,929,047
Compensation expense relating to common stock options granted	0	0	3,983,667	0	0	3,983,667
Balance at December 31, 2010	27,925,984	27,926	210,553,647	(2,462)	(127,457,371)	83,121,740
Comprehensive loss:						
Net loss	0	0	0	0	(33,189,977)	(33,189,977)
Other comprehensive loss:						
Net unrealized loss on foreign currency translation				(2,256)	0	(2,256)
Net unrealized gain on investments				9,208	0	9,208
Total comprehensive loss				6,952	(33,189,977)	(33,183,025)
Issuance of common stock	202,296	202	468,739	0	0	468,941
Compensation expense relating to common stock options granted	0	0	3,603,934	0	0	3,603,934
Balance at December 31, 2011	28,128,280	$28,128	$214,626,320	$ 4,490	$(160,647,348)	$ 54,011,590

See accompanying notes.

BIOMIMETIC THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2011	2010	2009
Cash flows from operating activities			
Net loss	$(33,189,977)	$ (33,937,151)	$(21,157,414)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and capital lease amortization expense	1,256,552	1,234,335	1,332,881
Patent license fee amortization	36,793	1,658,104	2,569,159
Gain on investments	0	0	(5,800,550)
Loss on disposal of equipment	0	200	32,074
Net unrealized (loss) gain on foreign currency translation	(2,256)	111	0
Bad debt expense	(1,175)	0	0
Impairment loss on equipment	2,939,601	0	0
Non-cash stock-based compensation expense	3,603,934	3,983,667	3,892,895
Non-cash issuance of common stock	154,402	283,188	374,211
Non-cash interest income from disposal of business	0	0	(217,685)
Changes in operating assets and liabilities:			
Receivables	(803,551)	213,590	1,164,527
Inventory	(1,270,578)	(1,213,888)	217,682
Prepaid expenses	103,353	(14,101)	(17,509)
Accounts payable, accrued payroll and other accrued expenses	(508,323)	1,480,741	(4,313,055)
Deferred revenue	(971,188)	(971,188)	(971,188)
Net cash used in operating activities	(28,652,413)	(27,282,392)	(22,893,972)
Cash flows from investing activities			
Capitalized patent license fees	(612,446)	(601,427)	(510,044)
Purchases of property and equipment	(1,907,898)	(534,097)	(2,310,910)
Equipment deposits	0	0	1,899,608
Purchases of investments	(76,118,386)	(126,807,284)	(58,370,400)
Sales of investments	113,930,000	99,550,000	90,379,590
Net proceeds from disposal of business	0	0	10,000,000
Net cash provided by (used in) investing activities	35,291,270	(28,392,808)	41,087,844
Cash flows from financing activities			
Payments on capital lease obligations	(78,664)	(73,445)	(18,187)
Issuance of common stock under compensation plans	314,539	831,221	432,085
Net proceeds from issuance of common stock	0	45,002,406	24,500,614
Payments on note payable	0	0	(39,100,000)
Net cash provided by (used in) financing activities	235,875	45,760,182	(14,185,488)
Net increase (decrease) in cash and cash equivalents	6,874,732	(9,915,018)	4,008,384
Cash and cash equivalents, beginning of period	11,628,329	21,543,347	17,534,963
Cash and cash equivalents, end of period	$ 18,503,061	$ 11,628,329	$ 21,543,347
Supplemental disclosures of cash flow information			
Interest paid	$ 5,339	$ 4,479	$ 529,265
Supplemental non-cash disclosures			
Acquisition of property and equipment through capital leases	$ 0	$ 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'') is a biotechnology company specializing in the development and commercialization of innovative products to promote the healing of musculoskeletal injuries and diseases, including therapies for orthopedic, sports medicine and spine applications.

The Company's first periodontal product, *GEM 21S*® Growth-factor Enhanced Matrix (''*GEM 21S*''), received regulatory approval from the U.S. Food and Drug Administration (''FDA'') in November 2005. The Company's first orthopedic product, Augment™ Bone Graft (''*Augment*''), received regulatory approval from Health Canada (''HC'') in November 2009, and was listed by the Australian Therapeutics Goods Administration (''TGA'') in October 2011 and the New Zealand Medicines and Medical Devices Safety Authority (''Medsafe'') in December 2011. The Company continues to seek FDA approval for the marketing of *Augment* in the United States, as well as regulatory approval of *Augment* in other jurisdictions such as the European Union (''EU'') the Middle East, Asia and Latin America.

The Company first recorded product sales revenue from sales of *GEM 21S* in December 2005. 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, hiring skilled employees, and developing its product and product candidates through pre-clinical studies, clinical trials and regulatory activities in the United States, Canada, Europe 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, BioMimetic Therapeutics Canada, Inc., and BioMimetic Therapeutics USA, Inc. Inter-company balances and transactions are eliminated in consolidation. As of December 31, 2011, BioMimetic Therapeutics Limited and BioMimetic Therapeutics Pty Ltd. had no employees and had no operating activities other than making and maintaining regulatory submissions for the Company's product candidates in the EU and Australia, respectively. BioMimetic Therapeutics Canada, Inc. was established in 2010 to facilitate sales activities in Canada for *Augment*, the Company's first orthopedic product, which received regulatory approval from HC in the fourth quarter of 2009. As of December 31, 2011, BioMimetic Therapeutics Canada, Inc. had no employees and had incurred certain operational expenses. BioMimetic Therapeutics USA, Inc., a Delaware corporation, was formed by the Company in 2011 to facilitate product sales activities in the United States.

1. Nature of the Business, Background and Basis of Presentation − (continued)

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, 2011 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 balances at December 31, 2011 and 2010 represent the amounts due from product sales of *Augment*. An allowance of $6,875 and $8,050 has been recorded as of December 31, 2011 and 2010, respectively, 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) accrued interest receivable, (3) third party reimbursements, and (4) 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.

2. Summary of Significant Accounting Policies − (continued)

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, 2011, no reserves have been recorded associated with these future purchase commitments.

Prepaid Expenses

Prepaid expenses consist of supplies, 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 February 2029.

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. During the year ended December 31, 2011, the Company recorded a $2,939,601 impairment loss on equipment intended to be used in its new manufacturing facility located on the same campus as its current office space in Franklin, Tennessee. The Company has not recognized any impairment losses on long-lived assets for the years ended December 31, 2010 and 2009.

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

2. Summary of Significant Accounting Policies − (continued)

that the Company does not identify certain costs that have begun to be incurred or the Company under- or over-estimates the level of services performed or the costs of such services, the actual expenses could differ from such estimates. The date on which certain services commence, the level of services performed on or before a given date, and the cost of such services are often subjective determinations. Management makes these estimates based upon the facts and circumstances known to it at the time and in accordance with U.S. generally accepted accounting principles. Milestone payments due within 12 months are considered short-term liabilities and those due in over 12 months are considered long-term liabilities.

Revenue Recognition

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

Product sales

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 Pharmaceuticals, Inc. (''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, 2011, 2010 or 2009. 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 in Ontario, Canada. Also, the Company received clearance from the TGA and Medsafe in October and December 2011, respectively, for the marketing and commercialization of *Augment* in Australia. Accordingly, the Company recorded product sales revenue from sales of *Augment* in each of the three years ended December 31, 2011.

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*.

2. Summary of Significant Accounting Policies − (continued)

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, once the proceeds of these milestone payments are received, the Company amortizes them 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 total proceeds from these milestones.

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 December 2011, the Company recorded a $2,939,601 impairment loss on equipment intended to be used in its new manufacturing facility located on the same campus as our current office space in Franklin, Tennessee. The Company has not recognized any impairment losses on long-lived assets for the years ended December 31, 2010 and 2009.

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 QTDP program cash grant. The three resulting government cash grants received by the Company during the year ended December 31, 2010 were recognized as other income when awarded.

In 2009, the Company had investments in certain auction rate securities (''ARS''). In December 2009, upon disposition of its remaining investments in ARS, the Company recorded a gain on arbitration settlement of $7,219,270, which is classified as a separate line item below loss from operations in the consolidated statement of operations for the year ended December 31, 2009.

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.

2. Summary of Significant Accounting Policies − (continued)

Income Taxes

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

The Company's 2001 Long-Term Stock Incentive Plan (the ''2001 stock incentive plan'') provided that incentive stock options (''ISOs''), non-qualified stock options (''NQSOs''), stock appreciation rights (''SARs''), stock units, restricted stock, restricted stock units, performance units, performance shares awards and other equity-based interests could be granted to key personnel at an exercise price determined by the Company's Compensation Committee, at the time the award was 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 2001 stock incentive plan was 10 years from the date of grant. The 2001 stock incentive plan expired in 2011 and no further options will be granted under this stock incentive plan. The Company's Board of Directors has approved the adoption of a new stock incentive plan subject to stockholder approval at the Company's 2012 annual meeting of stockholders.

Historically, the Company's long-term incentive compensation has consisted primarily of stock options. The stock options that the Company granted to employees were generally structured to qualify as ISOs or NQSOs, and stock options granted to non-employees, such as directors and consultants, were structured as NQSOs. 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, 2011 for share-based compensation arrangements due to the fact that the Company 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 2001 stock incentive plan vest 25% per year over a four-year period. The 2001 stock incentive plan 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 accelerated vesting percentage of a qualified 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,

2. Summary of Significant Accounting Policies − (continued)

75% vested if employed more than two years but less than three years, and 100% vested if employed three or more years. An employee will become a qualified employee following a change in control only upon the occurrence of certain events that impact the employee's employment.

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, 2011 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 there is a limited trading history for the Company's common stock, the expected volatility is based on historical data from three companies similar in size and value to the Company. The expected dividend yield is based on the Company's historical dividend experience, however, since its inception, the Company has not declared dividends. 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. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. The Company estimates pre-vesting forfeitures at the time of grant by analyzing historical data and revises those estimates in subsequent periods if actual forfeitures differ materially from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. 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 or consultants tend to hold the stock options longer term, represented by the higher end of the range.

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.

2. Summary of Significant Accounting Policies − (continued)

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 12.

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, 2011, the Company had short-term investments of $42,950,397 classified as available-for-sale. These short-term investments consist of U.S. government sponsored enterprise (''GSE'') securities, corporate bonds, municipal bonds, a bank bond and commercial paper. These investments have maturity dates ranging from January 2012 to November 2012 with coupon rates ranging from 0.256% to 6.95%.

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.

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 May 2011, the Financial Accounting Standards Board (''FASB'') issued Accounting Standards Update (''ASU'') No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (''ASU 2011-04''). The amendments in ASU 2011-04 generally represent a clarification of Topic 820, but also change certain fair value measurement principles and enhance the disclosure requirements particularly for level 3 fair value measurements (as defined in Note 12 below). ASU 2011-04 also provides a consistent definition of fair value and ensures that the requirements for measuring fair value and for disclosing information about fair value measurements are similar in accordance with U.S. generally accepted accounting principles and International Financial Reporting Standards (''IFRS''). The amendments are effective for interim and annual periods beginning after December 15, 2011 and are to be applied prospectively. Early application is not permitted. The Company does not expect the adoption of ASU 2011-04 to have a material impact on its consolidated financial statements.

2. Summary of Significant Accounting Policies − (continued)

Presentation of Comprehensive Income

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220) — Presentation of Comprehensive Income* (''ASU 2011-05''). ASU 2011-05 requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of equity, which is the Company's current presentation, and also requires presentation of reclassification adjustments from other comprehensive income to net income on the face of the financial statements.

In December 2011, the FASB issued ASU No. 2011-12, *Comprehensive Income (Topic 220)* (''ASU 2011-12''). ASU 2011-12 defers the requirement to present reclassification adjustments from other comprehensive income to net income on the face of the financial statements, pending further deliberation by the FASB.

These amendments are effective for interim and annual periods beginning after December 15, 2011 and are to be applied retrospectively. Early application is permitted, although the Company has not elected to adopt early. The Company does not expect the adoption of ASU 2011-05 and ASU 2011-12 to have a material impact on its consolidated financial statements, though it will change financial statement presentation once adopted in 2012.

3. Net Loss Per Share

The Company calculates net loss per share in accordance with Accounting Standards Codification (''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 2,748,331, 2,615,688 and 2,543,235 shares as of December 31, 2011, 2010 and 2009, 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 income (loss) and its components in the consolidated financial statements. The Company's comprehensive income (loss) as defined by ASC 220 is the total of net income (loss) and all other changes in equity resulting from non-owner sources including unrealized gains/losses on investments.

4. Comprehensive Loss − (continued)

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

	Years Ended December 31,		
	2011	2010	2009
Net loss	$(33,189,977)	$(33,937,151)	$(21,157,414)
Other comprehensive loss:			
Net unrealized (loss) gain on foreign currency translation	(2,256)	111	0
Net unrealized gain (loss) on investments classified as available for sale	9,208	(19,960)	(118,155)
Comprehensive loss	$(33,183,025)	$(33,957,000)	$(21,275,569)

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*. 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.

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*. As a result of this transaction, 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 had licensed a number of other third-party U.S. patents and their foreign counterparts covering various formulations of rhPDGF or manufacturing processes for rhPDGF. As a part of the licensing agreements with ZymoGenetics, Inc. (''ZymoGenetics'') 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 was 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. As a result of the Company's first shipment of *Augment* to a Canadian distributor in December 2009, the Company recognized a $1,000,000 liability and royalty expense in its consolidated balance sheet and statement of operations, respectively, as of and for the year ended December 31, 2010.

In October 2010, Bristol-Myers Squibb Company (''BMS'') acquired ZymoGenetics and assumed ZymoGenetics' rights and responsibilities under the licensing agreements. In June 2011, the Company entered into an Amendment to Patent License Agreement (''BMS Amendment'') with BMS which converts the

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

Company's exclusive world-wide licenses to royalty-free, fully paid up, irrevocable licenses for intellectual property covering various formulations of rhPDGF and manufacturing processes for rhPDGF. The BMS Amendment provides for a one-time, final payment from the Company to BMS totaling $1,500,000, which was paid in July 2011. This payment satisfied the $1,000,000 liability recognized as of December 31, 2010, and an additional $500,000 recognized as royalty expense in the consolidated statement of operations for the year ended December 31, 2011. No further royalty payments are due from the Company to BMS in accordance with the amendment. See Note 13.

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 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 January 2012, the Company announced receipt of the CE Mark for *GEM 21S* in the EU. The Company believes this CE Mark, obtained on behalf of Luitpold, triggers a $10,000,000 final milestone payment due to the Company from Luitpold pursuant to the terms of the sale of *GEM 21S* to Luitpold in 2008. At the request of Luitpold, the EU regulatory authorities are re-evaluating the CE Mark. Given this re-evaluation, the EU regulatory authorities have suspended the *GEM 21S* CE Mark until the re-evaluation process is finalized. Luitpold has therefore notified the Company that it is evaluating whether the milestone conditions have been satisfied. The Company is considering its options in the event Luitpold does not make the payment.

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, once the proceeds of these milestone payments are received, the Company amortizes them 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 proceeds from these milestones. If the Company receives the $10,000,000 milestone from Luitpold, it will be amortized and recorded to sublicense fee income.

6. Receivables — Other

Other receivables at December 31 are summarized as follows:

	2011	2010
Royalties receivable	$ 99,237	$133,959
Accrued interest receivable	138,461	323,122
Third party reimbursements	859,745	0
Franchise tax credit	22,627	0
Other	1,526	11,299
	$1,121,596	$468,380

The balance of third party reimbursements at December 31, 2011 includes an $843,892 receivable due from Luitpold for rhPDGF-BB shipped to Luitpold. During the fourth quarter of 2011, the Company purchased rhPDGF-BB inventory from Novartis Vaccines and Diagnostics (''Novartis''). Per agreements with Novartis and Luitpold, Novartis agreed to ship this inventory lot directly to Luipold, and Luitpold agreed to reimburse the Company for the purchase price plus shipping. Accordingly, the Company recorded a receivable from Lutipold, and a related payable to Novartis, as other receivables and accounts payable, respectively, on its consolidated balance sheet as of December 31, 2011. As discussed in Note 2, 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*. Luitpold utilizes rhPDGF-BB in its manufacture of *GEM 21S*.

7. Inventory

Inventory at December 31 is summarized as follows:

	2011	2010
Raw materials	$ 819,555	$1,413,306
Work in progress	2,458,001	902,550
Finished goods	285,397	234,206
	3,562,953	2,550,062
Reserve for obsolescence	(34,182)	(291,869)
	$3,528,771	$2,258,193

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* 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, 2011 due to shrinkage, waste or other loss. An allowance recorded as of December 31, 2010 consisted of $9,420 for shrinkage, and $282,449 for a product batch that was scrapped in the second quarter of 2011.

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.

8. Property and Equipment

Property and equipment at December 31 is summarized as follows:

	2011	2010
Equipment, IT hardware and purchased software	$ 4,092,877	$ 3,236,367
Furniture and fixtures	756,580	735,892
Leased equipment	316,041	190,208
Construction in process	0	1,160,301
Leasehold improvements	6,245,664	4,049,917
Equipment, IT hardware, purchased software, furniture and fixtures and leased equipment, not place in service	1,270,887	4,342,143
	12,682,049	13,714,828
Less accumulated depreciation and amortization	(7,377,484)	(6,122,008)
	$ 5,304,565	$ 7,592,820

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 facility located at the Company's headquarters. The new building shell was completed in October 2009, and the Company began recognizing rent expense at that time. The Company intends to utilize the new space as a good manufacturing practices (''GMP'') manufacturing facility and expects to move certain aspects of its manufacturing, warehousing and distribution operations to the new space once the facility is operational.

In April 2011, the Company entered into an amendment to the lease agreement for the new manufacturing and warehousing facility described above. The lease amendment, among other things, deletes certain provisions from the original lease agreement that provided for certain rent reductions if and to the extent that the building's occupancy increased, and replaced those provisions with automatic rent reductions that go into effect, on one or more occasions, either by a certain date or if the landlord rents space in the new building to a third party.

Since 2007, the Company has purchased manufacturing equipment, IT hardware and software, furniture and fixtures, and leased equipment that has not yet been placed into service. As of December 31, 2011, these purchases include $11,058 in lab equipment and IT hardware and software that the Company expects to place into service later in 2012, and $4,199,430 in manufacturing equipment that the Company intends to use in the new manufacturing, warehousing and distribution facility once build-out construction is completed. As described more fully in Note 2, 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. Due to the uncertainty surrounding the FDA's review of the Company's Pre-Market Approval (''PMA'') application for *Augment*, the uncertain timing of the related build-out construction of the new manufacturing facility and the need for immediate manufacturing operations, the uncertain future cash flows associated with the equipment, and the likelihood of deterioration and obsolescence of the equipment in the intervening years, the Company has determined that the equipment's fair value is impaired. In accordance with guidance from ASC 360, *Property, Plant and Equipment — Impairment and Disposal of Long-Lived Assets*, the Company discerned that the equipment's salvage value approximates its current fair market value. This equipment is highly technical and customized to the Company's specific needs, potentially inhibiting its re-sale value. Therefore, the estimated salvage value of the related equipment is based on independent broker quotes obtained for certain equipment items. As a result of such assessment, the salvage value is estimated to be 30% of the original cost. Therefore, as of December 31, 2011, the Company recorded a $2,939,601

8. Property and Equipment − (continued)

impairment loss on the manufacturing equipment intended to be used in its new manufacturing facility. Accordingly, the balance of manufacturing equipment not placed in service, net of impairment loss, is $1,259,829 as of December 31, 2011.

In addition, the Company has incurred engineering design/planning costs and build-out construction costs for the new manufacturing and warehousing facility which were recorded in construction in process as of December 31, 2010. As of December 31, 2011, the Company had cumulatively incurred $2,195,747 in such costs for the new facility, all of which were capitalized as leasehold improvements during the year ended December 31, 2011.

See Note 15 for additional information regarding the Company's operating lease agreements, leased equipment, and purchase commitments.

9. Deposits

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

10. Capitalized Patent License Fees

The Company has incurred, and continues to incur, costs related to patent license fees and patent applications for *Augment*, Augment® Injectable Bone Graft (''*Augment* Injectable''), Augment® Rotator Cuff Graft (''*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 February 2029. As of December 31, 2011 and 2010, the Company had remaining capitalized costs totaling $2,506,079 and $1,893,633, respectively, and accumulated amortization of $62,489 and $25,696, respectively, related to the acquisition of its patent licenses.

Based on agreements in place and payments made as of December 31, 2011, amortization expense related to capitalized patent license fees is $36,793 for the year ending December 31, 2011 and is expected to be $38,234 for each of the five years ending December 31, 2016.

11. Investments

As of December 31, 2011, the Company had short-term investments of $42,950,397 classified as available-for-sale. These short-term investments consist of $15,502,055 in U.S. government sponsored enterprise (''GSE'') securities, $10,090,930 in corporate bonds, $2,857,654 in municipal bonds, $3,000,240 in a bank bond and $11,499,518 in commercial paper. The short-term GSE securities have maturity dates ranging from May 2012 to August 2012 with coupon rates ranging from 0.256% to 0.35%. The corporate bonds have maturity dates ranging from February 2012 to November 2012 with coupon rates ranging from 1.875% to 6.95%. The municipal bonds have maturity dates ranging from January 2012 to March 2012 with coupon rates ranging from 2.0% to 5.25%. The bank bond has a maturity date of January 2012 with a coupon rate of 0.26%. The commercial paper investments have maturity dates ranging from January 2012 to June 2012.

In 2009, the Company had investments in certain auction rate securities (''ARS''). In December 2009, upon disposition of its remaining investments in ARS, the Company recorded a gain on arbitration settlement of $7,219,270. The Company did not have any investments in ARS as of December 31, 2011 or 2010.

In 2011, 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 net investment income in the accompanying consolidated statements of operations for the year ended December 31, 2011.

12. 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 — Observable inputs that reflect quoted prices (unadjusted) in active markets for identical assets and liabilities;

Level 2 — Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and

Level 3 — Unobservable inputs that are not corroborated by market data, therefore requiring the Company to develop its own assumptions.

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.

The financial assets and liabilities subject to fair value measurements at December 31 were as follows:

December 31, 2011	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$18,503,061	$ 0	$ 0	$18,503,061
Short-term investments (GSE securities, corporate, municipal and bank bonds, and commercial paper)	0	42,950,397	0	42,950,397
Total cash and investments	$18,503,061	$42,950,397	$ 0	$61,453,458

December 31, 2010	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$11,628,329	$ 0	$ 0	$11,628,329
Short-term investments (GSE securities and corporate bonds)	0	65,751,039	0	65,751,039
Long-term investments (GSE securities)	0	15,001,765	0	15,001,765
Total cash and investments	$11,628,329	$80,752,804	$ 0	$92,381,133

12. Fair Value Measurements − (continued)

Fair value estimate

At December 31, 2011 and 2010, the fair value measurement amounts for the Company's short-term and long-term investments consisted of marketable securities which are classified as available-for-sale. The carrying amounts reported in the consolidated balance sheets approximate the fair value of the Company's marketable securities based on quoted market prices or alternative pricing sources and models utilizing market observable inputs. 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.

To be consistent with the current presentation, the Company reclassified $80,752,804 of marketable securities previously reported as Level 1 assets as of December 31, 2010 to Level 2. The Company determined these assets should be classified as Level 2 because the investments are in corporate and agency notes, municipals, and commercial paper securities. At December 31, 2011 and 2010, the Company did not have any financial liabilities that were subject to fair value measurements.

13. Other Accrued Expenses

Other accrued expenses at December 31 are summarized as follows:

	2011	2010
Royalties payable	$ 39,082	$1,004,465
Professional fees	430,117	376,926
Legal fees	76,868	352,030
Taxes and licenses	40,929	89,206
Inventory	8,632	0
Patent costs	0	56,273
Facilities, supplies, equipment & utilities	2,624	21,262
Sales commissions payable	27,410	3,451
Other	8,554	5,067
	$634,216	$1,908,680

The balance of royalties payable at December 31, 2010 included a $1,000,000 liability representing royalties that were due under the Company's 2001 and 2003 Patent License Agreements with ZymoGenetics. In July 2011, after signing the BMS Amendment in June 2011, the Company paid to BMS a one-time payment of $1,500,000 as final payment under the Company's license agreements with ZymoGenetics. No further payments of any kind (milestone, royalty, minimum royalty, sales bonus, nor sublicense fees) will be due under the ZymoGenetics agreements. See Note 5 for more information.

14. 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.

15. Commitments and Contingencies

Litigation

In the ordinary course of business, the Company is subject to legal claims and assessments. Except as described below, the Company is not a party to any legal proceedings, claims or assessments that, in management's opinion, would have a material adverse effect on the Company's business, financial condition and results of operations.

In July 2011, a complaint was filed in the United States District Court, Middle District of Tennessee, against the Company and certain of its officers on behalf of certain purchasers of the Company's common stock. The complaint alleges that the Company and certain of its officers violated federal securities laws by making materially false and misleading statements regarding the Company's business, operations, management, future business prospects and the intrinsic value of the Company's common stock, the safety and efficacy of Augment, its prospects for FDA approval and inadequacies in Augment's clinical trials. The plaintiffs seek unspecified monetary damages and other relief.

In August 2011, a purported shareholder derivative complaint was filed in the United States District Court, Middle District of Tennessee, allegedly on behalf of and for the benefit of the Company, against all the members of the current Board of Directors of the Company, and names the Company as a nominal defendant. The shareholder derivative action makes factual allegations similar to the allegations in the class action lawsuit, and alleges breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets. The purported derivative action seeks modification of the Company's corporate governance policies and procedures, and also seeks monetary damages in an unspecified amount, including disgorgement of all profits, benefits and compensation obtained by the defendants, and plaintiff's costs and disbursements associated with the lawsuit, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses, and such other relief as the court deems just and proper.

If the Company is not successful in its defense of the class action litigation and the derivative litigation, the Company could be forced to make significant payments to, or enter into other settlements with, its stockholders and their lawyers, and such payments or settlement arrangements could have a material adverse effect on the Company's business, operating results and financial condition. Additional lawsuits with similar claims may be filed by other parties against the Company and its officers and directors. Even if such claims are not successful, these lawsuits or other future similar actions, or other regulatory inquiries or investigations, may result in substantial costs and have a significant adverse impact on the Company's reputation and divert management's attention and resources, which could have a material adverse effect on the Company's business, operating results or financial condition.

The Company plans to vigorously defend against the claims in both the class action litigation and the shareholder derivative litigation. The outcome of these matters is uncertain, however, and the Company cannot currently predict the manner and timing of the resolution of the lawsuits, or an estimate of a meaningful range of possible losses or any minimum loss that could result in the event of an adverse verdict in the lawsuits. In connection with these claims, during the year ended December 31, 2011, the Company recorded $262,500 for estimated legal defense costs under its applicable insurance policies.

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 2011, the Company paid Noblegene monthly rent of $55,251, as adjusted, plus additional proportionate operating and insurance costs

15. 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, which was June 2011; or (b) upon Noblegene obtaining a permanent mortgage on the new building, the timing of which is uncertain. 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 2011, the Company paid Noblegene monthly rent of $69,360, as adjusted.

15. Commitments and Contingencies − (continued)

The Company recognized rent expense of $1,678,304, $1,435,036 and $839,875 for the operating leases with Noblegene associated with the office space and new manufacturing space for the years ended December 31, 2011, 2010 and 2009, respectively. The future commitments as of December 31, 2011 under these operating lease agreements are as follows:

2012	$ 1,516,611
2013	1,562,109
2014	1,608,973
2015	1,657,242
2016	1,706,959
Thereafter	2,725,280
Total	$10,777,174

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 $326,737, $303,324 and $312,374 for the years ended December 31, 2011, 2010 and 2009, 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, 2011 and 2010 totaled $110,044 and $36,983, respectively. The net book value of such equipment at December 31, 2011 and 2010 totaled $205,997 and $279,058, respectively.

The future commitments as of December 31, 2011 under these capital lease agreements are as follows:

	Principal	Interest	Total
2012	$ 83,920	$3,691	$ 87,611
2013	85,668	1,943	87,611
2014	46,056	494	46,550
2015	0	0	0
2016	0	0	0
Total	$215,644	$6,128	$221,772

Manufacturing and Warehousing Facility and Equipment

The Company has executed agreements with various contractors and suppliers for engineering design/planning costs and build-out constructions costs for the new manufacturing and warehousing facility as well as for the manufacture of equipment that will be used in the new facility. Cumulatively as of December 31, 2011, the Company has incurred $2,180,504 in engineering design/planning costs and build-out constructions costs for the new facility and has paid a total of $4,199,430 for the manufacturing equipment. In 2011, the Company recorded an impairment loss on the manufacturing equipment. See Note 8 for more information.

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.

15. Commitments and Contingencies − (continued)

Supply Agreements

The Company has executed supply agreements with Novartis and Cam Bioceramics BV, and in February 2012, with Collagen Matrix, Inc. (''CMI''). Under these agreements, as of December 31, 2011, the Company has agreed to certain minimum purchase commitments or binding orders of which there are commitments and binding orders of $3,957,021 for 2012 and estimated aggregate commitments and binding orders of $13,112,704 for 2013 through 2015.

Milestones

Various milestone payments may be required under the Company's agreements with Kensey Nash Corporation (''Kensey Nash'') and CMI. The Company 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. Also, the agreement with CMI includes certain time-based milestone payments that the Company is obligated to pay to CMI based on the execution date of the agreement, and the Company may be required to make additional milestone payments to CMI if certain *Augmatrix* sales targets are achieved. With the exception of a $50,000 time-based milestone payment to CMI that is due six months after the February 2012 execution of the agreement, the remaining milestone payments that the Company is required to pay to Kensey Nash and CMI remain contingent and have not yet occurred. Because of the uncertainty regarding the potential sales growth for *Augmatrix* and uncertainty regarding the timing associated with the *Augment Injectable* development program in view of the Company's recent voluntary suspension of additional screening and enrollment of patients in the pivotal clinical study, the Company is unable to estimate the amount and timing of our remaining long-term (beyond 2013) milestone obligations.

16. Stock-Based Compensation

2001 Long-Term Stock Incentive Plan

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, 2011 as follows:

	2011	2010	2009
Risk free interest rate	2.27%	2.19%	2.11%
Expected dividend yield	0	0	0
Volatility factor of the expected market price	76%	76% − 77%	77% − 79%
Forfeiture rate	15.3%	8.9%	6.9%
Weighted average expected life of the option	4.4 to 8.0 years	4.4 to 8.0 years	4.2 to 8.0 years

Since there is a limited trading history for the Company's common stock, the expected volatility is based on historical data from three companies similar in size and value to the Company. The expected dividend yield is based on the Company's historical dividend experience. Since its inception, the Company has not declared dividends. 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.

The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest. The Company estimates pre-vesting forfeitures at the time of grant by analyzing historical data and revises those estimates in subsequent periods if actual forfeitures differ materially from those estimates. Ultimately, the total expense recognized over the vesting period will equal the fair value of the awards that actually vest. The forfeiture rate increased during the year ended December 31,

16. Stock-Based Compensation − (continued)

2011 due to employee turnover and the expiration of vested awards with an exercise price greater than the current market price. The Company believes the higher forfeiture rate is indicative of current expectations, and accordingly no changes were made to the Company's calculation methodology.

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 or consultants tend to hold the stock options longer term, represented by the higher end of the range.

As of December 31, 2011, a total of 2,748,331 options to purchase shares of common stock were issued and outstanding and a total of 1,366,563 shares of common stock had been issued upon the exercise of outstanding options. 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, 2009	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		
Granted	727,830	$12.23		
Exercised	(100,305)	$ 7.43		
Forfeited, tendered or expired	(494,882)	$11.53		
Options at December 31, 2011	2,748,331	$11.62	9.7 years	$4.5
Options exercisable at December 31, 2011	1,181,852	$11.36	9.3 years	$0.0

The weighted-average grant-date fair value of options granted during the years ended December 31, 2011, 2010 and 2009 was $12.23, $11.78 and $8.70, respectively. The total intrinsic value of options exercised during the years ended December 31, 2011, 2010 and 2009 was $865,740, $4,712,084 and $955,904, respectively.

The total fair value of options vested during the years ended December 31, 2011, 2010 and 2009 was $3,415,148, $5,141,862 and $3,968,981, 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.

16. Stock-Based Compensation − (continued)

A summary of the status of the Company's non-vested shares of stock options at December 31, 2011, and changes during the year ended December 31, 2011, is as follows:

	Shares	Weighted Average Grant-Date Fair Value
Non-vested at January 1, 2011	1,524,417	$11.60
Granted	727,830	$12.23
Vested	(290,062)	$11.77
Forfeited or expired (net of tenders)	(395,706)	$11.81
Non-vested at December 31, 2011	1,566,479	$11.81

Based on the Company's stock option grants outstanding at December 31, 2011, the Company has estimated the remaining unrecognized stock-based compensation expense to be $6,723,778 with a weighted average remaining amortization period of 3.0 years.

In accordance with the provisions of ASC 718, the Company recorded stock-based compensation expense in connection with the option plan totaling $3,603,934, $3,983,667 and $3,892,895 for the years ended December 31, 2011, 2010 and 2009, 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 and its stockholders approved the 2005 Employee Stock Purchase Plan (the ''purchase plan''), effective upon completion of the Company's initial public offering in May 2006. In November 2006, the Company's board of directors amended the purchase plan to expand the employees eligible to participate in the plan and to clarify the offering periods. The purchase plan provides the Company's employees and those of its subsidiaries with an opportunity to purchase shares of its common stock directly from the Company at a discount to the market price. The purchase plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the ''Code'').

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, 2011, a total of 50,596 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 $36,572, $48,771 and $34,260 during the years ended December 31, 2011, 2010 and 2009, respectively.

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. 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 Company's

16. Stock-Based Compensation − (continued)

matching contributions 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.

The Company provides matching contributions valued at up to 4% of eligible employee compensation, and generally consists of cash and shares of the Company's common stock. Such matching contributions are generally awarded during the first quarter of each calendar year, and cover the previous calendar year just ended resulting in compensation expense recorded in that previous calendar year.

As of December 31, 2011, after recording the issuance of 41,344 shares of the Company's common stock as matching contributions for 2011, there were no shares remaining available for issuance under the 401(k) plan. In addition, as of December 31, 2011, the Company recorded a liability for an additional $141,992 for the balance of 2011 matching contributions due to the employees. In accordance with the provisions of ASC 718, the Company recorded compensation expense in connection with the 401(k) plan of $259,823, $234,416 and $339,950 for the years ended December 31, 2011, 2010 and 2009, respectively.

17. Employee Benefits

Section 125 Cafeteria Plan

Effective May 10, 2004, the Company began offering employees the benefit of participating in a Section 125 Cafeteria Plan, which covered employee benefit coverage such as health, dental, life and disability insurance. Participation in the plan is optional. The Company made no contributions for the years ended December 31, 2011 and 2010, in lieu of a Section 223 Health Savings Account Plan implemented in 2010. The Company made contributions of $46,127 for the year ended December 31, 2009.

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 $294,500 and $345,353 for the years ended December 31, 2011 and 2010, respectively.

18. Income Taxes

At December 31, 2011, the Company had federal net operating loss (''NOL'') carryforwards of $124,623,592, of which $2,067,626 originated from the disqualifying disposition of stock options. The federal NOL carryforwards will begin to expire in 2022. State NOL carryforwards at December 31, 2011 totaled $110,181,839 and will expire between 2013 and 2031. To the extent of NOL carryforwards related to the stock option deductions for disqualifying dispositions, when realized, 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, 2011 indicating that the results of operations will generate sufficient taxable income to realize the net deferred tax asset in years beyond 2011. As a result, a valuation allowance was provided for the entire net deferred tax asset related to future years, including loss carryforwards.

The Company's ability to use its NOL carryforwards could be limited and subject to annual limitations. In connection with future years, 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.

18. Income Taxes − (continued)

The Company incurred net operating losses, and no income tax expense has been recorded, for the three years ended December 31, 2011.

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 2007.

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, 2011.

The benefit for income taxes consists of the following amounts:

	Years Ended December 31,		
	2011	2010	2009
Current:			
Federal	$ 0	$ 0	$ 0
State	0	0	0
Total current	0	0	0
Deferred:			
Federal	(11,344,678)	(11,282,566)	(6,575,611)
State	(485,018)	(489,727)	(284,703)
Total deferred	(11,829,696)	(11,772,293)	(6,860,314)
Total benefit, before valuation allowance	(11,829,696)	(11,772,293)	(6,860,314)
Change in valuation allowance	11,829,696	11,772,293	6,860,314
Total benefit, after valuation allowance	$ 0	$ 0	$ 0

18. Income Taxes − (continued)

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

	2011	2010
Deferred tax assets (liabilities) − current:		
Inventory reserve	$ 13,023	$ 111,377
Deferred revenue	371,037	370,605
Accrued salaries and paid time off	782,067	795,558
Other	40,155	9,998
Subtotal deferred tax assets − current	1,206,282	1,287,538
Deferred revenue − *GEM 21S*	0	0
Subtotal deferred tax liabilities − current	0	0
Total net deferred tax assets (liabilities) − current	$ 1,206,282	$ 1,287,538
Deferred tax assets (liabilities) − noncurrent:		
Net operating loss carryforwards	$ 46,411,437	$ 35,711,032
Fixed assets (tax basis difference)	2,212,661	948,954
Intangibles (tax basis difference)	0	0
Deferred revenue	5,183,368	5,563,152
Deferred compensation on stock options	528,648	329,082
Unrealized loss on investments	(2,528)	982
Other	477,834	347,266
Total deferred tax assets (liabilities) − noncurrent	54,811,420	42,900,468
Net deferred tax assets (liabilities)	56,017,702	44,188,006
Valuation allowance	(56,017,702)	(44,188,006)
Net deferred tax assets (liabilities)	$ 0	$ 0

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:

	2011	2010	2009
Federal income tax benefit at U.S. statutory rates	$(11,284,592)	$(11,538,476)	$(7,193,521)
State income taxes, net of federal benefit	(1,232,094)	(1,261,703)	(737,533)
Permanent differences	1,067,224	1,226,479	1,151,082
Change in valuation allowance	11,829,696	11,772,293	6,860,314
Other	(380,234)	(198,593)	(80,342)
Total income tax benefit for continuing operations	$ 0	$ 0	$ 0

19. Related Party Transactions

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

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, 2011, Harvard paid $14,151 to Dr. Lynch, for a cumulative total of $988,788 as of December 31, 2011, 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 Green Bankshares, Inc., a Tennessee chartered commercial bank where he is currently serving a one-year term expiring at the 2012 annual meeting. He also serves as a director of Capital Bank, N.A., a Southeastern regional bank with offices in Florida, North Carolina, South Carolina, Tennessee and Virginia. As of December 31, 2011, the Company maintained accounts at Capital Bank, N.A., including a portion of its cash and cash equivalents.

Consulting Agreement with a member of the Board of Directors

In August 2010, 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, including growth-factor based products, to treat orthopedic injuries and conditions. The 2010 agreement extends the consulting relationship that the Company had with Dr. Friedlaender pursuant to an August 2009 consulting agreement.

In September 2006, the Company appointed Dr. Friedlaender as a member of its board of directors. Prior to the September 2006 appointment, the Company's existing consulting arrangement with Dr. Friedlaender provided compensation for his consulting work 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 years ended December 31, 2011, 2010 and 2009, the Company paid Dr. Friedlaender $26,875, $10,000 and $5,000, respectively, for consulting services performed pursuant to the consulting agreements.

19. Related Party Transactions − (continued)

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

In December 2010, the Company entered into a one-year consulting agreement with Dr. Michael Ehrlich for consulting services relating to planning, design and evaluation of product candidates being developed for use in musculoskeletal applications including fracture repair, cartilage repair/regeneration and other sports medicine indications. The 2010 agreement extends the consulting relationship that the Company had with Dr. Ehrlich pursuant to a December 2009 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, 2011, 2010 and 2009, the Company paid Dr. Michael Ehrlich $5,500, $4,875 and $4,000, respectively, for consulting services performed pursuant to the consulting agreements.

20. 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, 2011					
1st Quarter	$398,685	$(7,993,408)	$(7,953,314)	$(0.28)	$(0.28)
2nd Quarter	439,281	(8,265,969)	(8,241,037)	(0.29)	(0.29)
3rd Quarter	428,627	(7,143,492)	(7,122,399)	(0.25)	(0.25)
4th Quarter	458,353	(6,947,478)	(9,873,227)	(0.35)	(0.35)

	Revenue	Loss From Operations	Net Income (Loss)	Net Income (Loss) Per Share − Basic	Net Income (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)

21. Subsequent Events

Amendment to the Amended and Restated Manufacturing and Supply Agreement

In February 2012, the Company and Novartis entered into an amendment (the ''Amendment'') to the Amended and Restated Manufacturing and Supply Agreement, effective December 1, 2009, between the Company and Novartis (the ''Agreement''). The Amendment is deemed to be effective as of January 1, 2012. Under the Amendment, the Company's obligations to purchase certain minimum quantities of rhPDGF-BB from Novartis have been modified, the parties adjusted the minimum shelf life requirement of rhPDGF-BB delivered to the Company's designated carrier and the parties agreed to bear their own costs associated with qualifying and licensing certain drug substance transfer changes. Additionally, the parties amended certain other compensation terms included in the Agreement.

Supply Agreement for Augmatrix Biocomposite Bone Graft

In February 2012, the Company and CMI entered into a supply agreement under which CMI will supply their Matrix product to the Company for resale to unrelated third parties as part of its *Augmatrix* product line. The agreement provides that the Company shall have the exclusive right to purchase the Matrix product from CMI and the exclusive right to sell the Matrix product in all countries where it is approved for marketing or sale by the applicable regulatory authority. The agreement also provides that CMI shall be the exclusive manufacturer and supplier of the Matrix product to the Company. The agreement includes certain milestone payments that the Company is obligated to pay CMI that are either time-based or based on certain cumulative sales thresholds of *Augmatrix*. In addition, the Company is obligated to meet annual minimum purchase commitments. The agreement also provides for certain termination penalties, including: (1) a termination fee if the Company terminates the agreement within the first year, (2) additional minimum purchase obligations if the Company terminates the agreement in the first or second years, and (3) a termination fee if the agreement is terminated by a third party that acquires the Company.

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 13, 2012

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 13, 2012
/s/ Larry Bullock Larry Bullock	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2012
/s/ Larry W. Papasan Larry W. Papasan	Chairman of the Board of Directors	March 13, 2012
/s/ Thorkil K. Christensen Thorkil K. Christensen	Director	March 13, 2012
/s/ Chris Ehrlich Chris Ehrlich	Director	March 13, 2012
/s/ Charles Federico Charles Federico	Director	March 13, 2012
/s/ Gary E. Friedlaender, M.D. Gary E. Friedlaender, M.D.	Director	March 13, 2012
/s/ James G. Murphy James G. Murphy	Director	March 13, 2012
/s/ Douglas Watson Douglas Watson	Director	March 13, 2012

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	Certificate of Amendment of the registrant's Amended and Restated Certificate of Incorporation (Incorporated by reference to the registrant's Form 8-K filed on June 15, 2011).
3.3	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 February 10, 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 February 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 February 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 February 10, 2006).
10.5**	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).
10.6**	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).
10.7*	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).
10.8*	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).
10.9**	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).
10.10	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).
10.11	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).
10.12**	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).

Exhibit No.	Description
10.13	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).
10.14	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).
10.15	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).
10.16*	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).
10.17*	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).
10.18*	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).
10.19*	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).
10.20	Lease Agreement between the registrant and Noblegene Development, LLC effective January 1, 2007 (Incorporated by reference to the registrant's Form 8-K filed on May 7, 2007).
10.21	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).
10.22**	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).
10.23**	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).
10.24**	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).
10.25**	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).

Exhibit No.	Description
10.30*	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).
10.31**	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).
10.32	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).
10.33	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).
10.34	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).
10.35*	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).
10.36*	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).
10.37*	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).
10.38*	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).
10.39**	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).
10.40**	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).
10.41**	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).
10.42**	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).
10.43**	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).
10.44**	Fourth Amendment to Development, Manufacturing and Supply Agreement, effective September 30, 2010, between the registrant and Kensey Nash Corporation (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010).

Exhibit No.	Description
10.45	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).
10.46	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).
10.47	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).
10.48**	Logistical Support Agreement between the registrant and Joint Solutions Alliance Corporation dated November 3, 2010 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010).
10.49**	Supply Agreement between the registrant and Integra LifeSciences Corporation dated July 15, 2010 (Incorporated by reference to the registrant's Annual Report on Form 10-K for the year ended December 31, 2010).
10.50	Third Amendment to Lease Agreement between the registrant and Noblegene Development, LLC dated April 8, 2011 (Incorporated by reference to the registrant's Form 8-K filed on April 14, 2011).
10.51	Amendment to Patent License Agreements between the registrant and Bristol-Myers Squibb Company dated June 30, 2011 (Incorporated by reference to the registrant's Form 8-K filed on July 1, 2011).
10.52**	Amendment to Amended and Restated Manufacturing and Supply Agreement, effective as of January 1, 2012, between the registrant and Novartis Vaccines and Diagnostics, Inc. (Incorporated by reference to the registrant's Form 8-K filed on February 27, 2012).
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
101	The following financial statements from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 formatted in eXtensible Business Reporting Language (XBRL): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows and (v) related notes.

* Indicates management contract or compensatory plan or arrangement

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

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EXHIBIT 21.1

Subsidiary	Jurisdiction of Incorporation
BioMimetic Therapeutics Limited	England and Wales
BioMimetic Therapeutics Pty Ltd.	Australia
BioMimetic Therapeutics Canada, Inc.	Canada
BioMimetic Therapeutics USA, Inc.	United States

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- Registration Statement (Form S-8 No. 333-135505) pertaining to the BioMimetic Therapeutics, Inc. 2001 Long-Term Stock Incentive Plan and BioMimetic Therapeutics, Inc. 2005 Employee Stock Purchase Plan,
- Registration Statement (Form S-8 No. 333-168104) pertaining to the BioMimetic Therapeutics, Inc. 2001 Long-Term Stock Incentive Plan,
- Registration Statement (Form S-8 No. 333-157999) pertaining to the BioMimetic Therapeutics, Inc. 401(k) Profit Sharing Plan & Trust,
- Registration Statement (Form S-3 No. 333-160400) of BioMimetic Therapeutics, Inc., and
- Registration Statement (Form S-3 No. 333-160676) of BioMimetic Therapeutics, Inc.

of our reports dated March 13, 2012 with respect to the consolidated financial statements of BioMimetic Therapeutics, Inc. and the effectiveness of internal control over financial reporting of BioMimetic Therapeutics, Inc., included in this Annual Report (Form 10-K) of BioMimetic Therapeutics, Inc. for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Nashville, Tennessee
March 13, 2012

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, 2011 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 13, 2012

/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, 2011 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 13, 2012

/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, 2011 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 13, 2012

/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, 2011 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 13, 2012

/s/ Larry Bullock

Larry Bullock
Chief Financial Officer

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