ANIKA THERAPEUTICS INC
Form 10-K
March 14, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2012

o 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 000-21326

Anika Therapeutics, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	04-3145961
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

32 Wiggins Avenue, Bedford, Massachusetts 01730
(Address of Principal Executive Offices) (Zip Code)

(781) 457-9000
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $.01 per share

Preferred Stock Purchase Rights

Name of Each Exchange on Which Registered: 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 o No x

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 o No x

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 x No o

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 x No o

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. x

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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. (Check one)

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

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

The aggregate market value of voting and non-voting equity held by non-affiliates of the Registrant as of June 30, 2012, the last day of the Registrant's most recently completed second fiscal quarter, was $187,079,886 based on the close price per share of Common Stock of $13.59 as of such date as reported on the NASDAQ Global Select Market. Shares of our Common Stock held by each executive officer, director and each person or entity known to the registrant to be an affiliate have been excluded in that such persons may be deemed to be affiliates; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. At March 8, 2013, there were issued and outstanding 13,919,215 shares of Common Stock, par value $.01 per share.

Documents Incorporated By Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2012. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

ANIKA THERAPEUTICS, INC.
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FORM 10-K
ANIKA THERAPEUTICS, INC.
For Fiscal Year Ended December 31, 2012

This Annual Report on Form 10-K, including the documents incorporated by reference into this Annual Report on Form 10-K, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding:

- Our future sales and product revenue, including geographic expansions, possible retroactive price adjustments, and expectations of unit volumes or other offsets to price reductions;
- Our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;
- The timing, scope and rate of patient enrollment for clinical trials;
- The development of possible line extensions and new products;
- Our ability to achieve and/or maintain compliance with laws and regulations;
- The timing of and/or receipt of Food and Drug Administration ("FDA"), foreign or other regulatory approvals, clearances, and/or reimbursement approvals of current, new or potential products, and any limitations on such approvals;
- Our intention to seek patent protection for our products and processes, and protect our intellectual property;
- Our ability to effectively compete against current and future competitors;
- Negotiations with potential and existing partners, including our performance under any of our existing and future distribution, license or supply agreements or our expectations with respect to sales and sales threshold milestones pursuant to such agreements;
- The level of our revenue or sales in particular geographic areas and/or for particular products, and the market share for any of our products;
- Our current strategy, including our Corporate objectives, research and development activities and collaboration activities;
- Our and Bausch & Lomb's performance under the non-exclusive, three-year contract for the supply of AMVISC® and AMVISC® Plus ophthalmic viscoelastic products, and our expectations regarding revenue from ophthalmic products;
- Our ability to commercialize AnikaVisc and AnikaVisc Plus and our expectations regarding such commercialization and the potential profits generated thereby;
- Our expectations regarding our joint health products, including expectations regarding new products, expanded uses of existing products, new distribution partnerships and revenue growth;
- Our intention to increase our market share for joint health products in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;

- Our expectations regarding next generation osteoarthritis/joint health product development, clinical trials, regulatory approvals and commercial launches;

- Our expectations regarding HYVISC sales;

- Our ability to identify a new distribution partner for HYDRELLE™ in the United States and the impact this may have on future sales of this product;

- Our ability to license our aesthetics product to new distribution partners outside of the United States; our ability, and the ability of our distribution partners, to market our aesthetic dermatology product; and our expectations regarding the distribution and sales of our ELEVESSTM product and the timing thereof;

- Our expectations regarding aesthetics product line extensions;

- Our expectations regarding product gross margin;

- Our expectations regarding obtaining FDA marketing approval for MONOVISCTM in the U.S., including our submission of a PMA amendment in connection with recent discussions with the FDA following their rejection of our appeal of the non-approvable letter;

- Our expectations regarding the commencement of a clinical trial for CINGALTM and our ability to obtain regulatory approvals for CINGAL;

- Our expectation for increases in operating expenses, including research and development and selling, general and administrative expenses;

- The rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy and usage of such cash;

- Our expectation for capital expenditures spending and future amounts of interest income and expense;

- Our ability to continue streamlining operations and improving our manufacturing capabilities;

- Possible negotiations or re-negotiations with existing or new distribution or collaboration partners;

- Our ability to remain in compliance with debt covenants;

- Our ability to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and other sources, to the extent our current sources of funds are insufficient;

- Our abilities to successfully complete the restructuring of Anika Therapeutics S.r.l. (“Anika S.r.l.”), and manage its operation from one with losses, into a company generating profits;

- Our ability to obtain U.S. approval for the orthopedic and other products of Anika S.r.l., including the timing and potential success of such efforts, and to expand sales of these products in the U.S., including the impact such efforts may have on our revenue;

- Our ability to satisfactorily resolve the dispute with Fidia Farmaceutici S.p.A regarding the Merogel Injectable product; and

- Our ability to successfully defend the Company against lawsuits and claims, including the Genzyme lawsuit, and the uncertain financial impact such lawsuits and claims and related defense costs may have on the Company.

Furthermore, additional statements identified by words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “i “seek,” “designed,” “develop,” “would,” “future,” “can,” “could” and other expressions that are predictions of or indicate events and trends and which do not relate to historical matters, also identify forward-looking statements.

You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled “Risk Factors” in this Annual Report on Form 10-K or elsewhere in this report. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from the anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed in the sections titled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” elsewhere in this Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors, new information, future events or other changes.

PART I

ITEM 1. BUSINESS

Overview

Anika Therapeutics, Inc. (“Anika,” and together with its subsidiaries, the “Company,” “we,” “us,” or “our”) was incorporated i 1992 as a Massachusetts company. Anika develops, manufactures and commercializes therapeutic products for tissue protection, healing and repair. These products are based on hyaluronic acid (“HA”), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

Anika Therapeutics, Inc.’s wholly-owned subsidiary, Anika Therapeutics S.r.l., has over 20 products currently commercialized, primarily in Europe. These products are also all made from hyaluronic acid, based on two technologies: “HYAFF”, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Both technologies are protected by an extensive portfolio of owned and licensed patents.

In December 2012 the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards established by the European Medicines Agency (“EMA”) for Advanced Therapy Medicinal Products (“ATMP”) (cell based) products that are effective January 1, 2013. The Company adopted a restructuring plan which includes a reduction-in-force of 12 people and provides for severance payments, disposals of related supplies, equipment, and other assets. The plan is expected to be substantially completed within the first six months of 2013. It is intended to improve the efficiency and financial performance of the Company's Italian operations by reducing costs and focusing on products and technology with strong commercial potential. In connection with the plan, the Company recorded a fourth quarter 2012 pre-tax charge of approximately $2.5 million, including $1.3 million for severance, various expenses, and write-offs of supplies and equipment, and a $1.2 million non-cash charge in connection with the abandonment of the Hyalograft C Autograft in-process R&D project. The cost reductions in employee wages and rent expense related to this closure are expected to result in annualized savings of approximately $0.5 million.

Anika’s proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies the HA to allow for longer residence time in the body. We offer therapeutic products from these aforementioned technologies in the following areas:

	Anika	Anika S.r.l.
Orthobiologics	X	X
Dermal		
Advanced wound care		X
Aesthetic dermatology	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care (“ENT”)		X
Ophthalmic	X	
Veterinary	X	

The following sections provide more specific information on our products and related activities:

Orthobiologics

Our orthobiologics products consist of joint health and orthopedic products. These products are used in a wide range of treatments from providing relief from the pain of osteoarthritis, to regenerating damaged tissue such as cartilage. Osteoarthritis is a debilitating disease causing pain, swelling and restricted movement in joints. It occurs when the cartilage in a joint gradually deteriorates due to the effects of mechanical stress, which can be caused by a variety of factors including the normal aging process. In an osteoarthritic joint, particular regions of articulating surfaces are exposed to irregular forces, which result in the remodeling of tissue surfaces that disrupt the normal equilibrium or mechanical function. As osteoarthritis advances, the joint gradually loses its ability to regenerate cartilage tissue and the cartilage layer attached to the bone deteriorates to the point where eventually the bone becomes exposed. Advanced osteoarthritis often requires surgery and the possible implantation of artificial joints. The current treatment options for osteoarthritis before joint replacement surgery include viscosupplementation, analgesics, non-steroidal anti-inflammatory drugs and steroid injections.

Our joint health products include ORTHOVISC®, ORTHOVISC® mini, and MONOVISCTM. ORTHOVISC is available in the U.S., Canada, Europe and other international markets for the treatment of osteoarthritis of the knee, and in Europe for the treatment of osteoarthritis in all joints. ORTHOVISC mini is available in Europe, and is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment indicated for all joints in Europe, and for the knee in Turkey and Canada. ORTHOVISC mini and MONOVISC are our two most recent joint health products which became available in certain international markets during the second quarter of 2008.

In the U.S., ORTHOVISC is indicated for the treatment of pain caused by osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics, such as acetaminophen. It is a sterile, clear, viscoelastic solution of hyaluronan dissolved in physiological saline, and dispensed in a single-use syringe. A complex sugar of the glycosaminoglycan family, hyaluronan is a high molecular weight polysaccharide composed of repeating disaccharide units of sodium glucuronate and N-acetyl glucosamine. ORTHOVISC is injected into joints in a series of three intra-articular injections one week apart. ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is marketed by DePuy Mitek ("Mitek"), under the terms of a ten-year licensing, distribution, supply and marketing agreement which was entered into in December 2003 (the "JNJ Agreement"). In November 2012, the JNJ Agreement was extended for an additional 5 years under the existing terms. Outside of the U.S., we have a number of distribution relationships servicing international markets including Canada, Europe, the Middle East, Latin America, and Asia. We will continue to seek to establish distribution relationships in other regions. See the sections captioned "Management's Discussion and Analysis of Financial Condition and Results of Operations—Management Overview" and "Risk Factors."

In addition to the three viscosupplementation products discussed above, we also offer several additional products used in connection with orthopedic regenerative medicine. These products are based on the HYAFF technology and are currently available in Europe and some other countries. They include Hyalofast®, a biodegradable support for human bone marrow mesenchymal stem cells which is used in connection with soft tissue regeneration; Hyalonect®, a woven gauze used as a graft wrap; and Hyaloss, HYAFF fibers used to mix blood/bone grafts to form a paste for bone regeneration. We also offer Hyaloglide®, an ACP gel used in tenolysis treatment, but with potential for use in flexor tendon adhesion prevention, and in the shoulder for adhesive capsulitis with additional clinical data. These products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea.

The Company is seeking U.S. approval of a number of these products, as we believe we have the opportunity to expand sales of these products in the U.S. In this regard, we previously submitted 510(k) applications at a time of significant change and uncertainty within the FDA regarding the 510(k) approval process. We have now selected two of these products, Hyalofast and Hyalonect, and have defined a pathway to complete the approval. The remaining work involves generating additional data for the 510(k) applications. We expect submissions with the new data towards the end of this year. There can be no assurance that clearance will be obtained for any of these Anika S.r.l. products. See also Item 1A. "Risk Factors."

Dermal

Our dermal products consist of advanced wound care products based on the HYAFF technology, and aesthetic dermal fillers based on the BCDI technology. Our HYAFF technology offers over five products for the treatment of skin wounds ranging from burns to diabetic ulcers. The products cover a variety of wound treatment solutions including debridement agents, advanced therapies and scaffolds used in connection with skin substitutes. Leading products include Hyalomatrix and Hyalofill, for treatment of complex wounds such as burns and ulcers, and Hyalograft 3D and Laserskin scaffolds, for use in connection with the regeneration of skin. The dermal products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea. Several of the products are also approved for sale in the United States including Hyalomatrix and Hyalofill. In 2012, the Company entered into a

distribution agreement for sales of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, Chile, and others.

Our aesthetic dermatology business is designed as a family of products for facial wrinkles and scar remediation, and is intended to compete with collagen-based and other HA-based products currently on the market. Our initial aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and is approved in Europe, Canada, the U.S., Korea and certain countries in South America. Internationally, this product is marketed under the ELEVESS name. In the U.S., the trade name is HYDRELLE, although the product is not currently marketed in the U.S.

Surgical

Our surgical business consists of products used to prevent surgical adhesions, and to treat ENT disorders. Hyalobarrier is a clinically proven post-operative adhesion barrier for use in the abdomino-pelvic area. The product is currently commercialized by Anika S.r.l. in Europe, the Middle East and certain Asian countries through a distribution network, but is not approved in the U.S. INCERT, approved for sale in Europe, Turkey, and Malaysia, is a chemically modified, cross-linked HA product, for the prevention of spinal post-surgical adhesions. There are currently no plans at this time to distribute INCERT in the U.S. Anika co-owns issued U.S. patents covering the use of INCERT for adhesion prevention. See the section captioned “Patent and Proprietary Rights.”

Surgical adhesions occur when fibrous bands of tissues form between adjacent tissue layers during the wound healing process. Although surgeons attempt to minimize the formation of adhesions, they nevertheless occur quite frequently after surgery. Adhesions in the abdominal and pelvic cavity can cause particularly serious problems such as intestinal blockage following abdominal surgery, and infertility following pelvic surgery. Fibrosis following spinal surgery can complicate re-operation and may cause pain.

Anika S.r.l. offers several products used in connection with the treatment of ENT disorders. The lead products are Merogel, a woven fleece nasal packing, and Merogel Injectable, a thick, viscous hydrogel composed of cross-linked hyaluronic acid—a biocompatible agent that creates a moist wound-healing environment. Anika S.r.l. has partnered with Medtronic for worldwide distribution of these products.

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. The ophthalmic products we manufacture include the AMVISC and AMVISC Plus product line, STAARVISC-IITM, Optivisc™ (formerly ShellGel™), AnikaVisc™, and AnikaVisc™ Plus. They are injectable, high molecular weight HA products used as viscoelastic agents in ophthalmic surgical procedures such as cataract extraction and intraocular lens implantation. These products coat, lubricate and protect sensitive tissue such as the endothelium, and maintain the shape of the eye, thereby facilitating ophthalmic surgical procedures.

Anika previously manufactured the AMVISC product line for Bausch & Lomb (“B&L”) under the terms of an exclusive supply agreement that expired on December 31, 2010 (the “2004 B&L Agreement”) for viscoelastic products used in ophthalmic surgery. Effective January 1, 2011, we entered into a non-exclusive, two year contract with B&L intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, low-cost supplier formerly affiliated with B&L, and continued to supply B&L with these products during 2011. Effective January 1, 2012, the parties agreed to a new three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes for 2012, with further reductions in 2013 and 2014.

B&L accounted for 11% of product revenue for the year ended 2012, and product revenue is expected to be significantly lower in 2013 under the new contract. Operating margins under the 2004 B&L Agreement were low and will remain at a similar level under the new contract. See also Item 1A. “Risk Factors.”

Veterinary

HYVISC is a high molecular weight injectable HA product for the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis. HYVISC has viscoelastic properties that lubricate and protect the tissues in horse joints. HYVISC is distributed by Boehringer Ingelheim Vetmedica, Inc. in the United States.

See Note 13 to our Consolidated Financial Statements, “Revenue by Product Group, by Significant Customer and by Geographic Region; Geographic Information” for a discussion regarding our segments and geographic sales.

Research and Development of Potential Products

Anika's research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities relative to our existing and new products. Our development focus includes products for tissue protection, healing and repair. For the years ended December 31, 2012, 2011 and 2010, these expenses were $5.4 million, $6.2 million, and $6.9 million, respectively. We anticipate that our research and development efforts, including clinical trials, will increase significantly in the near future.

Two key products under development or regulatory review include MONOVISC for U.S. marketing approval and CINGAL. Our first next generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary cross-linked HA-technology. We received Conformité Européenne ("CE") Mark approval for the MONOVISC product in October 2007, and began sales in Europe during the second quarter of 2008, following a small, post-marketing clinical study. In the U.S., we filed the final module of our MONOVISC PMA containing the clinical data in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter. In December 2012, the FDA upheld its non-approvable decision following our appeal. Subsequent to that decision, in January 2013, the Company submitted a new PMA amendment which is under review by the FDA. The Company continues to discuss pathways for MONOVISC approval with the FDA.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule designed to provide broad pain relief for a longer period of time. We have completed the formulation and biocompatibility studies of the product. We expect to commence a clinical trial during the first half of 2013 to obtain the needed clinical data for a CE Mark submission and approval.

The technologies obtained through our acquisition of Anika S.r.l. have enhanced our research and development capabilities, and our pipeline of candidate products. Anika S.r.l. has research and development programs for new products including Hyalofast, an innovative, biodegradable support for human bone marrow mesenchymal stem cells used in connection with soft tissue regeneration; Hyalospine, an adhesion prevention gel for use after spinal surgery; Hyalobone, a bone tissue filler; and Hemostatic Patch, a resorbable hemostatic pad for bleeding control and hemostasis promotion in various surgical procedures. Our research and development efforts may not be successful in (1) developing our existing product candidates, (2) expanding the therapeutic applications of our existing products, or (3) resulting in new applications for our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We may not be able to obtain regulatory approval for any new applications we develop. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that we will achieve meaningful sales of such products or applications. See Item 1A. "Risk Factors."

Patent and Proprietary Rights

Our products and trademarks, including our Company name, product names and logos, are proprietary. We rely on a combination of patent protection, trade secrets and trademark laws, license agreements, confidentiality and other contractual provisions to protect our proprietary information.

We have a policy of seeking patent protection for patentable aspects of our proprietary technology. Our issued patents have expiration dates through 2028. Anika co-owns certain U.S. patents and a patent application with claims relating to the chemical modification of HA and certain adhesion prevention uses and certain drug delivery uses of HA. Anika also solely owns patents covering composition of matter and certain manufacturing processes. Anika S.r.l.'s issued patents have expiration dates through 2028. The Anika S.r.l. patent estate is extensive and partly intertwined with its

former parent company, Fidia Farmaceutici S.p.A, through a cross-licensing agreement which provides both companies with access to each other's patents to the extent required to support their own products. We intend to seek patent protection for products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate relative to the potential benefits. See also the section captioned "Risk Factors—We may be unable to adequately protect our intellectual property rights."

In 2012 we were granted 4 new patents in the U.S. and in Europe. They include a CINGAL patent for the U.S., a Hyalospine patent in Europe, and 2 additional U.S. patents related to our aesthetic products.

Other entities have filed patent applications for, or have been issued patents concerning, various aspects of HA-related products or processes. In addition, the products or processes we develop may infringe the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations. See also the section captioned “Risk Factors—We may be unable to adequately protect our intellectual property rights.”

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require certain customers and vendors, and all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. These agreements, however, may not provide adequate protection. See also the section captioned “Risk Factors—We may be unable to adequately protect our intellectual property rights.”

We have granted DePuy Mitek an exclusive, non-transferable royalty bearing license to use and sell ORTHOVISC (and other products developed pursuant to the JNJ Agreement) in the U.S., as well as a license to manufacture, and have manufactured, such products in the event that we are unable to supply them with these products in accordance with the terms of the JNJ Agreement.

On December 21, 2011, the Company entered into a license, supply and distribution agreement (the “Mitek MONOVISC Agreement”) with DePuy Mitek, Inc. for an exclusive, multi-year license of the Company’s MONOVISC product, a highly purified, high molecular weight form of hyaluronic acid for treating pain in patients suffering from osteoarthritis of the knee. In connection with the execution of the Mitek MONOVISC Agreement, the Company received an initial payment of $2.5 million. The Company will also be entitled to receive additional payments from Mitek following the mutual decision to launch the product, related to future regulatory, clinical, and sales milestones, as well as receive royalties based on the net sales of MONOVISC generated by Mitek. The Mitek MONOVISC Agreement applies only to the United States.

The Mitek MONOVISC Agreement has an initial term of fifteen years, unless earlier terminated pursuant to any one of several early termination rights of each party, and provides for Anika to be the exclusive supplier to Mitek of MONOVISC.

Government Regulation

United States Regulation

Our research (including clinical research), development, manufacture, and marketing of products are subject to regulation by numerous governmental authorities in the U.S. and other countries. Medical devices and pharmaceuticals are subject to extensive and rigorous regulation by the FDA and by other federal, state and local authorities. The Federal Food, Drug and Cosmetic Act (“FDC Act”) and respective regulations govern the conditions of safety, efficacy, clearance, approval, manufacture, quality system requirements, labeling, packaging, distribution, storage, record keeping, reporting, marketing, advertising, and promotion of our products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or approval of products, withdrawal of clearances and approvals, and criminal prosecution.

Medical products regulated by the FDA are generally classified as drugs, biologics, and/or medical devices. Medical devices intended for human use are classified into three categories (Class I, II or III), on the basis of the controls deemed reasonably necessary by the FDA to assure their safety and efficacy. Class I devices are subject to general controls, for example, labeling and adherence to the FDA’s Good Manufacturing Practices/Quality System Regulation (“GMP/QSR”). Many Class I devices are exempt from the FDA 510(k) review process. Class II devices are subject to

general and special controls (for example, performance standards, post-market surveillance, and patient registries). Most Class II devices are subject to premarket notification and may be subject to clinical testing for purposes of premarket notification and clearance for marketing. Class III is the most stringent regulatory category for medical devices. Most Class III devices require premarket approval ("PMA") from the FDA.

AMVISC, AMVISC Plus, ShellGel/Optivisc, STAARVISC, and AnikaVisc are approved as Class III medical devices in the U.S. for intraocular ophthalmic surgical procedures used in humans. ORTHOVISC is approved as a Class III medical device in the U.S. for treatment of pain resulting from osteoarthritis of the knee in humans. HYDRELLE is approved as a Class III medical device in the U.S. for treatment of facial wrinkles and folds, such as nasolabial folds. HYVISC is approved as an animal drug for intra-articular injection in horse joints to treat degenerative joint disease associated with synovitis. Most HA products for human use are regulated as medical devices. We believe that our INCERT product, should we decide to seek U.S. approval to market, will have to meet the regulatory requirements for Class III devices and will require clinical trials and a PMA submission.

Our subsidiary, Anika S.r.l., has three advanced wound care products approved in the U.S. as Class II devices through premarket notification (510(k)): Hyalomatrix, Hyalofill-R, and Hyalofill-F. All of Anika S.r.l.'s ENT products are 510(k) cleared by Medtronic as Class II devices. The FDA's 510(k) clearance process is under review and changes to the process may have an impact on current or future product approvals. Three of our products were submitted for 510(k) clearance in 2010: Hyaloglide, Hyalofast and Hyalonect. The FDA has requested additional data to complete the reviews. The Company is unable to predict the timing of receipt of these clearances. There is no guarantee that the clearance process for these products will be successful or that additional data will not be required to support clearance.

Unless a new device is exempted from premarket notification, its manufacturer must obtain marketing clearance from the FDA through premarket notification (510(k)) or approval through PMA before the device can be introduced to the market. Product development and approval within the FDA regulatory framework takes a number of years and involves the expenditure of substantial resources. This regulatory framework may change or additional regulations may arise at any stage of our product development process and may affect approval of, or delay in, an application related to, a product, or require additional expenditures by us. There can be no assurance that the FDA review of marketing applications will result in product approval on a timely basis, if at all. The PMA approval process is lengthy, expensive, and typically requires, among other things, valid scientific evidence which generally includes extensive data such as pre-clinical and clinical trial data to demonstrate a reasonable assurance of safety and effectiveness.

Human clinical trials in the U.S. for significant risk devices must be conducted under Good Clinical Practice ("GCP") regulations through Investigational Device Exemption ("IDE"), which must be submitted to the FDA and either be approved or be allowed to become effective before the trials may commence. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials or future approval of the product. In addition, the IDE approval process could result in significant delays. Even if the FDA approves an IDE or allows an IDE for a clinical investigation to become effective, clinical trials may be suspended at any time for a number of reasons. Among others, these reasons may include: a) failure to comply with applicable requirements; b) inadequacy of informed consent; and c) the data generated suggests that: the risks to clinical subjects are not outweighed by the anticipated benefits to clinical subjects and the importance of the knowledge to be gained, the investigation is scientifically unsound, or there is reason to believe that the device, as used, is ineffective. A trial may be terminated if serious unanticipated adverse events present an unreasonable risk to subjects. If clinical studies are suspended or terminated, we may be unable to continue the development of the investigational products affected.

Upon completion of required clinical trials, for Class III medical devices, results might be presented to the FDA in a PMA application. In addition to the results of clinical investigations, the New Drug Application ("NDA") applicant must submit other information relevant to the safety and efficacy of the device, including, among other things, the results of non-clinical tests and clinical trials; a full description of the device and its components; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms to the FDA's current Quality System Regulation, formerly known as GMP. FDA review of the PMA may not result in timely, or any, PMA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Upon completion of required clinical trials for pharmaceuticals, results might be presented to the FDA in a NDA or New Animal Drug Application ("NADA"). In addition to the results of clinical investigations, the NDA or NADA applicant must submit other information relevant to the safety and efficacy of the product, including, among other things, the results of non-clinical tests and clinical trials; a full description of the product formulation; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms to the FDA's current Good Manufacturing Practices ("cGMP") related to pharmaceuticals. FDA review of the NDA or NADA may not result in timely, or any,

FDA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Post-approval product or manufacturing changes where such change affects the safety and efficacy of the medical products as well as the use of a different facility for manufacturing, could necessitate additional review and approval by the FDA. Post-approval changes in labeling, packaging or promotional materials may also necessitate further review and approval by the FDA.

Legally marketed products are subject to continuing requirements by the FDA relating to design control, manufacturing, quality control and quality assurance, maintenance of records and documentation, reporting of adverse events, and labeling and promotion. The FDC Act requires medical product manufacturers to comply with QSR for medical devices and cGMP regulations related to pharmaceuticals. The FDA enforces these requirements through periodic inspections of manufacturing facilities. To ensure full compliance with requirements set forth in the GMP/QSR regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Other federal, state, and local agencies may inspect manufacturing establishments as well.

A set of regulations known as the Medical Device Reporting and Drug Adverse Events Reporting System regulations obligates manufacturers to inform the FDA whenever information reasonably suggests that one of their medical products may have caused or contributed to a death or serious injury, or when one of their devices malfunctions and if the malfunction were to recur, the device or a similar device would be likely to cause or contribute to a death or serious injury.

The process of obtaining approvals from the FDA and foreign regulatory authorities can be costly, time consuming, and subject to unanticipated delays. Approvals of our products, processes or facilities may not be granted on a timely basis or at all, and we may not have available resources or be able to obtain the financing needed to develop certain of such products. Any failure or delay in obtaining such approvals could adversely affect our ability to market our products in the U.S. and in other countries.

In addition to regulations enforced by the FDA, we are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other existing and future federal, state and local laws and regulations as well as those of foreign governments. Federal, state and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

Foreign Regulation

In addition to regulations enforced by the FDA, we and our products are subject to certain foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, import restrictions, tariff regulations, duties, and tax requirements. ORTHOVISC is approved for sale and is marketed in Canada, Europe, Turkey, and parts of the Middle East and Asia. In the European Union (“EU”), ORTHOVISC is sold under the CE mark authorization, a certification required under European Union medical device regulations.

The CE mark, achieved in 1996, allows ORTHOVISC to be marketed without further approvals in most of the EU nations as well as other countries that recognize EU device regulations. ORTHOVISC mini, a treatment for osteoarthritis targeting small joints, is available in Europe under CE mark authorization received in 2008. In August 2004, we received a CE Design Examination Certificate which entitled us to affix a CE mark to INCERT-S as a barrier to adhesion formation following surgery. AMVISC and AMVISC Plus are CE marked, and in May 2005, we received an CE Design Examination Certificate which entitled us to affix a CE mark to ShellGel/Optivisc as an ophthalmic viscoelastic surgical device. We also received EU CE Mark for AnikaVisc Plus in October 2011. Staarvisc, an ophthalmic viscoelastic surgical device, is licensed in Canada from May 2002. We received EU CE Mark approval for ELEVESS during the second quarter of 2007. MONOVISC, a medical device for treatment of pain associated with osteoarthritis, was approved in the EU in October 2007 and in Canada in August 2009. In addition, Anika received approval for several of its products in Latin America, Korea, Turkey, the Middle East, including the UAE and Saudi Arabia, and other international markets.

Almost all of Anika S.r.l.'s products are CE marked for European sale. In addition, Anika S.r.l. has received approval for several of its products in Egypt, Hong Kong, Iran, Israel, Korea, Malaysia, Singapore, Mexico, Cyprus, Saudi Arabia, Taiwan, Turkey, and the United Arab Emirates. We may not be able to achieve and/or maintain the compliance required for CE marking or other foreign regulatory approvals for any or all of our products. The requirements relating to the conduct of clinical trials, product licensing, marketing, pricing, advertising, promotion and reimbursement also vary widely from country to country.

Competition

We compete with many companies, including, among others, large pharmaceutical firms and specialized medical products companies across all of our product lines. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations, which may be involved in research, development and commercialization of products. Many of our competitors also compete against us in securing relationships with collaborators for their research and development and commercialization programs.

Competition in our industry is based primarily on product efficacy, safety, timing and the scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, product pricing and patent protection. Some of the principal factors that may affect our ability to compete in our HA development and commercialization markets include:

- The quality and breadth of our technology and technological advances;
- Our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors;
- Our ability to recruit and retain skilled employees; and
- The availability of substantial capital resources to fund discovery, development and commercialization activities or the ability to defray such costs through securing relationships with collaborators for our research and development and commercialization programs.

We are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. All of the Company's products face substantial competition. There exist major worldwide competing products, made from HA and other materials, for use in ophthalmic surgery, orthopedics, surgical adhesion prevention, advanced wound care, ENT and cosmetic dermal fillers. There is a risk that we will be unable to compete effectively against our current or future competitors.

Employees

As of December 31, 2012, we had 106 employees, 23 of whom are located outside the U.S. We consider our relations with our employees to be good. None of our U.S. employees are represented by labor unions, and most of the employees based in Italy are represented by unions adding complexity and additional risks to the wage and employment decision process.

Environmental Laws

We believe that we are in compliance with all foreign, federal, state and local environmental regulations with respect to our manufacturing facilities and that the cost of ongoing compliance with such regulations does not have a material effect on our operations.

Product Liability

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and we cannot assure you that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have coverage under our insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate, we cannot assure you that if material claims arise in the future, our insurance will be adequate to cover all situations. Moreover, we cannot assure you that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operation.

Available Information

Our Annual Reports on Form 10-K, including our consolidated financial statements, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information, including amendments and exhibits to such reports, filed or furnished pursuant to the Securities Exchange Act of 1934, as amended, are available free of charge in the "SEC Filings" section of our website located at http://www.anikatherapeutics.com, as soon as reasonably practicable after the reports are filed with or furnished to the Securities and Exchange Commission ("SEC"). The information on our website is not part of this Annual Report on Form 10-K. Reports filed with the SEC may be viewed at www.sec.gov or obtained at the SEC Public Reference Room at 100 F Street NE, Washington, D.C. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and could in the future vary significantly depending on a number of factors. From time to time, information provided by us, or statements made by our employees, contain "forward-looking" information that involves risks and uncertainties. In particular, statements contained in this Annual Report on Form 10-K, and in the documents incorporated by reference into this Annual Report on Form 10-K, that are not historical facts, including, but not limited to statements concerning new products, product development and offerings, regulatory approvals, product and price competition, competition and strategy, customer diversification, product price and inventory, contingent consideration payments, deferred revenues, economic and market conditions, potential government regulation, seasonal factors, collection of non-U.S. accounts receivable, international expansion, revenue recognition, profits, growth of revenues, composition of revenues, cost of revenues, operating expenses, including research and development expenses, sales, marketing and support expenses, general and administrative expenses, restructuring charges, product gross profit, interest income, interest expense, anticipated operating and capital expenditure requirements, cash inflows, contractual obligations, taxes, tax rates, stock-based compensation, leasing and subleasing activities, acquisitions, liquidity, litigation matters, intellectual property matters, distribution channels, suppliers, stock price, third party licenses and potential debt or equity financings constitute forward-looking statements and are made under the safe harbor provisions of Section 27 of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are neither promises nor guarantees. Our actual results of operations and financial condition have varied and could in the future vary significantly from those stated in any forward-looking statements. The following factors, among others, including those elsewhere in this report, could cause actual results to differ materially from those contained in forward-looking statements made in this Form 10-K, in the documents incorporated by reference into this Form 10-K or presented elsewhere by our management from time to time. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition.

Our business is subject to comprehensive and varied government regulation and, as a result, failure to obtain FDA or other U.S. and foreign governmental approvals for our products may have a material adverse effect on our business, financial condition, and results of operations.

Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA will grant approval for our new products on a timely basis, if at all, or that FDA review will not involve delays that will adversely affect our ability to commercialize additional products or expand permitted uses of existing products, or that the regulatory framework will not change, or that additional regulation will not arise at any stage of our product development process which may adversely affect approval of, or delay in, an application or require additional expenditures by us. In the event our future products are regulated as human drugs or biologics, the FDA's review process of such products typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

Two key products under development or regulatory review include MONOVISC for U.S. marketing approval and CINGAL. Our first Next Generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary cross-linked HA-technology. We received Conformité Européenne ("CE") Mark approval for the MONOVISC product in October 2007, and began sales in Europe during the second quarter of 2008, following a small, post-marketing clinical study. In the U.S., we filed the final module of our MONOVISC PMA containing the clinical data in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter. In December 2012, the FDA upheld its non-approvable decision following our appeal. Subsequent to that decision, in January 2013, the Company submitted a new PMA amendment which is under review by the FDA. The Company continues to discuss pathways for MONOVISC approval with the FDA.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule designed to provide broad pain relief for a longer period of time. We have completed the formulation and biocompatibility studies of the product. We expect to commence a clinical trial during the first half of 2013 to obtain the needed clinical data for a CE Mark submission and approval.

In 2010 the Company filed 510(k) applications with the FDA to gain market clearance for several products as we believed we had the opportunity to expand sales of the products in the U.S. The aforementioned 510(k) applications were submitted at a time of significant change and uncertainty within the FDA regarding the 510(k) approval process. We have now selected two of these products, Hyalofast and Hyalonect, and have defined a pathway to complete the approval. The remaining work involves generating additional data for the 510(k) applications. We anticipate submissions with the new data towards the end of this year. There can be no assurance that clearance will be obtained for any of these Anika S.r.l. products.

In addition, we cannot assure you that:

- We will begin or successfully complete U.S. clinical trials for next generation products;
- The clinical data will support the efficacy of these products;
- We will be able to successfully complete the FDA or foreign regulatory approval or clearance process, where required;
- Additional clinical trials will support a PMA application and/or FDA approval or other foreign regulatory approvals, where required, in a timely manner or at all; or
- European and other regulations may not change for the marketing of cell-based products and thus impact our ability to continue commercialization of these products.

We also cannot assure you that any delay in receiving FDA approvals will not adversely affect our competitive position. Furthermore, even if we do receive FDA approval or clearance:

- The approval or clearance may include significant limitations on the indications and other claims sought for use for which the products may be marketed;
- The approval or clearance may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements; and
- Meaningful sales may never be achieved.

Once obtained, marketing approval can be withdrawn by the FDA for a number of reasons, including, among others, the failure to comply with regulatory requirements, or the occurrence of unforeseen problems following initial approval. We may be required to make further filings with the FDA under certain circumstances. The FDA's regulations require a PMA supplement for certain changes if they affect the safety and effectiveness of an approved device, including, but not limited to, new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Our failure to receive approval of a PMA supplement regarding the use of a different manufacturing facility or any other change affecting the safety or effectiveness of an approved device on a timely basis, or at all, may have a material adverse effect on our business, financial condition, and results of operations. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of such products. It

also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per FDA regulations of one or several of our products. Significant delay or cost in obtaining, or failure to obtain FDA approval to market products, any FDA limitations on the use of our products, or any withdrawal or suspension of approval or rescission of approval by the FDA could have a material adverse effect on our business, financial condition, and results of operations.

In addition, all FDA approved or cleared products manufactured by us must be manufactured in compliance with the FDA's cGMP regulations and, for medical devices, the FDA's QSR. Ongoing compliance with QSR and other applicable regulatory requirements is enforced through periodic inspection by state and federal agencies, including the FDA. The FDA may inspect our facilities, from time to time, to determine whether we are in compliance with regulations relating to medical device and pharmaceutical companies, including regulations concerning manufacturing, testing, quality control and product labeling practices. We cannot assure you that we will be able to comply with current or future FDA requirements applicable to the manufacture of our products.

FDA regulations depend heavily on administrative interpretation and we cannot assure you that the future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. In addition, changes in the existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products.

Failure to comply with applicable regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the FDA to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals and criminal prosecution.

In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local and foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, quality system and manufacturing requirements, import restrictions, tariff regulations, duties and tax requirements. We cannot assure you that we will be able to achieve and/or maintain compliance required for CE marking or other foreign regulatory approvals for any or all of our products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements. Federal, state, local and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

The process of obtaining approvals from the FDA and other regulatory authorities can be costly, time consuming, and subject to unanticipated delays. We cannot assure you that approvals or clearances of our products will be granted or that we will have the necessary funds to develop certain of our products. Any failure to obtain, or delay in obtaining, such approvals or clearances, could adversely affect our ability to market our products.

Uncertain economic conditions, including a credit crisis affecting the financial markets and global recession, could adversely affect our business, results of operations and financial condition.

The worldwide financial markets have experienced turmoil, characterized by volatility in security prices, rating downgrades of investments and reductions in available credit. These events materially and adversely impacted the availability of financing to a wide variety of businesses, and the resulting uncertainty led to reductions in capital investments, overall spending levels, future product plans, and sales projections across industries and markets.

The financial markets remain uncertain and renewed turmoil in the financial markets could have a material adverse impact on our business, our ability to achieve planned results of operations and our financial condition by:

- Reducing demand for our products;
- Increasing risk of order cancellations or delays;
- Increasing pressure on the prices for our products;

- Creating greater difficulty in collecting accounts receivable; and

- Increasing the risks to our liquidity, including the possibility that we might not have sufficient access to cash when needed.

We are unable to predict the likelihood of renewed disruption in financial markets and adverse economic conditions in the U.S. and other countries.

Substantial competition could materially affect our financial performance.

We compete with many companies, including, among others, large pharmaceutical companies, specialized medical products companies and healthcare companies. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations that may be involved in research, development and commercialization of products. Because a number of companies are developing or have developed HA products for similar applications and have received FDA approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. For example, we are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. There exist major competing products for the use of HA in ophthalmic surgery. In addition, certain HA products made by our competitors for the treatment of osteoarthritis in the knee have received FDA approval before ours and have been marketed in the U.S. since 1997, as well as select markets in Canada, Europe and other countries. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

We are uncertain regarding the success of our clinical trials.

Several of our products do require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. There can be no assurance that we will be able to successfully complete the U.S. or international regulatory approval process for any of our products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate these products to be safe and efficacious. We completed a pivotal clinical trial on MONOVISC and submitted the data as part of our PMA filing in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter. In December 2012, the FDA upheld its non-approvable decision following our appeal. Subsequent to that decision, in January 2013, the Company submitted a new PMA amendment which is under review by the FDA. The Company continues to discuss pathways to approval with the FDA. There can be no assurance that we will be successful in obtaining FDA approval for MONOVISC.

We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition and results of operations.

Our success will be dependent, in part, upon the efforts of our marketing and distribution partners and the terms and conditions of our relationships with such partners. We cannot assure you that such partners will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. We are continuing to seek to establish long-term distribution relationships in regions not covered by existing agreements, but can make no assurances that we will be successful in doing so. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such partners. There can be no assurance that we will obtain European or other reimbursement approvals or, if such approvals are obtained, that they will be obtained on a timely basis or at a satisfactory level of reimbursement.

We may need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.

Our future success depends upon market acceptance of our existing and future products.

Our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to adequately protect our intellectual property rights.

Our efforts to enforce our intellectual property rights may not be successful. We rely on a combination of copyright, trademark, patent and trade secret laws, confidentiality procedures and contractual provisions to protect our proprietary rights. Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties when necessary, and conduct our business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical products and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that any patent applications will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or commercial advantage, or will not be circumvented by others. In the event a third party has also filed one or more patent applications for any of its inventions, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in failure to obtain, or the loss of, patent protection for the inventions and the loss of any right to use the inventions. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us, and diversion of management's attention away from our operations. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others and the defense of patent infringement claims by others can be expensive and time consuming. There can be no assurance that in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, we could be subject to significant liabilities to such third party, and we could be required to license technologies from such third party. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate. However, no assurance can be given that any patent application will be filed, that any filed applications will result in issued patents or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents.

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. There can be no assurance that the products or processes developed by us will not infringe on the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and our technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

Our manufacturing processes involve inherent risks and disruption could materially adversely affect our business, financial condition and results of operations.

The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure or substandard performance of equipment, the occurrence of natural and other disasters, and the need to comply with the requirements of directives of government agencies, including the FDA. In addition, we rely on a single supplier for certain key raw materials and certain finished products, and a small number of suppliers for a number of other materials required for the manufacturing and delivery of our HA products. Although we believe that alternative sources for many of these and other components and raw materials that we use in our manufacturing processes are available, any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

Furthermore, our manufacturing processes and research and development efforts for some of our ophthalmic and veterinary products involve products derived from animals. We procure our animal-derived raw materials from qualified vendors, who control for contamination and have processes that effectively inactivate infectious agents; however, we cannot assure you that we can completely eliminate the risk of transmission of infectious agents. Furthermore, regulatory authorities could in the future impose restrictions on the use of animal-derived raw materials that could impact our business.

The utilization of animals in research and development and product commercialization is subject to increasing focus by animal rights activists. The activities of animal rights groups and other organizations that have protested animal based research and development programs or boycotted the products resulting from such programs could cause an interruption in our manufacturing processes and research and development efforts. The occurrence of material operational problems, including but not limited to the events described above, could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties.

Our financial performance depends on the continued growth and demand for our products and we may not be able to successfully manage the expansion of our operations.

Our future success depends on substantial growth in product sales. There can be no assurance that such growth can be achieved or, if achieved, can be sustained. There can be no assurance that even if substantial growth in product sales and the demand for our products is achieved, we will be able to:

- Develop the necessary manufacturing capabilities;
- Obtain the assistance of additional marketing partners;
- Attract, retain and integrate required key personnel; and
- Implement the financial, accounting and management systems needed to manage growing demand for our products.

Our failure to successfully manage future growth could have a material adverse effect on our business, financial condition, and results of operations.

We engage in acquisitions as a part of our growth strategy in which we will incur a variety of costs and may never realize the anticipated benefits of such acquisitions.

Our business strategy includes the acquisition of businesses, technologies, services or products that we believe are a strategic fit with our business. Such acquisitions could reduce stockholders' ownership, cause us to incur debt, expose us to liabilities and result in amortization expenses related to intangible assets with definite lives. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering new markets with which we have limited experience or where distribution alliances with experienced distributors are not available. Our future profitability may depend in part upon our ability to develop further our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. Moreover, we may fail to realize the anticipated benefits of any acquisition as rapidly as expected or at all, or the acquired business may not perform in accordance with our expectations. We may also incur significant expenditures in anticipation of an acquisition that is never realized.

We may not realize the expected benefits from acquisitions due to difficulties integrating the businesses, operations and product lines.

Our ability to achieve the benefits of acquisitions depends in part on the integration and leveraging of technology, products, operations, sales and marketing channels and personnel. If we undertake any acquisition, the process of integrating an acquired business may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business even if completed in a timely and efficient manner.

We may have difficulty successfully integrating acquired businesses, the domestic and foreign operations or the product lines, and as a result, we may not realize any of the anticipated benefits of the acquisitions. Moreover, we may lose key clients or employees of acquired businesses as a result of the change in ownership to us. Additionally, we cannot assure that our growth rate will equal the growth rates that have been experienced by us and the acquired companies, respectively, operating as separate companies in the past.

We may face circumstances in the future that will result in impairment charges, including, but not limited to, goodwill impairment charges.

If the fair value of any of our long-lived assets decreases as a result of an economic slowdown, a downturn in the markets where we sell products and services or a downturn in our financial performance and/or future outlook, we may be required to record an impairment charge on such assets, including goodwill.

We are required to test intangible assets with indefinite life periods for potential impairment annually and on an interim basis if there are indicators of a potential impairment. We also are required to evaluate amortizable intangible assets and fixed assets for impairment if there are indicators of a possible impairment. Impairment charges could have a negative impact on our results of operations and financial position, as well as on the market price of our common stock.

Customer, vendor and employee uncertainty about the effects of any acquisitions could harm us.

We and the customers of any companies we acquire may, in response to the consummation of any acquisitions, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by customers could adversely affect our business. Similarly, employees of acquired companies may experience uncertainty about their future role until or after we execute our strategies with regard to employees of acquired companies. This may adversely affect our ability to attract and retain key management, sales, marketing and technical personnel following an acquisition.

The acquisitions we have made or may make in the future may make us the subject of lawsuits from either an acquired company’s stockholders, an acquired company’s previous stockholders or our current stockholders.

We may be the subject of lawsuits from either an acquired company’s stockholders, an acquired company’s previous stockholders or our current stockholders, including our current dispute with Fidia regarding Merogel Injectable. These lawsuits could result from the actions of the acquisition target prior to the date of the acquisition, from the acquisition transaction itself or from actions after the acquisition. Defending potential lawsuits could cost us significant expense and detract management’s attention from the operation of the business. Additionally, these lawsuits could result in the cancellation of or the inability to renew, certain insurance coverage that would be necessary to protect our assets.

We may not satisfactorily resolve the dispute with Fidia Farmaceutici S.p.A.

We have begun an arbitration process with Fidia Farmaceutici S.p.A. to resolve a dispute related to the withdrawal of our Merogel Injectable product from the market in 2011 due to a labeling error on the product's packaging. We cannot guarantee that this dispute will be satisfactorily resolved without an adverse effect on our business or operating results. Please see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Management Overview – Surgical" for additional information regarding this dispute.

Attractive acquisition opportunities may not be available to us in the future.

We will consider the acquisition of other businesses. However, we may not have the opportunity to make suitable acquisitions on favorable terms in the future, which could negatively impact the growth of our business. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the continued tightening of the global credit markets. We expect that our competitors, many of which have significantly greater resources than we do, will compete with us to acquire compatible businesses. This competition could increase prices for acquisitions that we would likely pursue.

Sales of our products are largely dependent upon third party reimbursement and our performance may be harmed by health care cost containment initiatives.

In the U.S. and other markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third party payers, including Medicare, Medicaid and other health insurance and managed care plans, to reimburse all or part of the cost of the health care product. We depend upon the distributors for our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payers may depend on a number of factors, including the payer's determination that the use of our products is clinically useful and cost-effective, medically necessary and not experimental or investigational. Since reimbursement approval is required from each payer individually, seeking such approvals can be a time consuming and costly process which, in the future, could require us or our marketing partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payer separately. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and any failure or delay in obtaining reimbursement approvals can negatively impact sales of our new products. In addition, third party payers are increasingly attempting to contain the costs of health care products and services by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing in some cases to provide coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. Also, Congress and certain state legislatures have considered reforms that may affect current reimbursement practices, including controls on health care spending through limitations on the growth of Medicare and Medicaid spending. There can be no assurance that third party reimbursement coverage will be available or adequate for any products or services developed by us. Outside the U.S., the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems. Domestic and international reimbursement laws and regulations may change from time to time. Lack of adequate coverage and reimbursement provided by governments and other third party payers for our products and services, including change of classification by CMS for ORTHOVISC under a unique J-code for Medicare/Medicaid reimbursement, could have a material adverse effect on our business, financial condition, and results of operations.

We may seek financing in the future, which could be difficult to obtain and which could dilute your ownership interest or the value of your shares.

We had cash and cash equivalents of approximately $44.1 million at December 31, 2012. Our future capital requirements and the adequacy of available funds will depend, however, on numerous factors, including:

- Market acceptance of our existing and future products;
- The success and sales of our products under various distributor agreements;
- The successful commercialization of products in development;
- Progress in our product development efforts;
- The magnitude and scope of such product development efforts;
- Any potential acquisitions of products, technologies or businesses;
- Progress with preclinical studies, clinical trials and product approvals and clearances by the FDA and other agencies;
- The cost and timing of our efforts to manage our manufacturing capabilities and related costs;

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The cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and the cost of defending any other legal proceeding;

- Competing technological and market developments;
- The development of strategic alliances for the marketing of certain of our products;
- The terms of such strategic alliances, including provisions (and our ability to satisfy such provisions) that provide upfront and/or milestone payments to us;
- Our abilities to meet debt covenant and repayment requirements; and
- The cost of maintaining adequate inventory levels to meet current and future product demands.

To the extent funds generated from our operations, together with our existing capital resources are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. The terms of any future equity financings may be dilutive to you and the terms of any debt financings may contain restrictive covenants, which limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

We are subject to debt covenants and any failure to comply with these could materially adversely affect our business, financial condition and results of operations.

On January 31, 2008, we entered into a Credit Agreement with Bank of America (the “Credit Agreement”). Under the Credit Agreement, our lender made periodic loans to us through December 31, 2008. We borrowed $16,000,000 in 2008, the maximum allowed amount under the Credit Agreement. At December 31, 2008, the borrowings were converted into a 7-year term loan. On December 30, 2009, the Credit Agreement was amended as part of the Anika S.r.l. acquisition. The Credit Agreement was entered into in order to finance the construction and validation of our Bedford facility. Construction of the new facility commenced in the spring of 2007 and was substantially completed in mid-2008. See Note 15 to our Consolidated Financial Statements for additional information relative to this debt facility.

The Credit Agreement contains certain debt covenants, representations and warranties with which we must comply. If we do not comply with the specified covenants and restrictions, we could be in default under our Credit Agreement. Our ability to comply with the provisions of our Credit Agreement governing our other indebtedness may be affected by changes in the economic or business conditions or other events beyond our control.

We could become subject to product liability claims, which, if successful, could materially adversely affect our business, financial condition and results of operations.

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and there can be no assurance that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have an insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate to cover such claims should they arise, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition and results of operations.

Our business is dependent upon hiring and retaining qualified management and technical personnel.

We are highly dependent on the members of our management and technical staff, the loss of one or more of whom could have a material adverse effect on us. We have experienced a number of management changes in recent years. There can be no assurances that such management changes will not adversely affect our business. We believe that our future success will depend in large part upon our ability to attract and retain highly skilled, technical, managerial and manufacturing personnel. We face significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. There can be no assurance that we will be successful in hiring or retaining the personnel we require. The failure to hire and retain such personnel could have a material adverse effect on our business, financial condition and results of operations.

We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

We are subject to a variety of local, state, federal and foreign government regulations relating to the storage, discharge, handling, emission, generation, manufacture and disposal of toxic, or other hazardous substances used in the manufacture of our products. Any failure by us to control the use, disposal, removal or storage of hazardous chemicals or toxic substances could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

As our international sales and operations grow, including through our acquisition of Anika S.r.l., we could become increasingly subject to additional economic, political and other risks that could harm our business.

Since we manufacture and sell our products worldwide, our business is subject to risks associated with doing business internationally. During the years ended December 31, 2012, 2011 and 2010, approximately, 19%, 25%, and 31%, respectively, of our product sales were to international distributors. We continue to be subject to a variety of risks, which could cause fluctuations in the results of our international and domestic operations. These risks include:

- The impact of recessions and other economic conditions in economies, including Europe in particular, outside the United States;
- Sovereign risk associated with doing business with government financed healthcare hospitals and institutions in Italy;
- Instability of foreign economic, political and labor conditions;
- Unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non-competition agreements in the European Union;
- The impact of strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices or other collective bargaining disputes;
- Difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs or other trade barriers or by U.S. export laws;
- Imposition of governmental controls limiting the volume of international sales;
- Longer accounts receivable payment cycles;
- Potentially adverse tax consequences, including, if required, difficulties transferring funds generated in non-U.S. jurisdictions to the U.S. in a tax efficient manner;
- Difficulties in protecting intellectual property;
- Difficulties in managing international operations; and
- Burdens of complying with a wide variety of foreign laws.

Our success depends, in part, on our ability to anticipate and address these risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results.

Currency exchange rate fluctuations may have a negative impact on our reported earnings.

Approximately 8% of our business during fiscal year 2012 was conducted in functional currencies other than the U.S. dollar, which is our reporting currency. Thus, currency fluctuations among the U.S. dollar and the other currencies in which we do business have caused and will continue to cause foreign currency transaction gains and losses. Currently, we attempt to manage foreign currency risk through the matching of assets and liabilities. In the future, we may undertake to manage foreign currency risk through additional hedging methods. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the variability of currency exposure and the potential volatility of currency exchange rates.

Our stock price has been and may remain highly volatile, and we cannot assure you that market making in our common stock will continue.

The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, governmental regulation and approvals, developments in patent or other proprietary rights, public concern as to the safety of products developed by us and general market conditions may have a significant effect on the market price of our common stock. The trading price of our common stock could be subject to wide fluctuations in response to quarter-to-quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations which have particularly affected the market prices of many medical products companies and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such an event, the price of our common stock would likely decline, perhaps substantially.

No person is under any obligation to make a market in our common stock or to publish research reports on us, and any person making a market in our common stock or publishing research reports on us may discontinue market making or publishing such reports at any time without notice. There can be no assurance that an active public market in our common stock will be sustained.

Our charter documents contain anti-takeover provisions that may prevent or delay an acquisition of us.

Certain provisions of our Restated Articles of Organization and Amended and Restated By-laws could have the effect of discouraging a third party from pursuing a non-negotiated takeover of us and preventing certain changes in control. These provisions include a classified Board of Directors, advance notice to the Board of Directors of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, the provision that vacancies on the Board of Directors be filled by vote of a majority of the remaining directors. In addition, the Board of Directors renewed a Shareholders Rights Plan in April 2008. We are also subject to Chapter 110F of the Massachusetts General Laws which, subject to certain exceptions, prohibits a Massachusetts corporation from engaging in any of a broad range of business combinations with any “interested stockholder” for a period of three years following the date that such stockholder became an interested stockholder. These provisions could discourage a third party from pursuing a takeover of us at a price considered attractive by many stockholders, since such provisions could have the effect of preventing or delaying a potential acquirer from acquiring control of us and our Board of Directors.

Our revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations.

We have historically derived the majority of our revenues from a small number of customers, most of whom resell our products to end-users and most of whom are significantly larger companies than us. For the year ended December 31, 2012, five customers accounted for approximately 82% of product revenue. We expect to continue to be dependent on a small number of large customers for the majority of our revenues. Revenue generated under our new agreement with B&L is expected to be significantly less than under the prior 2004 B&L Agreement. Our failure to generate as much revenue as expected from these customers or the failure of these customers to purchase our products would seriously harm our business. In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders, or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreement, such renegotiations may have a material adverse effect on our business,

financial condition, and/or results of operations. Furthermore, in any future negotiations we may be subject to the perceived or actual leverage that these customers may have given their relative size and importance to us. Any termination, change, reduction or delay in orders could seriously harm our business, financial condition, and results of operations. Accordingly, unless and until we diversify and expand our customer base, our future success will significantly depend upon the timing and size of future purchases by our largest customers and the financial and operational success of these customers. The loss of any one of our major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations.

We may not fully realize the benefits of our acquisitions or strategic alliances.

We may not be able to realize the expected synergies and cost savings from the integration of acquired businesses or assets with our existing operations and technologies. In addition, the integration and/or reorganization processes for our acquisitions may be complex, costly, and time consuming and include unanticipated issues, expenses and liabilities. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company in a manner that enhances the performance of our combined businesses or product lines and allows us to realize value from expected synergies. Following an acquisition, we may not achieve the revenue or net income levels that justify the acquisition. Acquisitions may also result in one-time charges, such as write-offs or restructuring charges, impairment of goodwill or acquired IPR&D, which could adversely affect our operating results. Additionally, we may fund acquisitions of new businesses, strategic alliances or joint ventures by utilizing our cash, incurring debt, issuing shares of our common stock, or by other means.

We may not fully realize the benefits of our restructuring plan.

On December 28, 2012, the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards established by the European Medicines Agency for ATMP (cell based) products that are effective January 1, 2013. The restructuring plan adopted includes a reduction-in-force of 12 people, disposals of related supplies, equipment, and other assets. We expect to substantially complete the restructuring plan within the first six months of 2013. The restructuring plan is intended to improve the efficiency and financial performance of the Company's Italian operations, by reducing costs and focusing on products and technology with strong commercial potential. There is no guarantee that the restructuring plan can be implemented successfully, in the expected timeframe, or produce the expected future savings.

Information security breaches or business system disruptions may adversely affect our business.

We rely on our information technology infrastructure and management information systems to effectively run our business. We may be subject to information security breaches caused by illegal hacking, computer viruses, or acts of vandalism or terrorism. Our security measures or those of our third-party service providers may not detect or prevent such breaches. Any such compromise to our information security could result in an interruption in our operations, the unauthorized publication of our confidential business or proprietary information, the unauthorized release of customer, vendor, or employee data, the violation of privacy or other laws, and the exposure to litigation, any of which could harm our business and operating results.

The effects of new regulations relating to conflict minerals may adversely affect our business.

On August 22, 2012, under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC adopted new requirements for companies that use certain minerals and metals, known as conflict minerals, in their products, whether or not these products are manufactured by third parties. These requirements will require companies to review, disclose and report whether or not such minerals originate from the Democratic Republic of Congo and adjoining countries. While we currently believe our products do not include any conflict minerals, we will have to review whether such minerals are used in the manufacture of our products. However, the implementation of these new requirements could adversely affect the sourcing, availability and pricing of such minerals if they are found to be used in the manufacture of our products. In addition, we will incur additional costs to comply with the disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in our products. The first report is due on May 31, 2014 for the 2013 calendar year. Recently, the U.S. Chamber of Commerce, the National Association of Manufacturers and the Business Roundtable filed a petition challenging the adoption of the rules by the SEC and it is unclear if its implementation will be delayed.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Bedford, Massachusetts, where we lease approximately 134,000 square feet of administrative, research and development and manufacturing space. We entered into this lease on January 4, 2007, and the lease commenced on May 1, 2007 for an initial term of ten and a half years. We have an option under the lease to extend its terms for up to four periods beyond the original expiration date subject to the condition that we notify the landlord that we are exercising each option at least one year prior to the expiration of the original or current term thereof. The first three renewal options each extend the term an additional five years with the final renewal option extending the term six years. Our administrative, marketing, regulatory, and research and development personnel moved into the Bedford facility in November of 2007. The remaining build-out at the Bedford facility was completed in mid-2008.

We also lease, as part of the acquisition of Anika S.r.l., approximately 26,000 square feet of laboratory, warehouse and office space in Abano Terme, Italy. The lease commenced on December 30, 2009 for an initial term of six (6) years. For the year ended December 31, 2012, we had aggregate facility lease expenses of approximately $2,500,000.

ITEM 3. LEGAL PROCEEDINGS

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. On April 26, 2011, Genzyme filed a motion to add its newly-issued U.S. Patent No. 7,931,030 to this litigation and also filed a separate new complaint in the District of Massachusetts alleging that the Company's manufacture and sales of MONOVISC in the United States will infringe that patent. On May 23, 2011, the Court entered orders permitting Genzyme to file its supplement complaint adding its newly-issued U.S. Patent No. 7,931,030 to this litigation and requiring Genzyme to withdraw its separately filed complaint. On July 14, 2011, the Company filed an answer to the supplemental complaint, denying liability. On May 10, 2012, Genzyme dismissed its claim of infringement of U.S. Patent No. 5,399,351 and is no longer asserting that patent against the Company. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with DePuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product. On September 19, 2012, Genzyme and the Company jointly requested that the Court stay Genzyme's lawsuit against the Company pending the full resolution of the Seikagaku/Zimmer lawsuit, including through any appeal of the judgment entered in that lawsuit. The District Court granted the motion on September 28, 2012.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging, discovered by the Company. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. and we have made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has asserted a counterclaim against Anika for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. We have begun an arbitration process with Fidia in the London Court of International Arbitration to

resolve the matter. Management has assessed Fidia's claims and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency.

We are also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to have a material adverse effect on our financial position, results of operations or cash flow.

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

COMMON STOCK INFORMATION

Our common stock has traded on the NASDAQ Global Select Market since November 25, 1997, under the symbol "ANIK." The following table sets forth, for the periods indicated, the high and low sales prices of our common stock on the NASDAQ Global Select Market. These prices represent prices between dealers and do not include retail mark-ups, markdowns, or commissions and may not necessarily represent actual transactions.

Year Ended December 31, 2012	High	Low
First Quarter	$ 12.95	$ 9.00
Second Quarter	17.70	12.50
Third Quarter	16.29	11.77
Fourth Quarter	15.52	9.13

Year Ended December 31, 2011	High	Low
First Quarter	$ 11.67	$ 6.61
Second Quarter	10.22	6.44
Third Quarter	7.36	5.36
Fourth Quarter	9.80	5.24

At December 31, 2012, the closing price per share of our common stock was $9.94 as reported on the NASDAQ Global Select Market and there were 191 holders of record as of that date. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, for use in our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

Performance Graph (Unaudited)

Set forth below is a graph comparing the total returns of the Company, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes $100 is invested on December 31, 2007 in the Company's Common Stock and each of the indices.

	Dec-07	Dec-08	Dec-09	Dec-10	Dec-11	Dec-12
Anika Therapeutics, Inc.	$100.00	$20.89	$52.44	$45.84	$67.35	$68.32
NASDAQ Composite Index	$100.00	$59.46	$85.55	$100.02	$98.22	$113.85
NASDAQ Biotechnology Index	$100.00	$87.37	$101.03	$116.19	$129.91	$171.36

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2012 and 2011 and the Statement of Operations Data for each of the three years ended December 31, 2012, 2011 and 2010 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2010, 2009 and 2008, and the Statement of Operations Data for each of the two years in the period ended December 31, 2009 and 2008 have been derived from the audited Consolidated Financial Statements for such years not included in this Annual Report on Form 10-K.

Statement of Operations Data
(In thousands, except per share data)

	Years ended December 31,				
	2012	2011	2010	2009	2008
Product Revenue	$ 68,010	$ 61,956	$ 52,736	$ 37,321	$ 33,055
Licensing, milestone and contract revenue	3,348	2,822	2,821	2,815	2,725
Total revenue	71,358	64,778	55,557	40,136	35,780
Cost of product revenue	28,989	26,784	23,827	13,670	13,189
Product gross profit	39,021	35,172	28,909	23,651	19,866
Product gross margin	57%	57%	55%	63%	60%
Total operating expenses	51,643	50,811	48,019	34,549	31,533
Net Income	11,757	8,467	4,316	3,688	3,629
Diluted net income per common share	$ 0.82	$ 0.62	$ 0.32	$ 0.32	$ 0.32
Diluted common shares outstanding	14,345	13,748	13,647	11,562	11,461

Balance Sheet Data
(In thousands)

	Years ended December 31,				
	2012	2011	2010	2009	2008
Cash and cash equivalents	$ 44,067	$ 35,777	$ 28,202	$ 24,427	$ 43,194
Working capital	62,932	49,600	36,952	33,307	46,798
Total assets	142,069	132,844	128,937	129,431	95,821
Long term obligations	9,600	11,200	12,800	14,400	16,000

Retained earnings	46,010	34,252	25,786	21,470	17,782
Stockholders' equity	108,925	94,763	85,190	82,144	60,757

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

The following section of this Annual Report on Form 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of the federal securities laws. These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievement to differ materially from anticipated results, performance, or achievement, expressed or implied in such forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. We discuss many of these risks and uncertainties at the beginning of this Annual Report on Form 10-K and under Item 1 "Business" and Item 1A "Risk Factors." The following discussion should also be read in conjunction with the Consolidated Financial Statements of Anika Therapeutics, Inc. and the Notes thereto appearing elsewhere in this report.

Management Overview

Anika Therapeutics, Inc. ("Anika," and together, with its subsidiaries, the "Company") develops, manufactures and commercializes therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid ("HA"), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells. Together with our wholly-owned subsidiary, Anika S.r.l., the Company offers therapeutic products in the following areas:

	Anika	Anika S.r.l.
Orthobiologics	X	X
Dermal		
Advanced wound care	X	X
Aesthetic dermatology		
Ophthalmic	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care ("ENT")		X
Veterinary	X	

Orthobiologics

Anika's orthobiologics business contributed 74% to our product revenue for the year ended December 31, 2012. Our orthobiologics products consist of joint health and orthopedic products. Joint health products include ORTHOVISC, ORTHOVISC mini, and MONOVISC. ORTHOVISC is available in the U.S., Canada, and some international markets for the treatment of osteoarthritis of the knee, and in Europe for the treatment of osteoarthritis in all joints. ORTHOVISC mini is available in Europe and is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment indicated for all joints in Europe, and for the knee in Turkey and Canada. ORTHOVISC mini, and MONOVISC are our two most recent joint health products which

became available in certain international markets during the second quarter of 2008.

Anika has marketed ORTHOVISC, our product for the treatment of osteoarthritis of the knee, internationally since 1996 through various distribution agreements. International sales of ORTHOVISC contributed 7% of product revenue for the year ended December 31, 2012.

Our strategy is to continue to add new products, to expand the indications for usage of these products, and to add additional countries to our distribution network. The joint health area has been the fastest growing area for the Company, growing from 57% of our product revenue in 2008 to approximately 74% of our product revenue in 2012. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2013 compared to 2012.

We currently offer several orthopedic products used in connection with regenerative medicine. The products currently available in Europe include Hyalofast, a biodegradable support for human bone marrow mesenchymal stem cells; Hyalonect, a woven gauze used as a graft wrap; and Hyaloss, HYAFF fibers used to mix blood/bone grafts to form a paste for bone regeneration. We also offer Hyaloglide, an ACP gel used in tenolysis treatment, but with additional clinical data may demonstrate potential for flexor tendon adhesion prevention, and in the shoulder for adhesive capsulitis. These products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea. Anika believes that the U.S. market offers excellent expansion potential to increase revenue, and this will continue to be a major focus area for the Company.

Dermal

Our dermal products contributed 2% to our product revenue for the year ended December 31, 2012, and consist of advanced wound care products based on the HYAFF technology, and aesthetic dermal fillers. Anika S.r.l. offers over seven products for the treatment of skin wounds ranging from burns to diabetic ulcers. The products cover a variety of wound treatment solutions including debridement agents, advanced therapies and scaffolds used in connection with skin substitutes. Leading products include Hyalomatrix and Hyalofill, for treatment of complex wounds such as burns and ulcers, and Hyalograft 3D and Laserskin scaffolds, for use in connection with the regeneration of skin. Anika S.r.l.'s dermal products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea. Several of the products are also approved for sale in the United States including Hyalomatrix and Hyalofill. In 2012, the Company entered into a distribution agreement for sales of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, Chile, and others.

Our aesthetic dermatology business is designed as a family of products for facial wrinkles and scar remediation, and is intended to compete with collagen-based and other HA-based products currently on the market. Our initial aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and is approved in Europe, Canada, the U.S., Korea and certain countries in South America. Internationally, this product is marketed under the ELEVESS name. In the U.S., the trade name is HYDRELLE, although the product is not currently marketed in the U.S.

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2012, sales of ophthalmic products contributed 13% of our product revenue. Anika previously manufactured the AMVISC product line for Bausch & Lomb under the terms of a supply agreement that expired on December 31, 2010 (the "2004 B&L Agreement") for viscoelastic products used in ophthalmic surgery. Effective January 1, 2011, the parties entered into a non-exclusive, two year contract intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, low-cost supplier formerly affiliated with B&L, and we continued to supply B&L with these products during 2011. Effective January 1, 2012, the parties agreed to a new three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes for 2012, with lower committed volumes in 2013 and 2014.

B&L accounted for 11% of product revenue for the year ended 2012, but is expected to be significantly lower in 2013 under the new contract. Operating margins under the 2004 B&L Agreement were low and will remain at a similar level under the new contract. See Item 1A. "Risk Factors."

Surgical

Our surgical group consists of products used to prevent surgical adhesions, and to treat ENT disorders. For the year ended December 31, 2012, sales of surgical products contributed 7% of our product revenue. Hyalobarrier is a clinically proven post-operative adhesion barrier for use in the abdomino–pelvic area. The product is currently commercialized in Europe, the Middle East and certain Asian countries through a distribution network, but is not approved in the U.S. INCERT, approved for sale in Europe, Turkey, and Malaysia, is a chemically modified, cross-linked HA product, for the prevention of spinal post-surgical adhesions. There are currently no plans at this time to distribute INCERT in the U.S. Anika co-owns issued U.S. patents covering the use of INCERT for adhesion prevention. See the section captioned "Patent and Proprietary Rights" for additional information.

Anika S.r.l. also offers several products used in connection with the treatment of ENT disorders. The lead products are Merogel, a woven fleece nasal packing, and Merogel Injectable, a thick, viscous hydrogel composed of

cross-linked hyaluronic acid, a biocompatible agent that creates a moist wound-healing environment. Anika S.r.l. is partnered with Medtronic for worldwide distribution of these products.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error, by the third-party contract manufacturer on the product's packaging, discovered by the Company. We settled the matter related to this dispute with Medtronic in August, 2012 and began shipping the product again in December 2012. As this labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A, we have made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has made claims against us for refusing to release the Anika shares that were put into escrow in connection with the S.r.l. acquisition. We have begun an arbitration process in the London Court of International Arbitration.

Veterinary

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 4% to product revenue for the year ended December 31, 2012. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Research and Development

Anika's research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities relative to our existing and new products. Our development focus includes products for tissue protection, healing and repair. Our investment in R&D has been important over the years, and varies considerably depending on the number and size of clinical trials and studies underway. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

With the acquisition of Anika S.r.l., we have enhanced our research and development capabilities, our technology base, and our pipeline of candidate products. Anika S.r.l. has research and development programs for new products including Hyalobone, a bone tissue filler; Hyalospine, an adhesion prevention gel for use after spinal surgery; and Hyalofast, an innovative product for cartilage tissue repair. Other key projects include obtaining FDA approval to market Anika S.r.l.'s suite of orthopedic products in the U.S. These products consist of Hyalofast, Hyaloglide, and Hyalonect.

Two key products under development or regulatory review include MONOVISC for U.S. marketing approval and CINGAL. Our first next generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary cross-linked HA-technology. We received Conformité Européenne ("CE") Mark approval for the MONOVISC product in October 2007, and began sales in Europe during the second quarter of 2008, following a small, post-marketing clinical study. In the U.S., we filed the final module of our MONOVISC PMA containing the clinical data in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter. In December 2012, the FDA upheld its non-approvable decision following our appeal. Subsequent to that decision, in January of 2013, the Company submitted a new PMA amendment which is under review by the FDA. The Company continues to discuss pathways to approval with the FDA.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule to provide broad pain relief for a long period of time. During the past year, we have integrated the research and development efforts of Anika and Anika S.r.l., and prioritized our new product development activities and expect to make progress on a clinical trial in support of CINGAL during 2013.

Business Developments

We received FDA approval to manufacture our terminally sterilized product, ELEVESS, in our Bedford facility in November 2010. In the first quarter of 2012, we received FDA approval to sell ORTHOVISC, HYVISC, and INCERT manufactured in our Bedford plant, and received approval to manufacture our ophthalmic products in the Bedford facility in the second quarter of 2012. Our Bedford facility is approved to manufacture all Anika CE marked products, as well as Anika S.r.l. CE marked ACP gel products, and Merogel Injectable for distribution in the U.S.

Restructuring Plan

On December 28, 2012 the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards, established by the EMA for Advanced Therapy Medicinal Products, which are effective January 1, 2013. The restructuring plan primarily involves a workforce reduction, the disposal of related supplies and equipment, and the termination of the Hyalograft C Autograft in-process R & D project. We recorded restructuring and related impairment charges in the fourth quarter of 2012 of approximately $2.5 million. Of the total restructuring and related impairment charges, approximately $1.6 million related to the noncash disposal of assets. The remaining $0.9 million relates to cash payments anticipated to occur in 2013, primarily for employee termination costs. We expect to substantially complete the restructuring plan within the first six months of 2013. These reductions are expected to result in annualized savings of approximately $0.5 million.

Summary of Critical Accounting Policies; Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We monitor our estimates on an on-going basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout “Management’s Discussion and Analysis of Financial Condition and Results of Operations” where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 2 in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K for the year ended December 31, 2012.

Foreign Currency Translation

The functional currency of our foreign subsidiary is the Euro. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using the monthly average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as a component of accumulated currency translation adjustment.

The Company recognized gains from foreign currency transactions of $200,452 during the year ended December 31, 2012, and losses from foreign currency transactions of $623,093, and $7,698 in 2011 and 2010, respectively.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and consider assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and

minimize the use of unobservable inputs when measuring fair value.

A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Three levels of inputs that may be used to measure fair value are:

Level 1 – Valuation is based upon quoted prices for identical instruments traded in active markets. Level 1instruments include securities traded on active exchange markets, such as the New York Stock Exchange.

Level 2 – Valuation is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market.

Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect our own estimates of assumptions market participants would use in pricing the asset or liability.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. In determining the adequacy of the allowance for doubtful accounts, management specifically analyzes individual accounts receivable, historical bad debts, customer concentrations, customer credit-worthiness, current economic conditions, accounts receivable aging trends and changes in our customer payment terms.

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead.

The Company’s policy is to write-down inventory when conditions exist that suggests inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for the Company’s products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including, but not limited to: historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Purchasing requirements and alternative usage avenues are explored within these processes to mitigate inventory exposure.

As part of the restructuring plan we adopted during the fourth quarter of 2012, we wrote down inventory related to our tissue engineering operation and included an expense of approximately $0.1 million as a component of the overall restructuring charge. See “Restructuring Charges.”

Revenue Recognition - General

We recognize revenue from product sales when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collection from the customer is reasonably assured.

Product Revenue

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon shipment to the customer. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. When determining whether risk of loss has transferred to customers on product sales, or if the sales price is fixed or determinable, the Company evaluates both the contractual terms and conditions of its distribution and supply agreements as well as its business practices.

Product revenue also includes royalties. Royalty revenue is based on our distributors’ sales and recognized in the same period our distributors record their sale of products manufactured by us. On a quarterly basis we record royalty

revenue based upon sales projections provided to us by our distributor customers. If necessary we adjust our estimates based upon final sales data received prior to issuing our annual audited financial statements.

Licensing, Milestone and Contract Revenue

Licensing, milestone, and contract revenue consists of revenue recognized on initial and milestone payments, as well as contractual amounts received from partners. The Company’s business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company’s products.

The terms of the agreements typically include non-refundable license fees, funding of research and development, and payments based upon achievement of certain milestones. The Company adopted Accounting Standards Update ("ASU") 2009-13, Revenue Recognition, in January 2011, which amends Accounting Standards Codification ("ASC") Subtopic 605-25, Multiple Element Arrangements (“ASC 605-25”) to require the establishment of a selling price hierarchy for determining the allocable selling price of an item. Under ASC 605-25, as amended by ASU 2009-13, in order to account for an element as a separate unit of accounting, the element must have objective and reliable evidence of selling price of the undelivered elements. In general, non-refundable upfront fees and milestone payments that do not relate to other elements are recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Computer hardware and software are typically amortized over three to five years, and furniture and fixtures over five to seven years. Leasehold improvements are amortized over the shorter of their useful lives or the remaining terms of the related leases. Property and equipment under capital leases are amortized over the lesser of the lease terms or their estimated useful lives. Maintenance and repairs are charged to expense when incurred; additions and improvements are capitalized. When an item is sold or retired, the cost and related accumulated depreciation is relieved, and the resulting gain or loss, if any, is recognized in income.

Goodwill and Acquired In-Process Research and Development

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired In-Process Research and Development ("IPR&D") represents the fair value assigned to research and development assets that we acquire that have not been completed at the date of acquisition or are pending regulatory approval in certain jurisdictions. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value.

Goodwill and IPR&D are evaluated for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors we consider important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, significant negative industry or economic trends, a significant decline in our stock price for a sustained period, or a reduction of our market capitalization relative to net book value.

To conduct impairment tests of goodwill, the fair value of the acquired reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. We estimate the fair value for reporting units using discounted cash flow valuation models which require the use of significant estimates and assumptions including but not limited to: risk free rate of return on an investment, weighted average cost of capital, future revenue, operating margin, working capital and capital expenditure needs. Our annual assessment for impairment of goodwill as of November 30, 2012 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit. Anika S.r.l. is our only acquired reporting unit and currently holds 100% of the goodwill associated with the 2009 acquisition of that company.

To conduct impairment tests of IPR&D, the fair value of the IPR&D projects is compared to the carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. We estimate the fair values for IPR&D projects using discounted cash flow valuation models which require the use of significant estimates and assumptions including, but not limited to: estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. Excluding our fourth quarter 2012 restructuring and related impairment charges, our annual assessment for impairment of IPR&D indicated that the fair value of our IPR&D as of November 30, 2012 exceeded their respective carrying values.

Through December 31, 2012 there have not been any events or changes in circumstances that indicate that the carrying value of goodwill or acquired intangible assets may not be recoverable. The fair value of the equity of the Anika S.r.l. reporting unit over its carrying value at November 30, 2012 declined from the prior year. The Company

continues to monitor and evaluate the financial performance of the Anika S.r.l. business including the impact of general economic conditions, to assess the potential for the fair value of the reporting unit to decline below its book value. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

As part of the restructuring plan we adopted during the fourth quarter of 2012, we terminated an IPR&D project related to our tissue engineering operation and included an expense of approximately $1.2 million as a component of the overall restructuring charge. See “Restructuring Charges.”

Long-Lived Assets

Long-lived assets primarily include property and equipment and intangible assets with finite lives (including purchased software and trade names). Purchased software is amortized over 2 to 10 years and trade names are amortized over 10 years. We review long-lived assets for impairment when events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of those assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis.

As part of the restructuring plan we adopted during the fourth quarter of 2012, we disposed of long-lived assets related to our tissue engineering operation and included an impairment charge of approximately $0.3 million as a component of the overall restructuring charge. See “Restructuring Charges.”

Restructuring Charges

Restructuring charges are primarily comprised of severance costs, activity termination costs and costs of facility closure. Restructuring charges are recorded upon approval of a formal management plan and are included in the operating results of the period in which such plan is approved and the expense becomes estimable. To estimate restructuring charges, management utilizes assumptions such as the number of employees that would be involuntarily terminated and the future costs to operate and eventually terminate the subject activity. Estimated restructuring expenses are subject to the rules of fair value accounting and may change as management executes the approved plan.

Of the $2.5 million in restructuring charges recognized during the fourth quarter of 2012, approximately $1.6 million related to the abandonment and noncash impairment of assets. The balance of the restructuring charges related to employee termination costs and other one-time costs directly related to the tissue engineering facility closure.

Research and Development

Research and development costs consist primarily of salaries and related expenses for personnel and fees paid to outside consultants and outside service providers, including costs associated with licensing, milestone and contract revenue. Research and development costs are expensed as incurred.

Stock-Based Compensation

We measure the compensation cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the underlying award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award. See Note 10 of the accompanying Consolidated Financial Statements for a description of the types of stock-based awards granted, the compensation expense related to such awards, and detail of equity-based awards outstanding. See Note 14 of the accompanying Consolidated Financial Statements for details relative to the tax benefit recognized in the consolidated statement of operations for stock-based compensation.

Income Taxes

Our income tax expense includes U.S. and international income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these differences are reported as deferred tax assets and liabilities. Deferred tax assets are recognized for the estimated future tax effects of deductible temporary differences and tax operating loss and credit carry-forwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that it is more likely than not that all or a portion of deferred tax assets will not be realized, we establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we include an expense within the tax provision in the consolidated statement of operations.

Comprehensive Income

Comprehensive income consists of net income and other comprehensive income (loss), which includes foreign currency translation adjustments. For the purposes of comprehensive income disclosures, we do not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as we intend to indefinitely reinvest undistributed earnings of our foreign subsidiary. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity and, as of December 31, 2012 and 2011, was comprised solely of cumulative translation adjustments.

Segment Information

Operating segments, as defined under U.S. GAAP, are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. Based on the criteria established by ASC 280, Segment Reporting, the Company has one reportable operating segment, the results of which are disclosed in Note 13 of the accompanying Consolidated Financial Statements.

Results of Operations

Year ended December 31, 2012 compared to year ended December 31, 2011

Statement of Operations Detail

	Year Ended December 31,			
	2012	2011	Inc/(Dec)	Inc/(Dec)
Product revenue	$ 68,010,169	$ 61,956,386	$ 6,053,783	9.8 %
Licensing, milestone and contract revenue	3,348,336	2,822,249	526,087	18.6 %
Total revenue	71,358,505	64,778,635	6,579,870	10.2 %
Operating expenses:				
Cost of product revenue	28,988,621	26,783,738	2,204,883	8.2 %
Research & development	5,388,036	6,168,937	(780,901)	-12.7 %
Selling, general & administrative	14,728,662	17,858,558	(3,129,896)	-17.5 %
Restructuring charges	2,537,988	-	2,537,988	-
Total operating expenses	51,643,307	50,811,233	832,074	1.6 %
Income from operations	19,715,198	13,967,402	5,747,796	41.2 %
Interest income (expense), net	(187,777)	(182,388)	(5,389)	3.0 %
Income before income taxes	19,527,421	13,785,014	5,742,407	41.7 %
Provision for income taxes	7,769,961	5,318,334	2,451,627	46.1 %
Net income	$ 11,757,460	$ 8,466,680	$ 3,290,780	38.9 %
Product gross profit	$ 39,021,548	$ 35,172,648	$ 3,848,900	10.9 %
Product gross margin	57 %	57 %		

Total Revenue. Total revenue for the year ended December 31, 2012 increased by $6,579,870 to $71,358,505. The increase in total revenue was primarily due to increased Joint Health product revenue in 2012 as compared to 2011.

Product revenue by product line. Product revenue for the year ended December 31, 2012 was $68,010,169, an increase of $6,053,783, or 10%, compared to the prior year.

	Year Ended December 31,			
	2012	2011	Inc/(Dec)	Inc/(Dec)
Orthobiologics	$ 49,954,112	$ 39,858,139	$ 10,095,973	25 %
Dermal	1,384,403	3,681,166	(2,296,763)	-62 %
Ophthalmic	8,784,011	10,963,822	(2,179,811)	-20 %
Surgical	5,022,456	4,976,261	46,195	1 %
Veterinary	2,865,187	2,476,998	388,189	16 %
	$ 68,010,169	$ 61,956,386	$ 6,053,783	10 %

Revenue from orthobiologics increased $10,095,973, or 25%, in 2012 compared to 2011. The improvement in orthobiologics product revenue was due primarily to increases in domestic ORTHOVISC sales, offset by decreases in Anika S.r.l.'s orthopedic revenue which was down in all geographic regions. Our U.S. joint health product revenue for 2012 increased 42% compared to 2011. This increase reflects DePuy Mitek's continued market penetration to an estimated market share of 15% in 2012 versus 14% share in 2011. International orthobiologics product revenue in 2012 decreased 21% compared to 2011. The decrease in international revenue was driven primarily by the continued economic stagnation being experienced throughout Europe. We continue to expect orthobiologics revenue will increase in 2013 compared to 2012, both domestically and internationally, as economic conditions improve.

Dermal revenue decreased $2,296,763, or 62%, in 2012 compared to 2011. The decrease was primarily due to Anika S.r.l.'s advanced wound care products revenue which totaled $976,388 in 2012, as compared to $3,311,618 in 2011, due to continued economic challenges faced in the Italian market as well as the impact of changing to a distributor-based sales model in 2012 in Italy, combined with the poor performance of Anika S.r.l.'s distributor in the U.S. territory. Aesthetic dermatology revenue was $408,015 for the year ended December 31, 2012, versus $369,548 for the prior year.

Revenue from ophthalmic products in 2012 decreased $2,179,811, or 20%, compared to revenue for these products in 2011. The decrease was primarily attributable to B&L's plan to shift manufacturing to an alternative supplier. B&L accounted for 11% of product revenue for the year ended 2012, but is expected to be significantly lower in 2013 due to the lower minimum purchase requirements under the new three year contract. Operating margins under the expired 2004 B&L Agreement were low, and remain at a similar level under the new contract.

Sales of our surgical products increased $46,195, or 1%, as compared to 2011. This product group consists primarily of Anika S.r.l.'s Hyalobarrier anti-adhesion and ENT products. Our anti-adhesion products include INCERT and Hyalobarrier. Our leading ear, nose and throat care product is Merogel. Anika S.r.l. is partnered with Medtronic for worldwide distribution (except for Italy) of its ENT products. We expect surgical product revenue to increase moderately in 2013 compared to 2012.

Veterinary revenue increased $388,189, or 16%, in 2012 as compared to 2011. Sales of HYVISC are made to a single customer under an exclusive agreement which expires December 31, 2014. We expect HYVISC revenue to be relatively flat in 2013 compared to 2012.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the year ended December 31, 2012 was $3,348,336, compared to $2,822,249 for 2011. Licensing and milestone revenue includes the ratable recognition of the $27,000,000 in up-front and milestone payments related to the JNJ Agreement. These amounts are being recognized in income ratably over the ten-year initial term of the agreement, or $2,700,000 per year. The year 2013 will be the last year for the recognition of these milestone payments. In November 2012, Mitek

exercised its option and extended the JNJ Agreement for an additional five years through December 2018.

In December 2011, the Company entered into a fifteen-year licensing and supply agreement with DePuy Mitek, Inc. to market MONOVISC in the U.S. The Company received an initial payment of $2,500,000 in December 2011, which is also being recognized ratably over the life of the underlying agreement of fifteen years. The Company is entitled to receive additional payments from DePuy Mitek, following FDA approval and the mutual decision to launch the product, as well as payments related to future regulatory, clinical and sales milestones.

Product gross profit and margin. Product gross profit for the year ended December 31, 2012 was $39,021,548, or 57.4% of product revenue, compared with $35,172,648, or 56.8% of product revenue, for the year ended December 31, 2011. The increase in product gross profit was primarily due to improvements in Anika's overall product sales mix, as compared to the prior year, with increasing sales of our higher-margin orthobiologics products as a percent of our overall product sales being the primary driver, as well as the realization of operational efficiencies from our new manufacturing facility after consolidation of sites. The positive effect of the improved product sales mix was partially offset by the negative impact of a previously disclosed temporary scale-up issue experienced as we consolidated all of our manufacturing activities into our Bedford facility from our now-closed Woburn facility. Anika S.r.l. outsources manufacturing of its medical devices to its former parent company, Fidia Farmaceutici, contributing to its current lower gross margins. The Company continues to make progress on its plan to transfer a significant portion of Anika S.r.l.'s medical device product manufacturing to our Bedford facility and successfully began manufacturing ACP gel products there during the fourth quarter of 2012. We expect this to have a favorable impact on gross margins starting in the first half of 2013. Looking forward, we expect gross margin in the U.S. to remain under pressure from government healthcare cost control initiatives.

Research and development. Research and development ("R&D") expenses for the year ended December 31, 2012 decreased by $780,901, or 13%, as compared to the prior year, due to the timing of the start of certain clinical trials. R&D as a percentage of revenue was 8% and 10% for the years ended 2012 and 2011, respectively. We expect research and development expenses will increase significantly in 2013 and thereafter compared to 2012 with commencement of clinical studies for CINGAL, as well as other line extension, new product, and early-stage development projects.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2012 decreased by $3,129,896, or 18%, as compared to 2011. This decrease was primarily due to valuation gains associated with the re-measurement of euro-based assets into U.S. dollars as the Dollar weakened during 2012, as compared to 2011, combined with the placing in service the remainder of the Bedford manufacturing facility, and lower legal and professional fees, offset by exit costs associated with the closing of our Woburn facility. We expect general and administrative expenses for 2013 will increase modestly reflective of the support required to grow our business both domestically and internationally.

Restructuring charges. On December 28, 2012 the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards, established by the EMA, which are effective January 1, 2013. As a result of the plan, the Company recorded restructuring and associated impairment charges in the fourth quarter of approximately $2.5 million. Of the total restructuring and associated impairment charges, approximately $1.6 million related to the abandonment and noncash impairment of assets. The remaining $0.9 million relates to cash payments anticipated to occur in 2013, primarily for employee termination costs. We plan to substantially complete the Plan by the end of the first six months of 2013. These reductions are expected to result in annualized savings of approximately $0.5 million.

Interest income (expense), net. Net interest expense was $187,777 for the year ended December 31, 2012, as compared to $182,388 in the same period ended 2011. The modest increase is the result of increased rates on our outstanding variable interest rate debt.

Income taxes. Provisions for income taxes were $7,769,961 and $5,318,334 for the years ended December 31, 2012 and 2011, respectively. The increase in effective tax rate in 2012 of 1.2%, as compared to 2011, is primarily due to an increase in the federal statutory tax rate and the accompanying foreign rate differential, partially offset by increased domestic production deductions all resulting from increased domestic taxable income.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	Year ended December 31,			
	2012		2011	
Statutory federal income tax rate	35.0	%	34.0	%
State tax expense, net of federal benefit	6.4	%	5.7	%
Permanent items, including nondeductible expenses	0.9	%	0.9	%
State investment tax credit	(0.2	)%	(0.2	)%
Federal, state and foreign research and development credits	(1.2	)%	(0.4	)%
Foreign rate differential	2.5	%	0.9	%
Domestic production deduction	(3.6	)%	(2.3	)%
Effective income tax rate	39.8	%	38.6	%

As of December 31, 2012, the Company had net operating losses ("NOL") for federal income tax purposes in Italy of $9,144,154 with no expiration date. For Massachusetts state income tax purposes, the Company also had an investment tax credit carry-forward of $298,769 expiring through 2021.

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its NOL carry-forward and its investment tax credit carry-forward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that those deferred tax assets not otherwise subject to a valuation allowance are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at December 31, 2012, and 2011, respectively.

The 2009 through 2012 tax years remain subject to examination by the Internal Revenue Service ("IRS") and other taxing authorities for U.S. federal and state purposes. The 2009 through 2012 tax years remain subject to examination by the applicable governmental authorities in Italy.

Net income. For the year ended December 31, 2012, net income was $11,757,460, or $0.82 per diluted share, compared to $8,466,680, or $0.62 per diluted share, for the same period last year. The primary drivers behind this increase in net income were an increase in product sales with a more favorable product mix, lower clinical spending due to timing of clinical trial efforts, and lower legal and professional fees. These items were partially offset by the fourth quarter 2012 restructuring charge and an increase in our effective tax rate.

Year ended December 31, 2011 compared to year ended December 31, 2010

Statement of Operations Detail

	Year Ended December 31,			
	2011	2010	Inc/(Dec)	Inc/(Dec)
Product revenue	$ 61,956,386	$ 52,735,730	$ 9,220,656	17 %
Licensing, milestone and contract revenue	2,822,249	2,820,864	1,385	0 %
Total revenue	64,778,635	55,556,594	9,222,041	17 %
Operating expenses:				
Cost of product revenue	26,783,738	23,826,604	2,957,134	12 %
Research & development	6,168,937	6,874,633	(705,696)	-10 %
Selling, general & administrative	17,858,558	17,317,671	540,887	3 %
Total operating expenses	50,811,233	48,018,908	2,792,325	6 %
Income from operations	13,967,402	7,537,686	6,429,716	85 %
Interest income (expense), net	(182,388)	(194,620)	12,232	-6 %
Income before income taxes	13,785,014	7,343,066	6,441,948	88 %
Provision for income taxes	5,318,334	3,027,071	2,291,263	76 %
Net income	$ 8,466,680	$ 4,315,995	$ 4,150,685	96 %
Product gross margin	35,172,648	28,909,126	6,263,522	22 %
Product gross margin	57 %	55 %		

Total Revenue. Total revenue for the year ended December 31, 2011 increased by $9,222,041 to $64,778,635. The increase in total revenue was primarily due to increased Joint Health product revenue in 2011 as compared to 2010.

Product revenue by product line. Product revenue for the year ended December 31, 2011 was $61,956,386, an increase of $9,220,656, or 17%, compared to the prior year. Excluding the contributions of Anika S.r.l., Anika's product revenue grew 16% for the year compared to the prior year.

	Year Ended December 31,			
	2011	2010	Inc/(Dec)	Inc/(Dec)
Orthobiologics	$ 39,858,139	$ 30,741,305	$ 9,116,834	30 %
Dermal	3,681,166	3,564,616	116,550	3 %
Ophthalmic	10,963,822	11,971,787	(1,007,965)	-8 %
Surgical	4,976,261	3,883,444	1,092,817	28 %
Veterinary	2,476,998	2,574,578	(97,580)	-4 %
	$ 61,956,386	$ 52,735,730	$ 9,220,656	17 %

Revenue from orthobiologics increased $9,116,834, or 30%, in 2011 compared to 2010. The improvement in orthobiologics product revenue was due to increases in domestic ORTHOVISC revenue, as well as increased sales of MONOVISC in Europe, Turkey and Canada and Anika S.r.l.'s orthopedic revenue in Europe. Our U.S. joint health product revenue for 2011 increased 30% compared to 2010. This increase reflects DePuy Mitek's continued market penetration to an estimated market share of 14% in 2011 versus 12% share in 2010. International orthobiologics product revenue in 2011 increased 26% compared to 2010. The increase in international revenue was driven by higher product shipments to new and existing customers in Eastern Europe and the Middle East, partially offset by continued weakness in sales in Southern Europe. Anika S.r.l.'s orthopedic product revenue for 2011 increased 40% compared to 2010.

Dermal revenue increased $116,550, or 3%, in 2011 compared to 2010. The increase was primarily due to Anika S.r.l.'s advanced wound care products revenue which totaled $3,311,618 in 2011 as compared to $3,064,552 in 2010. Aesthetic dermatology revenue was $369,548 for the year ended December 31, 2011, versus $500,064 for the prior year.

Revenue from ophthalmic products in 2011 decreased $1,007,965, or 8%, compared to revenue for these products in 2010. The decrease was primarily attributable to B&L's plan to shift manufacturing to an alternative supplier. B&L accounted for 16% of product revenue for the year ended 2011.

Sales of our surgical products increased $1,092,817, or 28%, as compared to 2010. This product group consists primarily of Anika S.r.l.'s anti-adhesion and ENT products acquired in December 2009. The increase was attributable to increased sales of surgical and anti-adhesion products by Anika S.r.l., mostly in Europe and Korea, coupled with a modest increase in the sale of INCERT. Our anti-adhesion products include INCERT and Hyalobarrier. Our leading ear, nose and throat care product is Merogel. Anika S.r.l. is partnered with Medtronic for worldwide distribution (except for Italy) of its ENT products.

Veterinary revenue decreased $97,580, or 4%, in 2011 as compared to 2010. Sales of HYVISC are made to a single customer under an exclusive agreement which expires December 31, 2014.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the year ended December 31, 2011 was $2,822,249, compared to $2,820,864 for 2010. Licensing and milestone revenue includes the ratable recognition of the $27,000,000 in up-front and milestone payments related to the JNJ Agreement. These amounts are being recognized in income ratably over the ten-year expected life of the agreement, or $2,700,000 per year.

In December 2011, the Company entered into a fifteen-year licensing and supply agreement with DePuy Mitek, Inc., a member of the Johnson & Johnson family of companies, to market MONOVISC in the U.S. The Company received an initial payment of $2,500,000 in December 2011, which will be recognized ratably over the fifteen year term of the agreement as there was no stand-alone value associated with this payment, thus up-front recognition is prohibited. The Company is entitled to receive additional payments from DePuy Mitek, following FDA approval and the mutual decision to launch the product, as well as payments related to future regulatory, clinical and sales milestones.

Product gross profit and margin. Product gross profit for the year ended December 31, 2011 was $35,172,648, or 57% of product revenue, compared with $28,909,126, or 55% of product revenue, for the year ended December 31, 2010. The increase in product gross profit was primarily due to improvements in Anika's overall product sales mix, as compared to the prior year, with increasing sales of our orthobiologics products as a percent of our overall product sales being the primary driver. The positive effect of the improved product sales mix was partially offset by the negative effect of the 2011 inventory write-downs and duplicate manufacturing expenditures during the transition from the Woburn facility to the Company's Bedford facility. Anika S.r.l. only manufactured the tissue engineered products and operated at a lower volume. In 2011, Anika S.r.l. outsourced manufacturing of its medical devices to its former parent company, Fidia Farmaceutici, contributing to its lower gross margins.

The Company wrote down inventory by approximately $750,000 during 2011 related to equipment problems, in addition to other production losses, experienced in our Woburn facility.

Research and development. Research and development ("R&D") expenses for the year ended December 31, 2011 decreased by $705,696, or 10%, as compared to the prior year. R&D as a percentage of revenue was 10% and 12% for the years ended 2011 and 2010, respectively. The decrease in research and development expenses was primarily due to higher costs incurred in 2010 in connection with the Company's U.S.-based clinical trials for MONOVISC. This decrease was partially offset by the continued manufacturing validation activities at our Bedford facility, as well as other continuing new product development projects in Italy and the U.S.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2011, increased by $540,887, or 3%, as compared to 2010. This increase was primarily due to valuation losses associated with the re-measurement of euro-based assets into U.S. dollars as the Dollar strengthened in the second half of 2011, in addition to higher legal fees, partially offset by operational streamlining at Anika S.r.l. as we in-sourced financial and administrative services from an outside service provider.

Interest income, net. Net interest expense was $182,388 for the year ended December 31, 2011, as compared to $194,620 in the same period ended 2010. The modest decrease is the direct result of our continuing debt service and the decreasing principal balance in 2011 as compared to 2010.

Income taxes. Provisions for income taxes were $5,318,334 and $3,027,071 for the years ended December 31, 2011 and 2010, respectively. The decrease in effective tax rate in 2011 of 2.6%, as compared to 2010, is primarily due to decreased state tax expense, increased domestic production deductions resulting from increasing domestic taxable income, and improving financial results experienced by Anika S.r.l. which has permitted the Company to benefit more from the lower effective tax rate in Italy.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	Year ended December 31,	
	2011	2010
Statutory federal income tax rate	34.0%	34.0%
State tax expense, net of federal benefit	5.7%	7.8%
Permanent items, including nondeductible expenses	0.9%	2.2%
State investment tax credit	(0.2)%	(0.8)%
Federal and state research and development credits	(0.4)%	(2.5)%
Foreign rate differential	0.9%	2.6%
Domestic production deduction	(2.3)%	(2.1)%
Tax expense	38.6%	41.2%

During 2010, the Company concluded its audit by the IRS for its 2008 tax return, with no changes made by that authority.

Net income. For the year ended December 31, 2011 net income was $8,466,680, or $0.62 per diluted share, compared to $4,315,995, or $0.32 per diluted share, for the same period last year. The primary drivers behind this increase in net income were an increase in product sales with a more favorable product mix, lower clinical spending, and a decrease in our effective tax rate.

Liquidity and Capital Resources

We require cash to fund our operating expenses and to make capital expenditures. We expect that our requirements for cash to fund these uses will increase as our operations expand. Historically we have generated positive cash flow from operations, which together with our available cash and investments and debt, have met our cash requirements. Cash and cash equivalents totaled $44.1 million and $35.8 million, and working capital totaled approximately $62.9 million and $49.6 million, at December 31, 2012 and December 31, 2011, respectively. The Company believes it has adequate financial resources to support its business over the next twelve months.

Cash provided by operating activities was $10,548,677, $10,173,134 and $7,853,461 for 2012, 2011, and 2010, respectively. Cash provided by operating activities increased by $375,543 in 2012 from 2011. The increase was attributable to increased profits in the current year combined with noncash restructuring charges and the effect of deferred income taxes. These were partially offset by an increase in net working capital requirements, the most significant components of which were an increase in trade receivables, due to the timing of fourth quarter sales, and an increase in inventories, due to the timing of raw material purchases. In December 2011, the Company received a milestone payment from Depuy Mitek which favorably impacted cash from operations.

Cash used in investing activities was $1,504,707, $1,400,348 and $2,679,677 in 2012, 2011 and 2010, respectively. The increase in cash used in investing activities in 2012, as compared to the same period in the prior year, is a result of planned capital maintenance projects associated with our Bedford facility during the current year.

Cash used in financing activities was $758,854, $1,165,340, and $1,337,320 for 2012, 2011, and 2010, respectively. Cash used was primarily due to the required principal payments on long-term debt of $1.6 million in each period. Also reflected in the cash provided by financing activities for all three years were proceeds received from the exercise of stock options, including any associated tax benefits.

Concentration of Risk

A significant portion of the Company's accounts receivable arising from product sales within Italy by Anika S.r.l. are due from public hospitals and other government-funded healthcare agencies. As of December 31, 2012, the Company's accounts receivable from all Italian customers totaled approximately $1.2 million of which public hospital and agency receivables were approximately $0.3 million.

The history with our Italian customers has been such that many of the public healthcare providers funded by the Italian government have been slow to pay with several maintaining outstanding balances over one year past due. The Company continuously evaluates these accounts receivables for potential risks associated with, among other things, governmental funding and reimbursement practices. We have established an allowance against the gross value of these trade receivables based upon specifically identifiable risks and other currently available information. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers, monitor the economic situation and take appropriate actions as necessary.

See Note 13, Revenue by Product Group, by Significant Customer and by Geographic Region; Geographic Information, in the accompanying Consolidated Financial Statements for information regarding significant customers.

We do not use special purpose entities or other off-balance sheet financing techniques except for operating leases as disclosed in the contractual obligations table below that we believe have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital resources.

Recent Accounting Pronouncements

On May 12, 2011, the Financial Accounting Standards Board ("FASB"), together with the International Accounting Standards Board, jointly issued Accounting Standards Update ("ASU") 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S.GAAP and IFRS. The provisions of ASU 2011-04 give fair value the same meaning between U.S. GAAP and International Financial Reporting Standards, and improve consistency of disclosures relating to fair value. For public entities, the amendments are effective during interim and

annual periods beginning after December 15, 2011. Early application by public entities was not permitted. The adoption of this new guidance did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The amendments in this ASU require all non-owner changes in stockholders' equity to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. For public entities, the amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In September 2011, the FASB issued ASU 2011-08, Intangibles – Goodwill and Other. This ASU's objective is to simplify the process of performing impairment testing for Goodwill. With this update a company is allowed to first assess qualitative factors to determine if it is more likely than not (greater than 50%) that the fair value of its Goodwill and intangible assets is less than the carrying amount. This step is done prior to performing the two-step goodwill impairment testing, as prescribed by Topic 350. This ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations or cash flows.

In July 2012, the FASB issued ASU 2012-02, Intangibles-Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This amendment is an update of ASU 2011-08, specifically for consistency of approach in assessing impairment for Indefinite-Lived assets. With this update a company is allowed to first assess qualitative factors to determine if it is more likely than not (greater than 50%) that the fair value of its indefinite-lived assets is less than the carrying amount. This ASU is effective for fiscal years beginning after September 15, 2012 with early adoption permitted. The adoption of this amendment will not have a material impact on our consolidated financial position, results of operations or cash flows.

Contractual Obligations and Other Commercial Commitments

We have incurred significant capital investments related to the build-out of our new facility in Bedford, Massachusetts, as well as the Anika S.r.l. acquisition. Our future capital requirements and the adequacy of available funds will depend, on numerous factors, including:

- Market acceptance of our existing and future products;
- The success and sales of our products under current and future distribution agreements;
- The successful commercialization of products in development;
- Progress in our product development efforts;
- The magnitude and scope of such efforts;
- Any potential acquisitions of products, technologies or businesses;
- Progress with pre-clinical studies, clinical trials and product approvals and clearances by the FDA and other agencies;
- The cost of maintaining adequate manufacturing capabilities;
- The cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- Competing technological and market developments;
- The development of strategic alliances for the marketing of certain of our products;
- The terms of such strategic alliances, including provisions (and our ability to satisfy such provisions) that provide upfront and/or milestone payments to us;
- The cost of maintaining adequate inventory levels to meet current and future product demands;

- The contractual obligation to make principal and interest debt payments; and

- The successful reorganization of Anika S.r.l.

We cannot assure you that we will record profits in future periods. To the extent that funds generated from our operations, together with our existing capital resources are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners, or through other sources. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise. However, we believe that our existing cash and cash equivalents and future cash provided by operating activities will be sufficient to meet our working capital and capital expenditure needs over the next 12 months. See Item 1A. “Risk Factors.”

The terms of any future equity financings may be dilutive to our stockholders and the terms of any debt financings may contain restrictive covenants, which could limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets. No assurance can be given that any additional financing may be made available to us or may be available on acceptable terms should such a need arise.

The table below summarizes our non-cancelable operating leases and contractual obligations at December 31, 2012:

		Payments due by period			
	Total	Less than 1 year	2 - 3 years	4 - 5 years	More than 5 years
Operating Leases (1)	$ 11,265,433	$ 1,519,613	$ 2,945,320	$ 1,943,000	$ 4,857,500
Purchase Commitments	1,956,410	1,956,410	-	-	-
Long Term Debt (2)	9,998,768	1,761,663	8,237,105	-	-
Total	$ 23,220,611	$ 5,237,686	$ 11,182,425	$ 1,943,000	$ 4,857,500

(1) Included in this line is a lease we entered into on January 4, 2007, pursuant to which we lease our Corporate Headquarters facility, The Facility consists of approximately 134,000 square feet of general office, R&D and manufacturing space located in Bedford, Massachusetts. The Lease has an initial term of ten and one- half years, and commenced on May 1, 2007. We have an option under the Lease to extend its terms for up to four periods beyond the original expiration date subject to the condition that we notify the landlord that we are exercising each option at least one year prior to the expiration of the original or current term thereof. The first three renewal options each extend the term an additional five years with the final renewal option extending the term six years. Our administrative and R&D personnel began occupying the Bedford facility in November of 2007. The build-out and validation for the Bedford manufacturing space was substantially completed in 2011. Also included in the table above is the lease entered into in Italy related to Anika S.r.l. The lease for our Italian facility commenced on December 30, 2009 for a period of six years.

(2) On January 31, 2008, the Company entered into an unsecured Credit Agreement (the “Agreement”) with Bank of America. Pursuant to the terms of the Agreement, our lender agreed to provide the Company with an unsecured revolving credit facility through December 31, 2008 of up to a maximum principal amount at any time outstanding of $16,000,000. The Company borrowed the maximum amount as of December 31, 2008. On December 31, 2008, all outstanding revolving credit loans were converted into a term loan with quarterly principal payments of $400,000 and a final installment of $5,200,000 due on the maturity date of December 31, 2015. In connection with the acquisition of Anika S.r.l., the Company entered into a Consent and First Amendment to our original loan with Bank of America. As part of this amendment, the interest rate for Eurodollar-based loans was increased and is payable at a rate based upon (at the Company’s election) Bank of America’s prime rate or LIBOR plus 125 basis points. This represented an increase from the original facility which was prime rate or LIBOR plus 75 basis points. In addition, the Company pledged to the lender sixty-five percent (65%) of the stock of Anika S.r.l. The Agreement contains customary representations and warranties of the Company, affirmative and negative covenants regarding the Company’s operations, financial

covenants regarding the maintenance by the Company of a specified quick ratio and consolidated fixed charge coverage ratio, and events of default. The table includes expected principal and interest payments. For the purpose of this calculation, interest payments are based on the carrying rate of the debt at December 31, 2012, throughout the life of the obligation.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2012, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments for which fair value disclosure would be required under ASC 825, Financial Instruments. Our investments consist of money market funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk and currency exchange rate risk. We have two major supplier contracts denominated in foreign currencies. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of changes in currency exchange rates for the two contracts on our financial statements were immaterial in 2012. Currently, we attempt to manage foreign currency risk through the matching of assets and liabilities. In the future, we may undertake to manage foreign currency risk through additional hedging methods. We recognize foreign currency gains or losses arising from our operations in the period incurred. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations, changes in credit quality of the issuer, or otherwise. As of December 31, 2012, the Company is subject to interest rate risk on $9.6 million of variable rate debt. The interest payable on our debt is determined based (at the Company's election) on either an interest rate based on LIBOR plus 1.25% or the lender's prime rate and, therefore, is affected by changes in market interest rates. Based on the outstanding debt amount as of December 31, 2012, we would have a decrease (increase) in future annual cash flow of approximately $88,000 for every 1% increase (decrease) in the interest rate.

A significant portion of Anika S.r.l.'s revenue, and all operating expenses, are denominated in Euros which leaves the Company vulnerable to foreign exchange risk.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Anika Therapeutics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive income, of stockholders' equity, and of cash flows present fairly, in all material respects, the financial position of Anika Therapeutics, Inc. and its subsidiaries as of December 31, 2012 and December 31, 2011 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

PricewaterhouseCoopers LLP

Boston, Massachusetts
March 13, 2013

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	December 31, 2012	2011
Current assets:		
Cash and cash equivalents	$ 44,067,477	$ 35,777,222
Accounts receivable, net of reserves of $337,459 and $334,473 at December 31, 2012 and 2011, respectively	21,462,481	17,307,786
Inventories	8,283,472	7,302,483
Current portion deferred income taxes	2,031,583	1,918,926
Prepaid expenses and other	1,539,477	1,831,127
Total current assets	77,384,490	64,137,544
Property and equipment, at cost	52,376,013	50,850,630
Less: accumulated depreciation	(17,263,032)	(14,380,752)
	35,112,981	36,469,878
Long-term deposits and other	171,053	205,042
Intangible assets, net	20,334,636	23,148,563
Goodwill	9,065,891	8,883,407
Total Assets	$ 142,069,051	$ 132,844,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,341,838	$ 4,299,680
Accrued expenses	5,837,044	5,321,594
Deferred revenue	2,875,067	2,866,667
Current portion of long-term debt	1,600,000	1,600,000
Income taxes payable	1,798,669	450,482
Total current liabilities	14,452,618	14,538,423
Other long-term liabilities	1,541,124	1,548,652
Long-term deferred revenue	2,152,778	5,019,440
Deferred tax liability	6,997,397	7,375,141
Long-term debt	8,000,000	9,600,000
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at December 31, 2012 and 2011, respectively	-	-
Common stock, $.01 par value; 30,000,000 shares authorized, 13,866,060 and 13,630,607 shares issued and outstanding at December 31, 2012 and 2011, respectively	138,659	136,305
Additional paid-in-capital	65,431,424	63,441,433
Accumulated currency translation adjustment	(2,654,630)	(3,067,181)
Retained earnings	46,009,681	34,252,221
Total stockholders' equity	108,925,134	94,762,778
Total Liabilities and Stockholders' Equity	$ 142,069,051	$ 132,844,434

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Income

	For the Years Ended December 31,		
	2012	2011	2010
Product revenue	$ 68,010,169	$ 61,956,386	$ 52,735,730
Licensing, milestone and contract revenue	3,348,336	2,822,249	2,820,864
Total revenue	71,358,505	64,778,635	55,556,594
Operating expenses:			
Cost of product revenue	28,988,621	26,783,738	23,826,604
Research & development	5,388,036	6,168,937	6,874,633
Selling, general & administrative	14,728,662	17,858,558	17,317,671
Restructuring charges	2,537,988	-	-
Total operating expenses	51,643,307	50,811,233	48,018,908
Income from operations	19,715,198	13,967,402	7,537,686
Interest income (expense), net	(187,777)	(182,388)	(194,620)
Income before income taxes	19,527,421	13,785,014	7,343,066
Provision for income taxes	7,769,961	5,318,334	3,027,071
Net income	$ 11,757,460	$ 8,466,680	$ 4,315,995
Basic net income per share:			
Net income	$ 0.89	$ 0.65	$ 0.34
Basic weighted average common shares outstanding	13,260,739	13,064,051	12,624,495
Diluted net income per share:			
Net income	$ 0.82	$ 0.62	$ 0.32
Diluted weighted average common shares outstanding	14,344,577	13,747,813	13,646,533
Net income	$ 11,757,460	$ 8,466,680	$ 4,315,995
Other comprehensive income (loss)			
Foreign currency translation adjustment	412,551	(519,405)	(2,547,776)
Comprehensive income	$ 12,170,011	$ 7,947,275	$ 1,768,219

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity

	Common Stock				Accumulated Currency	Total
	Number of Shares	$.01 Par Value	Additional Paid in Capital	Retained Earnings	Translation Adjustment	Stockholders' Equity
Balance, December 31, 2009	13,418,772	$ 134,188	$ 60,539,768	$ 21,469,546	$ -	$ 82,143,502
Issuance of common stock for employee equity awards	63,612	635	196,609	-	-	197,244
Tax benefit related to stock based compensation	-	-	(21,188)	-	-	(21,188)
Stock based compensation expense	-	-	1,102,369	-	-	1,102,369
Net income	-	-	-	4,315,995		4,315,995
Other comprehensive income (loss)	-	-	-		(2,547,776)	(2,547,776)
Balance, December 31, 2010	13,482,384	134,823	61,817,558	25,785,541	(2,547,776)	85,190,146
Issuance of common stock for employee equity awards	148,223	1,482	158,988	-	-	160,470
Tax benefit related to stock based compensation	-	-	274,190	-	-	274,190
Stock based compensation expense	-	-	1,190,697	-	-	1,190,697
Net income	-	-	-	8,466,680	-	8,466,680
Other comprehensive income (loss)	-	-	-	-	(519,405)	(519,405)
Balance, December 31, 2011	13,630,607	136,305	63,441,433	34,252,221	(3,067,181)	94,762,778
Issuance of common stock for employee equity awards	235,453	2,354	386,321	-	-	388,675
	-	-	452,471	-	-	452,471

Tax benefit related to stock based compensation						
Stock based compensation expense	-	-	1,151,199	-	-	1,151,199
Net income	-	-	-	11,757,460	-	11,757,460
Other comprehensive income (loss)	-	-	-	-	412,551	412,551
Balance, December 31, 2012	13,866,060	$ 138,659	$ 65,431,424	$ 46,009,681	$ (2,654,630)	$ 108,925,134

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

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows

	For the year ended December 31,		
	2012	2011	2010
Cash flows from operating activities:			
Net income	$ 11,757,460	$ 8,466,680	$ 4,315,995
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	4,525,247	4,002,391	3,320,352
Stock-based compensation expense	1,151,199	1,190,697	1,102,617
Deferred income taxes	(10,269)	1,989,708	1,953,946
Provision for doubtful accounts	135,353	331,528	302,723
Provision for inventory	1,310,953	1,427,862	699,057
Tax benefit from exercise of stock options	(452,471)	(274,190)	(65,434)
Non-cash restructuring and impairment charges	1,604,256	-	-
Changes in operating assets and liabilities:			
Accounts receivable	(4,271,129)	(2,998,037)	(3,716,478)
Inventories	(2,370,318)	224,714	(1,220,359)
Prepaid expenses and other current assets	200,453	947,263	445,650
Long-term deposits and other	33,995	179,939	28,239
Accounts payable	(2,879,330)	(6,594,292)	5,784,731
Accrued expenses	1,420,131	1,042,845	(2,188,082)
Deferred revenue	(2,858,262)	(213,888)	(2,751,468)
Income taxes payable	1,268,442	450,482	-
Other long-term liabilities	(17,033)	(568)	(158,028)
Net cash provided by operating activities	10,548,677	10,173,134	7,853,461
Cash flows from investing activities:			
Purchase of property and equipment, net	(1,504,707)	(1,400,348)	(2,784,977)
Reduction in purchase price of acquisition	-	-	105,300
Net cash used in investing activities	(1,504,707)	(1,400,348)	(2,679,677)
Cash flows from financing activities:			
Principal payments on debt	(1,600,000)	(1,600,000)	(1,600,000)
Proceeds from exercise of stock options	388,675	160,470	197,246
Tax benefit from exercise of stock options	452,471	274,190	65,434
Net cash used in financing activities	(758,854)	(1,165,340)	(1,337,320)
Exchange rate impact on cash	5,139	(32,156)	(61,522)

Increase in cash and cash equivalents	8,290,255	7,575,290	3,774,942
Cash and cash equivalents at beginning of period	35,777,222	28,201,932	24,426,990
Cash and cash equivalents at end of period	$ 44,067,477	$ 35,777,222	$ 28,201,932
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 6,496,000	$ 2,651,212	$ 360,000
Cash paid for interest	$ 184,881	$ 193,880	$ 222,919

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

Anika Therapeutics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Business

Anika Therapeutics, Inc. (“Anika,” the “Company,” “we,” “us,” or “our”) develops, manufactures and commercializes therapeutic products for tissue protection, healing and repair. These products are based on hyaluronic acid (“HA”), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

The Company is subject to risks common to companies in the biotechnology and medical device industries including, but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, commercialization of existing and new products, and compliance with FDA and foreign regulations and approval requirements as well as the ability to grow the Company’s business.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America 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.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiaries, Anika Securities, Inc. (a Massachusetts Securities Corporation), and Anika Therapeutics S.r.l. All intercompany balances and transactions have been eliminated in consolidation. Certain prior period amounts have been reclassified to conform to the current period presentation. There was no impact on operating income.

Foreign Currency Translation

The functional currency of our foreign subsidiary is the Euro. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using the monthly average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as a component of accumulated currency translation adjustment.

The Company recognized gains from foreign currency transactions of $200,452 during the year ended December 31, 2012, and losses from foreign currency transactions of $623,093, and $7,698 in 2011 and 2010, respectively.

Fair Value Measurements

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, we consider the principal or most

advantageous market in which we would transact and consider assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. The accounting standard establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Three levels of inputs that may be used to measure fair value are:

Level 1 – Valuation is based upon quoted prices for identical instruments traded in active markets. Level 1 instruments include securities traded on active exchange markets, such as the New York Stock Exchange.
Level 2 – Valuation is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market.
Level 3 – Valuation is generated from model-based techniques that use significant assumptions not observable in the market. These unobservable assumptions reflect our own estimates of assumptions market participants would use in pricing the asset or liability.

Our significant financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2012 and 2011 were as follows:

	December 31, 2012			
	Level 1	Level 2	Level 3	Total
Cash equivalents - money market accounts	$34,264,268	$-	$-	$34,264,268

	December 31, 2011			
	Level 1	Level 2	Level 3	Total
Cash equivalents - money market accounts	$20,263,766	$-	$-	$20,263,766

The carrying value of our debt instrument was $9,600,000 and $11,200,000 at December 31, 2012 and 2011, respectively. The estimated fair value of our debt instrument approximated book value at both dates using market observable inputs and interest rate measurements.

Allowance for Doubtful Accounts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. In determining the adequacy of the allowance for doubtful accounts, management specifically analyzes individual accounts receivable, historical bad debts, customer concentrations, customer credit-worthiness, current economic conditions, accounts receivable aging trends and changes in our customer payment terms. Our allowance for doubtful accounts on trade accounts receivable was $337,459 and $334,473 at December 31, 2012 and 2011, respectively.

	December 31,	
	2012	2011
Balance, beginning of the year	$ 334,473	$ 30,000
Amounts provided	138,339	306,520
Amounts written off	(135,353)	(2,047)
Balance, end of the year	$ 337,459	$ 334,473

Uncollectible trade accounts receivable written-off were $135,353, $2,047, and $301,984 in 2012, 2011, and 2010, respectively. Provisions for bad debt expense were $138,339, $306,520, and $302,723 in 2012, 2011, and 2010, respectively, and are included in general and administrative expenses in the accompanying consolidated statements of operations.

Revenue Recognition - General

We recognize revenue from product sales when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collection from the customer is reasonably assured.

Product Revenue

Revenues from product sales are recognized when title and risk of loss have passed to the customer, which is typically upon shipment to the customer. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. When determining whether risk of loss has transferred to customers on product sales, or if the sales price is fixed or determinable, the Company evaluates both the contractual terms and conditions of its distribution and supply agreements as well as its business practices.

Product revenue also includes royalties. Royalty revenue is based on our distributors' sales and recognized in the same period our distributors record their sale of products manufactured by us. On a quarterly basis we record royalty revenue based upon sales projections provided to us by our distributor customers. If necessary we adjust our estimates based upon final sales data received prior to issuing our annual audited financial statements.

Licensing, Milestone and Contract Revenue

Licensing, milestone, and contract revenue consist of revenue recognized on initial and milestone payments, as well as contractual amounts received from partners. The Company's business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company's products.

The terms of the agreements typically include non-refundable license fees, funding of research and development, and payments based upon achievement of certain milestones. The Company adopted Accounting Standards Update 2009-13, Revenue Recognition, in January 2011, which amends Accounting Standards Codification Subtopic 605-25, Multiple Element Arrangements ("ASC 605-25") to require the establishment of a selling price hierarchy for determining the allocable selling price of an item. Under ASC 605-25, as amended by ASU 2009-13, in order to account for an element as a separate unit of accounting, the element must have objective and reliable evidence of selling price of the undelivered elements. In general, non-refundable upfront fees and milestone payments that do not relate to other elements are recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Cash, Cash Equivalents and Marketable Investments

We consider only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. Marketable investments are those with original maturities in excess of three months.

At December 31, 2012 and 2011, respectively, cash equivalents were comprised of money market funds secured by U.S. Treasury obligations, which approximates fair market value. We had no marketable investments at December 31, 2012 and 2011, respectively.

Concentration of Credit Risk and Significant Customers

The Company has no significant off-balance sheet risks related to foreign exchange contracts, option contracts or other foreign hedging arrangements. The Company currently maintains its cash equivalent balance with one major international financial institution.

The Company, by policy, routinely assesses the financial strength of its customers. As a result, the Company believes that its accounts receivable credit risk exposure is limited.

As of December 31, 2012, DePuy Mitek, Inc., Medtronic Xomed, Soylu Medikal San ve Dis Tic Ltd., Rivex Pharma, and Takeda/Nycomed/Biomeks, combined, represented 78% of the Company's accounts receivable balance. As of December 31, 2011, DePuy Mitek, Inc., Bausch and Lomb, Medtronic Xomed, Azienda USL Roma, and A.T. Grade, combined, represented 58% of the Company's accounts receivable balance.

Inventories

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead.

The Company's policy is to write-down inventory when conditions exist that suggests inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for the Company's products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including, but not limited to: historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Purchasing requirements and alternative usage avenues are explored within these processes to mitigate inventory exposure.

When recorded, inventory write-downs are intended to reduce the carrying value of inventory to its net realizable value. Inventory of $8,283,472 and $7,302,483 as of December 31, 2012 and 2011 is stated net of inventory write-downs of $1,161,805 and $1,375,150, respectively. If actual demand for the Company's products deteriorates, or market conditions are less favorable than those projected, additional inventory write-downs may be required.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Computer hardware and software are typically amortized over three to five years, and furniture and fixtures over three to eight years. Leasehold improvements are amortized over the shorter of their useful lives or the remaining terms of the related leases which range from six months to 25 years at December 31, 2012. Property and equipment under capital leases are amortized over the lesser of the lease terms or their estimated useful lives. Maintenance and repairs are charged to expense when incurred; additions and improvements are capitalized. When an item is sold or retired, the cost and related accumulated depreciation is relieved, and the resulting gain or loss, if any, is recognized in income.

Goodwill and Acquired Intangible Assets

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired In-Process Research and Development ("IPR&D") represents the fair value assigned to research and development assets that we acquire that have not been completed at the date of acquisition or are pending regulatory approval in certain jurisdictions. The value assigned to the acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value.

Goodwill and IPR&D are evaluated for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors we consider important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, significant negative industry or economic trends, a significant decline in our stock price for a sustained period, or a reduction of our market capitalization relative to net book value.

To conduct impairment tests of goodwill, the fair value of the acquired reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. We estimate the fair value for reporting units using discounted cash flow valuation models which require the use of significant estimates and assumptions including but not limited to; risk free rate of return on an investment, weighted average cost of capital, future revenue, operating margin, working capital and capital expenditure needs. Our annual assessment for impairment of goodwill as of November 30, 2012 indicated that the fair value of our reporting units exceeded the carrying value of the reporting units. Anika S.r.l. is our only acquired reporting unit and currently holds 100% of the goodwill associated with the 2009 acquisition of that company.

To conduct impairment tests of IPR&D, the fair value of the IPR&D project is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. We estimate the fair values for IPR&D projects using discounted cash flow valuation models which require the use of significant estimates and assumptions including but not limited to: estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. Excluding the restructuring and related impairment charges we recognized during the fourth quarter of 2012, our annual assessment for impairment of IPR&D indicated that the fair value of our IPR&D as of November 30, 2012 exceeded their respective carrying values. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

As part of the restructuring plan we adopted during the fourth quarter of 2012, we terminated an IPR&D project related to our tissue engineering operation and included an impairment charge of approximately $1.2 million as a component of the overall restructuring charge. See “Restructuring Charges,” below, and Note 16 for additional disclosure.

Long-Lived Assets

Long-lived assets primarily include property and equipment and intangible assets with finite lives (including purchased software and trade names). Purchased software is amortized over 2 to 10 years and trade names are amortized over 10 years. We review long-lived assets for impairment when events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of those assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis.

As part of the restructuring plan we adopted during the fourth quarter of 2012, we disposed of long-lived assets related to our tissue engineering operation and included an impairment charge of approximately $0.3 million as a component of the overall restructuring charge. See “Restructuring Charges,” below, and Note 16 for additional disclosure.

Restructuring Charges

Restructuring charges are primarily comprised of severance costs, activity termination costs and costs of facility closure. Restructuring charges are recorded upon approval of a formal management plan and are included in the operating results of the period in which such plan is approved and the expense becomes estimable. To estimate restructuring charges, management utilizes assumptions such as the number of employees that would be involuntarily terminated and the future costs to operate and eventually terminate the subject activity. Estimated restructuring expenses are subject to the rules of fair value accounting and may change as management executes the approved plan.

Of the $2.5 million in restructuring charges recognized during the fourth quarter of 2012, approximately $1.6 million related to the abandonment and noncash impairment of assets. The balance of the restructuring charges related to employee termination costs and other one-time costs directly related to the facility closure.

Research and Development

Research and development costs consist primarily of salaries and related expenses for personnel and fees paid to outside consultants and outside service providers, including costs associated with licensing, milestone and contract revenue. Research and development costs are expensed as incurred.

Stock-Based Compensation

We measure the compensation cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the underlying award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award. See Note 10 for a description of the types of stock-based awards granted, the compensation expense related to such awards, and detail of equity-based awards outstanding. See Note 14 for detail of the tax benefit recognized in the consolidated statement of operations related to stock-based compensation.

Income Taxes

Our income tax expense includes U.S. and international income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these timing differences are reported as deferred tax assets and liabilities. Deferred tax assets are recognized for the estimated future tax effects of deductible temporary differences, tax operating losses, and tax credit carry-forwards (including investment tax credits). Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that it is more likely than not that all or a portion of deferred tax assets will not be realized, we establish a valuation allowance to reduce the deferred tax assets to the appropriate valuation. To the extent we establish a valuation allowance or increase or decrease this allowance in a given period, we include the related tax expense or tax benefit within the tax provision in the consolidated statement of operations in that period.

Comprehensive Income

Comprehensive income consists of net income and other comprehensive income (loss), which includes foreign currency translation adjustments. For the purposes of comprehensive income disclosures, we do not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as we intend to reinvest permanently undistributed earnings of our foreign subsidiary. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity and, as of December 31, 2012 and 2011, respectively, was comprised solely of cumulative translation adjustments.

Segment Information

Operating segments, as defined under U.S. GAAP, are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company’s chief operating decision maker is its Chief Executive Officer. Based on the criteria established by ASC 280, Segment Reporting, the Company has one reportable operating segment the results of which are disclosed in the accompanying consolidated financial statements.

Recent Accounting Pronouncements

On May 12, 2011, the FASB, together with the International Accounting Standards Board, jointly issued ASU 2011-04, Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRS. The provisions of ASU 2011-04 give fair value the same meaning between U.S. GAAP and International Financial Reporting Standards, and improve consistency of disclosures relating to fair value. For public entities, the amendments are effective during interim and annual periods beginning after December 15, 2011. Early application by public entities was not permitted. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The amendments in this ASU require all non-owner changes in stockholders’ equity to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. For public entities, the amendments are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In September 2011, the FASB issued ASU 2011-08, Intangibles – Goodwill and Other. This ASU's objective is to simplify the process of performing impairment testing for Goodwill. With this update a company is allowed to first assess qualitative factors to determine if it is more likely than not (greater than 50%) that the fair value of its Goodwill and intangible assets is less than the carrying amount. This step is done prior to performing the two-step goodwill impairment testing, as prescribed by Topic 350. This ASU is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations or cash flows.

In July 2012, the FASB issued ASU 2012-02, Intangibles-Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment. This amendment is an update of ASU 2011-08, specifically for consistency of approach in assessing impairment for Indefinite-Lived assets. With this update a company is allowed to first assess qualitative factors to determine if it is more likely than not (greater than 50%) that the fair value of its indefinite-lived assets is less than the carrying amount. This ASU is effective for fiscal years beginning after September 15, 2012 with early adoption permitted. The adoption of this amendment will not have a material impact on our consolidated

financial position, results of operations or cash flows.

3. Earnings per Share (“EPS”)

Basic EPS is calculated by dividing net income by the weighted average number of shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic earnings per share. Diluted EPS is calculated by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, stock appreciation rights (“SAR’s”), restricted shares and restricted stock units (collectively “RSA’s”) using the treasury stock method.

The following table provides share information used in the calculation of the Company's basic and diluted earnings per share:

	Year ended December 31,		
	2012	2011	2010
Shares used in the calculation of Basic earnings per share	13,260,739	13,064,051	12,624,495
Effect of dilutive securities:			
Stock options, SAR's, RSA's, and shares held in escrow	1,083,838	683,762	1,022,038
Diluted shares used in the calculation of earnings per share	14,344,577	13,747,813	13,646,533

Stock options to purchase 131,273, 1,142,840 and 1,210,970 shares for 2012, 2011 and 2010, respectively, were excluded from the computation of diluted EPS as their effect would have been anti-dilutive.

At December 31, 2012, 2011 and 2010, 54,124, 59,196 and 20,630 shares of issued and outstanding unvested restricted stock, respectively, were excluded from the basic earnings per share calculation in accordance with ASC 260.

4. Inventories

Inventories consist of the following:

	December 31,	
	2012	2011
Raw materials	$ 6,109,807	$ 4,091,366
Work-in-process	777,056	1,503,565
Finished goods	1,396,609	1,707,552
Total	$ 8,283,472	$ 7,302,483

5. Property and Equipment

Property and equipment is stated at cost and consists of the following:

	December 31,	
	2012	2011
Machinery and equipment	$ 22,863,921	$ 10,429,816
Furniture and fixtures	1,274,477	840,350
Leasehold improvements	28,195,345	12,421,398
Construction in progress	42,270	27,159,066
Subtotal	52,376,013	50,850,630
	(17,263,032)	(14,380,752)

Less accumulated depreciation		
Total	$ 35,112,981	$ 36,469,878

Depreciation expense was $2,496,749, $1,816,188 and $1,308,713 for the years ended December 31, 2012, 2011 and 2010, respectively.

6. Acquired Intangible Assets, Net

In November 2007, in connection with the termination of the agreement with Galderma which originally granted to Galderma the worldwide rights to commercialization, distribution, and marketing of ELEVESS products, the Company reacquired the worldwide rights and control of the future development and marketing of ELEVESS. The intangible asset realized during this process was the ELEVESS trade name.

On December 30, 2009, in connection with the acquisition of Anika S.r.l., the Company purchased various intangible assets. The Company finalized the purchase price allocation relative to this acquisition during the fourth quarter of 2010.

Excluding our fourth quarter of 2012 restructuring and impairment charges, we completed our annual impairment review as of November 30, 2012 and concluded that no impairment in the carrying value exists as of that date with respect to both goodwill and IPR&D. Through December 31, 2012 there have not been any events or changes in circumstances that indicate that the carrying value of goodwill or acquired intangible assets may not be recoverable. The fair value of the equity of the Anika S.r.l. reporting unit over its carrying value at November 30, 2012 declined from the prior year. The Company continues to monitor and evaluate the financial performance of the Anika S.r.l. business including the impact of general economic conditions, to assess the potential for the fair value of the reporting unit to decline below its book value. See Note 16, Restructuring, for additional disclosure.

Amortization expense was $2,028,498, $2,186,203, and $2,011,639 for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, amortization expense on intangible assets for the next five years is expected to be approximately $2.0 million annually.

Intangible assets, stated at cost, consist of the following:

	December 31, 2012					December 31, 2011	
	Gross Value	Currency Translation Adjustment	Abandonments and Other Adjustments	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	$16,700,000	$(1,369,787)	$ -	$ (2,960,171)	$12,370,042	$13,228,351	15
In-process research & development	6,698,000	(522,112)	(1,195,314)	-	4,980,574	5,955,066	Indefinite
Distributor relationships	4,700,000	(424,639)	-	(2,541,908)	1,733,453	2,547,842	5
Patents	1,000,000	(81,824)	-	(169,010)	749,166	790,555	16
Elevess trade name	1,000,000	-	-	(498,599)	501,401	626,749	9
Total	$30,098,000	$(2,398,362)	$ (1,195,314)	$ (6,169,688)	$20,334,636	$23,148,563	

7. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2012	2011
Payroll and benefits	$ 2,477,833	$ 2,366,412

Professional fees	642,853	793,430
Clinical trial costs	102,414	-
SRL research grants	110,350	989,556
Restructuring costs	933,732	-
Other	1,569,862	1,172,196
Total	$ 5,837,044	$ 5,321,594

8. Deferred Revenue

In December 2003, the Company entered into a ten-year licensing and supply agreement (the “JNJ Agreement”) with Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies, to market ORTHOVISC in the U.S. In mid-2005, the agreement was assigned to DePuy Mitek, Inc., a subsidiary of Johnson & Johnson. Under the JNJ Agreement, DePuy Mitek performs sales, marketing and distribution functions and licenses the right to further develop and commercialize ORTHOVISC as well as other new products for the treatment of pain associated with osteoarthritis based on the Company’s viscosupplementation technology. In support of the license, the JNJ Agreement provides that DePuy Mitek will fund post-marketing clinical trials for new indications of ORTHOVISC. The Company received an initial payment of $2,000,000 upon entering into the JNJ Agreement, a milestone payment of $20,000,000 in February 2004, as a result of obtaining FDA approval of ORTHOVISC and a milestone payment of $5,000,000 in December 2004 for planned upgrades to our manufacturing operations. The Company evaluated the terms of the JNJ Agreement and determined that the upfront fee and milestone payments did not meet the conditions to be recognized separately from the supply agreement.

In December 2011, the Company entered into a fifteen-year licensing and supply agreement (the "Mitek MONOVISC Agreement") with DePuy Mitek, Inc., a member of the Johnson & Johnson family of companies, to market MONOVISC in the U.S. The Company received an initial payment of $2,500,000 in December 2011, which is recognized ratably over the fifteen year term of the Mitek MONOVISC Agreement as there was no stand-alone value associated with this payment, thus up-front recognition is prohibited. The Company may receive additional payments from DePuy Mitek, following the mutual decision to launch the product, related to future regulatory, clinical and sales milestones.

Current and long-term deferred revenue related to the JNJ Agreement, the Mitek MONOVISC Agreement and other agreements was $5,027,845 and $7,886,107 at December 31, 2012 and 2011, respectively.

9. Commitments and Contingencies

Leasing Arrangements

The Company's headquarters facility is located in Bedford, Massachusetts, where the Company leases approximately 134,000 square feet of administrative, manufacturing, and research and development ("R&D") space. This lease was entered into on January 4, 2007, and the lease commenced on May 1, 2007 for an initial term of ten and one-half years. The Company has an option under the lease to extend its terms for up to four additional periods beyond the original expiration date subject to the condition that we notify the landlord that we are exercising each option at least one year prior to the expiration of the original or current term thereof. The first three renewal options each extend the term an additional five years with the final renewal option extending the term six years.

The Company's administrative and R&D personnel moved into the Bedford facility in November of 2007. The build-out of the Bedford facility, including the required validation process for the manufacturing space, was substantially completed during 2011. The Bedford facility was fully validated and approved by applicable regulatory authorities in 2012.

As part of the acquisition of Anika S.r.l., the Company now leases approximately 26,000 square feet of laboratory, warehouse and office space in Abano Terme, Italy. The lease commenced on December 30, 2009 for an initial term of six (6) years.

Rental expense in connection with the various facility leases totaled $2,486,849, $3,479,632 and $2,888,277, for the years ended December 31, 2012, 2011, and 2010, respectively.

The Company's future lease commitments as of December 31, 2012 are as follows:

2013	$1,519,613
2014	1,484,015
2015	1,461,305
2016	971,500
2017 and thereafter	5,829,000
	$11,265,433

Warranty and Guarantor Arrangements

In certain of our contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate, or breach any U.S. patent or intellectual property rights, trade

secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligence or acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes the estimated fair value of these indemnification agreements is immaterial. The Company has no accrued warranties at December 31, 2012 and 2011, respectively, and has no history of claims paid.

Legal Proceedings

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. On April 26, 2011, Genzyme filed a motion to add its newly-issued U.S. Patent No. 7,931,030 to this litigation and also filed a separate new complaint in the District of Massachusetts alleging that the Company's manufacture and sales of MONOVISC in the United States will infringe that patent. On May 23, 2011, the Court entered orders permitting Genzyme to file its supplement complaint adding its newly-issued U.S. Patent No. 7,931,030 to this litigation and requiring Genzyme to withdraw its separately filed complaint. On July 14, 2011, the Company filed an answer to the supplemental complaint, denying liability. On May 10, 2012, Genzyme dismissed its claim of infringement of U.S. Patent No. 5,399,351 and is no longer asserting that patent against the Company. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with DePuy Mitek, Inc. in December 2011, DePuy Mitek agreed to assume certain obligations of the Company related to this litigation. On August 3, 2012, a jury in the United States District Court for the District of Massachusetts held U.S. Patent No. 7,931,030 invalid as obvious and not infringed in litigation between Genzyme and Seikagaku Corporation, Zimmer Holdings Inc., Zimmer, Inc. and Zimmer U.S., Inc. concerning the Gel-One product. On September 19, 2012, Genzyme and the Company jointly requested that the Court stay Genzyme's lawsuit against the Company pending the full resolution of the Seikagaku/Zimmer lawsuit, including through any appeal of the judgment entered in that lawsuit. The District Court granted the motion on September 28, 2012.

In 2011, Merogel Injectable was withdrawn from the market due to a labeling error on the product's packaging, discovered by the Company. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error relates to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. and we have made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia has informed us that it does not believe that it has liability for this matter, and has asserted a counterclaim against Anika for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. We have begun an arbitration process with Fidia in the London Court of International Arbitration to resolve the matter. Management has assessed Fidia's claims and determined that contingent losses related to this matter are not probable. Therefore, pursuant to ASC 450, Contingencies, an accrual has not been recorded for this loss contingency.

We are also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to have a material adverse effect on our financial position, results of operations or cash flow.

10. Equity Incentive Plan

The Anika Therapeutics, Inc. Stock Option and Incentive Plan, as amended, (the "2003 Plan") provides for grants of nonqualified and incentive stock options, common stock, restricted stock, restricted stock units, and stock appreciation rights ("SAR's") to employees, directors, officers and consultants. The 2003 Plan was originally approved by the Board of Directors on April 4, 2003, approved by the Company's shareholders on June 4, 2003, and reserved 1,500,000 shares of common stock for grant pursuant to its terms.

On May 29, 2009, the Board of Directors approved changes to the 2003 Plan and adopted the Amended and Restated 2003 Stock Option and Incentive Plan (the "Amended 2003 Plan"), to increase the number of shares available to grant by 850,000. The Amended 2003 Plan was approved by the Company's shareholders on June 5, 2009, and resulted in a total of 2,350,000 shares of common stock being reserved for issuance under the Amended 2003 Plan.

At the 2011 Annual Meeting of Stockholders on June 7, 2011, the shareholders of the Company approved the Anika Therapeutics, Inc. Second Amended and Restated Stock Option and Incentive Plan (the "2003 Plan"), which, among other things, increased the number of shares reserved for issuance under the Company's predecessor stock option and incentive plan by 800,000 to 3,150,000 shares.

The Company may satisfy the awards upon exercise, or upon fulfillment of the vesting requirements for other equity-based awards, with either newly-issued shares or shares reacquired by the Company. Stock-based awards are granted with an exercise price equal to the market price of the Company's stock on the date of grant. Awards contain service or performance conditions and generally become exercisable ratably over one to four years.

The 2003 Plan succeeds the Anika Therapeutics, Inc. 1993 Stock Option Plan ("1993 Plan") which expired according to its terms in 2003. As of December 31, 2012, there were 1,938 shares still outstanding under the 1993 Plan included in the total outstanding options of 1,793,685. There are 763,145 options available for future grant at December 31, 2012.

The Company estimates the fair value of stock options and SAR's using the Black-Scholes valuation model. Fair value of restricted stock is measured by the grant-date price of the Company's shares. Key input assumptions used to estimate the fair value of stock options and SAR's include the exercise price of the award, the expected award term, the expected volatility of the Company's stock over the option's expected term, the risk-free interest rate over the award's expected term, and the Company's expected annual dividend yield.

The Company uses historical data on exercise of stock options and other factors to estimate the expected term of share-based awards. The Company also evaluates forfeitures periodically and adjusts accordingly. The expected volatility assumption is based on the historical volatility of the Company's common stock. The risk-free interest rate assumption is based on U.S. Treasury interest rates at the time of grant.

The fair value of each stock option and SAR award during 2012, 2011, and 2010 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	December 31,		
	2012	2011	2010
Risk free interest rate	0.63% to 0.64%	1.1% to 1.51%	1.11% to 1.88%
Expected volatility	57.60%	57.60%	57.60%
Expected lives (years)	4	4	4
Expected dividend yield	0.00%	0.00%	0.00%

The Company recorded $1,151,199, $1,190,697 and $1,102,617 of share-based compensation expense for the years ended December 31, 2012, 2011 and 2010, respectively, for stock options, SAR's and restricted stock awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to each of its employees.

Combined stock options and SAR's activity under our plans is summarized as follows for the years ended December 31, 2012 and, 2011 respectively:

	2012		2011	
	Number of Shares	Weighted Average Exercise Price Per Share	Number of Shares	Weighted Average Exercise Price Per Share
Options and SAR's outstanding at beginning of year	2,108,003	$7.26	1,625,253	$6.92
Granted	204,000	$12.06	679,000	$6.98
Cancelled	(212,749)	$6.58	(74,187)	$6.41
Expired	(7,714)	$1.68	(875)	$3.04
Exercised	(297,855)	$4.74	(121,188)	$1.60
Options and SAR's outstanding at end of year	1,793,685	$8.30	2,108,003	$7.26

Of the 1,793,685 options and SAR's outstanding at December 31, 2012, approximately 1,763,000 are vested or are expected to vest with a weighted-average exercise price of approximately $8.56 as well as an aggregate intrinsic value of approximately $4 million related to these awards. The weighted average remaining contractual term of the vested and expected to vest options and SAR's was 4.63 years as of December 31, 2012.

As of December 31, 2012, total unrecognized compensation costs related to non-vested options and SAR's was approximately $1,826,000 and is expected to be recognized over a weighted average period of 2.4 years.

There were 247,934 incentive stock options (ISOs) exercisable at December 31, 2012 with a weighted-average exercise price of $8.71 and a weighted-average remaining contractual term of 4.14 years for these awards.

There were 222,002 non-qualified stock options exercisable at December 31, 2012 with a weighted-average exercise price of $8.94 and a weighted-average remaining contractual term of 3.13 years.

There were 570,460 SAR's exercisable at December 31, 2012 with a weighted-average exercise price of $8.35 and a weighted-average remaining contractual term of 5.43 years for these awards.

The aggregate intrinsic value of stock options and SAR's fully vested at December 31, 2012 and 2011 was $2,115,267 and $2,390,591 respectively. The aggregate intrinsic value of stock options and SAR's outstanding at December 31, 2012 and, 2011 was $4,074,471 and $6,107,869, respectively.

The total intrinsic value of options and SAR's exercised was $2,214,516 and, $679,401 for the years ended December 31, 2012 and 2011, respectively.

The total fair value of options and SAR's vested during the years ended December 31, 2012 and 2011 was $997,194 and $774,648, respectively.

The Company received $388,676 and, $160,470 for exercises of stock options during the years ended December 31, 2012 and 2011, respectively.

The restricted stock activity for the years ended December 31, 2012 and 2011 is as follows:

	2012		2011	
	Number of Shares	Weighted Average Grantd Date Fair Value	Number of Shares	Weighted Average Grantd Date Fair Value
Nonvested at Beginning of year	59,196	$5.71	77,085	$5.48
Granted	31,312	$9.10	29,978	$6.98
Cancelled	(25)	$3.05	(850)	$3.05
Expired	-	$-	-	$-
Vested/Released	(21,527)	$5.08	(47,017)	$6.13
Nonvested at end of year	68,956	$6.87	59,196	$5.71

The total fair value of restricted stock and restricted stock units vested during the year ended December 31, 2012 was $203,485.

11. Shareholder Rights Plan

On April 4, 2008 the Board of Directors of the Company adopted a Shareholder Rights Plan ("2008 Plan") that replaced the Company's former Shareholder Rights Plan. Under the 2008 Plan, the Rights generally become exercisable if:

(1) A person becomes an "Acquiring Person" by acquiring 15% or more of the Company's Common Stock, or
(2) A person commences a tender offer that would result in that person owning 15% or more of the Company's Common Stock.

In the event that a person becomes an "Acquiring Person," each holder of a Right (other than the Acquiring Person) would be entitled to acquire such number of shares of preferred stock which are equivalent to shares of the Company's Common Stock having a value of twice the exercise price of the Right. If, after any such event, the Company enters into a merger or other business combination transaction with another entity, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right.

The current exercise price per Right is $75.00. The Rights may be redeemed in whole, but not in part, at a price of $0.01 per Right (payable in cash, shares of the Company's Common Stock, or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of :

(1) The time at which any person becomes an "Acquiring Person", or
(2) The Expiration Date.

At any time after any person becomes an "Acquiring Person", the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of the Company's Common Stock at an exchange ratio specified in the Rights Plan. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to affect such exchange at any time after any person becomes the beneficial owner of 50% or more of the Company's Common Stock.

In connection with the establishment of the Rights Plan, the Board of Directors approved the creation of Preferred Stock of the Company designated as Series B Junior Participating Cumulative Preferred Stock with a par value of

$0.01 per share. The Board also reserved 175,000 shares of preferred stock for issuance upon exercise of the Rights. Until a Right is exercised, the holder will have no rights as a stockholder of the Company, beyond those as an existing stockholder, including the right to vote or to receive dividends.

12. Employee Benefit Plan

U.S. employees are eligible to participate in the Company's 401(k) savings plan. Employees may elect to contribute a percentage of their compensation to the plan, and the Company will make matching contributions up to a limit of 5% of an employee's compensation. In addition, the Company may make annual discretionary contributions. For the years ended December 31, 2012, 2011, and 2010, the Company made matching contributions of $326,007, $279,816 and $291,107 respectively.

13. Revenue by Product Group, by Significant Customer and by Geographic Region; Geographic Information

Product revenue by product group is as follows:

	Year Ended December 31,								
	2012			2011			2010		
	Revenue	Percentage of Product Revenue		Revenue	Percentage of Product Revenue		Revenue	Percentage of Product Revenue	
Orthobiologics	$49,954,112	73.5	%	$39,858,139	64.3	%	$30,741,305	58.3	%
Dermal	1,384,403	2.0	%	3,681,166	5.9	%	3,564,616	6.8	%
Surgical	5,022,456	7.4	%	4,976,261	8.1	%	3,883,444	7.3	%
Ophthalmic	8,784,011	12.9	%	10,963,822	17.7	%	11,971,787	22.7	%
Veterinary	2,865,187	4.2	%	2,476,998	4.0	%	2,574,578	4.9	%
	$68,010,169	100.0	%	$61,956,386	100.0	%	$52,735,730	100.0	%

Product revenue by significant customers as a percent of product revenues is as follows:

	Percent of Product Revenue Year Ended December 31,		
	2012	2011	2010
DePuy Mitek	61.2%	47.1%	42.7%
Bausch & Lomb Inc.	11.4%	15.8%	21.2%
Boehringer	4.2%	4.0%	4.9%
Medtronic	3.1%	5.6%	10.2%
Rivex Pharma	2.0%	1.3%	1.5%
	81.9%	73.8%	80.5%

Revenues by geographic location in total and as a percentage of total revenues are as follows:

	Year Ended December 31,								
	2012			2011			2010		
	Revenue	Percentage of Total Revenue		Revenue	Percentage of Total Revenue		Revenue	Percentage of Total Revenue	
United States	$ 57,904,290	81.1	%	$ 48,366,140	74.7	%	$ 38,313,594	69.0	%
Europe	6,267,830	8.8	%	10,988,664	16.9	%	12,976,985	23.3	%
Other	7,186,385	10.1	%	5,423,831	8.4	%	4,266,015	7.7	%
Total	$ 71,358,505	100.0	%	$ 64,778,635	100.0	%	$ 55,556,594	100.0	%

The Company recorded licensing, milestone and contract revenue of $3,348,336, $2,822,249 and $2,820,864 for the years ended December 31, 2012, 2011, and 2010, respectively. Substantially all licensing, milestone and contract revenue was derived in the United States for each year presented.

Net long-lived assets, consisting of net property and equipment, are subject to geographic risks because they are generally difficult to move and to effectively utilize in another geographic area in a reasonable time period and because they are relatively illiquid.

Net tangible long-lived assets by principal geographic areas were as follows:

	Years Ended December 31,	
	2012	2011
United States	$ 33,792,325	$ 34,565,770
Italy	1,320,656	1,904,108
Total	$ 35,112,981	$ 36,469,878

14. Income Taxes

Income Tax Expense

The components of the Company's income before income taxes and our provision for (benefit from) income taxes consist of the following:

	Year ended December 31,		
	2012	2011	2010
Income (loss) before income taxes			
Domestic	$ 26,170,313	$ 15,962,992	$ 11,944,795
Foreign	(6,642,892)	(2,177,978)	(4,601,729)
	$ 19,527,421	$ 13,785,014	$ 7,343,066

	Year ended December 31,		
	2012	2011	2010
Provision for (benefit from) income taxes:			
Current provision:			
Federal	$ 7,594,287	$ 3,327,626	$ 1,063,841
State	885,958	155,855	(6,920)
Foreign	(188,650)	90,626	-
	8,291,595	3,574,107	1,056,921
Deferred provision:			
Federal	776,486	1,907,408	2,828,029
State	602,447	570,869	479,529
Foreign	(1,900,567)	(734,050)	(1,337,408)
	(521,634)	1,744,227	1,970,150
Total provision	$ 7,769,961	$ 5,318,334	$ 3,027,071

Deferred Tax Assets and Liabilities

Significant components of the Company's deferred tax assets and liabilities consist of the following:

	December 31,	
	2012	2011
Deferred tax assets:		
Deferred revenue	$ 1,988,509	$ 2,072,931
Stock-based compensation expense	1,584,583	1,496,910
Tax credit carry forward	194,364	695,914
Net operating loss carryforward, foreign	2,520,746	1,839,924
Accrued expenses and other	954,559	825,884
Inventory reserve	405,302	417,726
Deferred tax asset	$ 7,648,063	$ 7,349,289

	December 31,	
	2012	2011
Deferred tax liabilities:		
Intangibles related to Srl acquisition	$ (6,482,404)	$ (7,594,729)
Depreciation	(6,131,473)	(5,210,775)
Deferred tax liability	$ (12,613,877)	$ (12,805,504)

Tax Rate

The reconciliation between the U.S. federal statutory rate and our effective rate is summarized as follows:

	Year ended December 31,		
	2012	2011	2010
Statutory federal income tax rate	35.0 %	34.0 %	34.0 %
State tax expense, net of federal benefit	6.4 %	5.7 %	7.8 %
Permanent items, including nondeductible expenses	0.9 %	0.9 %	2.2 %
State investment tax credit	(0.2)%	(0.2)%	(0.8)%
Federal, state and foreign research and development credits	(1.2)%	(0.4)%	(2.5)%
Foreign rate differential	2.5 %	0.9 %	2.6 %
Domestic production deduction	(3.6)%	(2.3)%	(2.1)%
Effective income tax rate	39.8 %	38.6 %	41.2 %

As of December 31, 2012, the Company had net operating losses ("NOL") for federal income tax purposes in Italy of $9,144,154 with no expiration date. For Massachusetts state income tax purposes, the Company also had an investment tax credit carry-forward of $298,769 expiring through 2021.

In connection with the preparation of the financial statements, the Company performed an analysis to ascertain if it was more likely than not that it would be able to utilize, in future periods, the net deferred tax assets associated with its NOL carry-forward and its investment tax credit carry-forward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that those deferred tax assets not otherwise subject to a valuation allowance are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at December 31, 2012, and 2011, respectively.

Accounting for Uncertainty in Income Taxes

A reconciliation of the beginning and ending amount of our unrecognized tax benefits is summarized as follows:

	Year ended December 31,		
	2012	2011	2010
Unrecognized tax benefit, beginning of year	$ 56,170	$ 37,428	$ 40,900
Tax positions related to current year	-	38,329	-
Tax positions related to prior years	38,329	(19,587)	37,427
Settlements	-	-	(3,089)
Statute expirations	(38,329)	-	(37,810)
Unrecognized tax benefit, end of year	$ 56,170	$ 56,170	$ 37,428

In the normal course of business, Anika and its subsidiaries may be periodically examined by various taxing authorities. We file income tax returns in the U.S. federal jurisdiction, in certain U.S. states, and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. The 2009 through 2012 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The 2009 through 2012 tax years remain subject to examination by the appropriate governmental authorities for Italy.

We do not anticipate experiencing any significant increases or decreases in our unrecognized tax benefits within the twelve months following December 31, 2012.

We incurred expenses related to stock-based compensation in 2012, 2011 and 2010 of $1,151,199, $1,190,697, and $1,102,617, respectively. Accounting for the tax effects of certain stock-based awards requires that we establish a deferred tax asset as the compensation expense is recognized for financial reporting prior to recognizing the related tax deduction upon exercise of the awards. The tax benefit recognized in the consolidated statement of operations related to stock-based compensation totaled $285,068, $219,626, and $244,746 in 2012, 2011 and 2010, respectively.

Upon the settlement of the certain stock-based awards (i.e., exercise, vesting, forfeiture or cancellation), the actual tax deduction is compared with the cumulative financial reporting compensation cost and any excess tax deduction related to these awards is considered a windfall tax benefit, and is tracked in a "windfall tax benefit pool" to offset any future tax deduction shortfalls and will be recorded as increases to additional paid-in capital in the period when the tax deduction reduces income taxes payable. We follow the with-and-without approach for the direct effects of windfall/shortfall items and to determine the timing of the recognition of any related benefits. We recorded a net windfall of approximately $452,000 and $274,000 in 2012 and 2011, respectively and a net shortfall of approximately $21,000 in 2010.

15. Long-term Debt

On January 31, 2008, the Company entered into an unsecured Credit Agreement (the “Agreement”) with Bank of America, under which the Company was provided with a revolving credit line through December 31, 2008 of up to a maximum principal amount outstanding of $16,000,000. The Company borrowed the maximum amount of $16,000,000 in 2008 to finance its new facility construction and capital project validation. On December 31, 2008, the outstanding revolving credit loans were converted into a term loan with quarterly principal payments of $400,000 and a final installment of $5,200,000 due on the maturity date of December 31, 2015. Interest on the term loan was originally payable at a rate based upon, at the Company’s election, either Bank of America’s prime rate or LIBOR plus 75 basis points. The Company recorded approximately $171,000 as deferred issuance costs which continue to be amortized over the life of the debt facility.

In connection with the acquisition of Anika S.r.l., the Company entered into a Consent and First Amendment to the original loan facility with Bank of America. As part of this amendment, the interest rate for Eurodollar based loans was increased and is payable at a rate based upon, at the Company's election, either Bank of America's prime rate or LIBOR plus 125 basis points. In addition, the Company pledged to the lender sixty-five percent (65%) of the stock of Anika Therapeutics S.r.l. We also incurred $74,000 of fees charged by Bank of America which were capitalized in accordance with ASC Subtopic 470-50, Debt – Modifications and Extinguishments, as the Consent and First Amendment represents a debt modification. The fees are being amortized over the remaining life of the debt facility.

The Agreement contains customary representations and warranties of the Company, affirmative and negative covenants regarding the Company's operations, financial covenants regarding maintenance by the Company of a specified quick ratio and consolidated fixed charge coverage ratio, and events of default. We are in compliance with all covenants specified in the debt agreement.

As of December 31, 2012 and 2011, the Company had a total outstanding debt balance of $9,600,000 and $11,200,000, respectively, of which $1,600,000 was recorded as current at each date.

Long-term debt principal payments are $1,600,000 for each of the next two years with the remaining principal of $6,400,000 due in the third and final year. The estimated fair value of our debt instrument approximated book value at December 31, 2012.

16. Restructuring

In December 2012 the Company announced the closure of its tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards, effective January 1, 2013, established by the EMA for Advanced Therapy Medicinal Products. The restructuring plan primarily involves a workforce reduction as well as associated asset abandonments. We recorded restructuring and impairment charges in the fourth quarter of approximately $2.5 million. Of the total restructuring and impairment charges related to our tissue engineering operation, approximately $1.2 million related to the noncash termination and related impairment of an IPR&D project, $0.3 million related to the noncash disposal of property and equipment, and $0.1 million related to the disposal of inventory. The remaining $0.9 million relates to cash payments anticipated to occur in 2013, primarily for employee termination costs. We expect to substantially complete the restructuring plan by the end of the first six months of 2013.

17. Related Party

In connection with the acquisition of Anika S.r.l. by Anika on December 30, 2009, Fidia Farmaceutici S.p.A ("Fidia") acquired ownership of 1,981,192 shares of the Company's common stock, or approximately 14.3% of the outstanding shares of the Company as of December 31, 2012 and approximately 14.5% of the outstanding shares as of December 31, 2011, respectively, thus becoming a "related party" under the Securities and Exchange Commission regulations.

As part of the acquisition, the Company, primarily through Anika S.r.l., entered into a series of operating agreements with Fidia as follows:

Agreement Type	Description	Term in Years
Lease	Rent of space in Abano Terme, Italy	Six
Finished goods supply	Manufacture and supply of goods	Five
Raw material supply	Hyaluronic acid powder	Three
Services	Finance, administrative, security	One to Six
Accounts receivable	Collection of trade receivables outstanding as of	Two
management	December 30, 2009 (EXPIRED).	
Marketing and Promotion	Promote Anika Srl products in Italy through	Three
	Fidia sales force (TERMINATED).	

Historically Anika S.r.l. has relied on Fidia, its former parent company, for several functional activities. In connection with the purchase of Anika S.r.l., the Company has negotiated a lease for approximately 26,000 square feet of office, laboratory and warehouse space in Abano Terme, Italy, and a finished goods supply agreement. At December 31, 2012 and 2011, Anika S.r.l. had a net payable to Fidia for past products purchased of approximately $0.7 million and $0.8 million, respectively.

18. Quarterly Financial Data (Unaudited)

Year 2012	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Product revenue	$21,459,124	$14,055,440	$18,882,277	$13,613,328
Total revenue	22,606,465	14,766,611	19,624,769	14,360,660
Cost of product revenue	7,269,886	7,221,028	8,084,226	6,413,481
Gross profit on product revenue	14,189,238	6,834,412	10,798,051	7,199,847
Net income	$4,463,223	$1,645,250	$3,736,868	$1,912,119
Per common share information:				
Basic net income per share	$0.33	$0.12	$0.28	$0.15
Basic common shares outstanding	13,324,942	13,287,463	13,262,023	13,162,824
Diluted net income per share	$0.31	$0.11	$0.26	$0.14
Diluted common shares outstanding	14,299,211	14,459,154	14,443,794	14,089,946

Year 2011	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Product revenue	$17,725,546	$17,756,000	$15,414,681	$11,060,159
Total revenue	18,444,287	18,455,817	16,140,852	11,737,679
Cost of product revenue	7,128,450	7,394,922	6,655,804	5,604,562
Gross profit on product revenue	10,597,096	10,361,078	8,758,877	5,455,597
Net income	$2,883,110	$2,976,518	$2,282,641	$324,412
Per common share information:				
Basic net income per share	$0.22	$0.23	$0.18	$0.03
Basic common shares outstanding	13,122,004	12,817,910	12,725,216	12,688,819
Diluted net income per share	$0.21	$0.22	$0.17	$0.02
Diluted common shares outstanding	13,804,806	13,765,533	13,739,836	13,744,710

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (“Exchange Act”), 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 end of the period covered by this report. Based upon that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including our chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal year 2012 that have materially affected, or that are reasonably likely to materially affect, our internal controls 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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our 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.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control—Integrated Framework.

Based on our assessment and those criteria, our management believes that the Company maintained effective internal control over financial reporting as of December 31, 2012.

The effectiveness of our internal control over financial reporting as of December 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm as stated in their report which is included herein.

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 to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2012.

ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2012.

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

The information required under this item and Item 5 of this Annual Report on Form 10-K under the heading "Equity Compensation Plan Information" is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2012.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2012.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2012.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of Form 10-K.

(1) Financial Statements

Report of Independent Registered Public Accounting Firm	[48]
Consolidated Balance Sheets	[49]
Consolidated Statements of Operations	[50]
Consolidated Statements of Stockholder's Equity	[51]
Consolidated Statements of Cash Flows	[52]
Notes to Consolidated Financial Statements	[53-71]

(2) Schedules

Schedules have been omitted as all required information has been disclosed in the financial statements and related footnotes.

(3) Exhibits

The list of Exhibits filed as a part of this Annual Report on Form 10-K is set forth in the Exhibit Index (b) below.

(b) Exhibit No.	Description
(2) Plan of Acquisition, Reorganization, Arrangement, Liquidation or Succession:	
2.1	Sale and Purchase Agreement, dated December 30, 2009, by and between Fidia Farmaceutici S.p.A., as Seller, and the Company, as Buyer, incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
(3) Articles of Incorporation and Bylaws:	
3.1	Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
3.2	Certificate of Vote of Directors Establishing a Series of Convertible Preferred Stock, incorporated herein by reference to the Exhibits to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
3.3	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarterly period ended November 30, 1996 (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997.
3.4	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarterly period ended June 30, 1998 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 1998.
3.5	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2002.
3.6	Amended and Restated Certificate of Vote of Directors Establishing a Series of Preferred Stock of the Company classifying and designating the Series B Junior Participating Cumulative Preferred Stock, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 2008.
3.7	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File no. 001-14027), filed with the Securities and Exchange Commission on March 9, 2009.

3.8	Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.6 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2002.
(4) Instruments Defining the Rights of Security Holders	
4.1	Shareholder Rights Agreement, dated as of April 7, 2008, between the Company and American Stock Transfer & Trust Company, incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 2008.
(10) Material Contracts	
10.1	Commercial Lease, dated March 10, 1995, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
10.2	Amendment to Lease #1, dated December 11, 1997, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.3	Lease Extension, dated March 23, 1998, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
10.4	Amendment to Lease #2, dated September 27, 1999, between the Company and Cummings Properties LLC, incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
10.5	Commercial Lease, dated July 9, 1999, between the Company and Cummings Properties LLC, incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
10.6	Stipulation and Agreement of Compromise, Settlement and Release, dated May 25, 2001, in connection with In Re Anika Therapeutics, Inc. Securities Litigation, incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2001.
10.7	Amendment to Lease #3, dated November 1, 2001, between the Company and Cummings Properties, LLC, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2001 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2001.
10.8	Lease Extension, dated October 8, 2003, between the Company and Cummings Properties, LLC, incorporated herein by reference to Exhibit 10.36 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2003 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2003.
**10.9	License Agreement, dated as of December 20, 2003, by and between the Company and Ortho Biotech Products, L.P., incorporated herein by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (File no. 001-14027), filed with the Securities and Exchange Commission on March 30, 2004.
**10.10	Supply Agreement, dated as of December 15, 2004, by and between the Company and Bausch & Lomb Incorporated, incorporated herein by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (File no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2005.
†10.11	Form of Incentive Stock Option Agreement under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 5, 2004.
†10.12	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 5, 2004.
†10.13	Form of Stock Appreciation Right Agreement for Employees under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006 (File no. 001-14027), filed with the Securities and Exchange Commission on May 9, 2006.
†10.14	Form of Stock Appreciation Right Agreement for Non-Employee Directors under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March

31, 2006 (File no. 001-14027), filed with the Securities and Exchange Commission on May 9, 2006.

10.15	Lease, dated January 3, 2007, between the Company and Farley White Wiggins, LLC, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 10, 2007.
10.16	Credit Agreement, dated as of January 31, 2008, among the Company, Anika Securities, Inc., Bank of America, N.A., and the other lenders party thereto (the "Credit Agreement"), incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
†10.17	Anika Therapeutics, Inc. Senior Executive Incentive Compensation Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
†10.18	Form of Performance Share Award Agreement under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
†10.19	Employment Agreement, dated October 17, 2008, between the Company and Charles H. Sherwood, Ph.D., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 22, 2008.
†10.20	Employment Agreement, dated October 17, 2008, between the Company and Kevin Quinlan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 22, 2008.
†10.21	Form of Restricted Stock Award Agreement for Employees under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File no. 001-14027), filed with the Securities and Exchange Commission on March 12, 2008.
†10.22	Anika Therapeutics, Inc. Non-Employee Director Compensation Policy, incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File no. 001-14027), filed with the Securities and Exchange Commission on March 12, 2008.
†10.23	Form of Restricted Deferred Stock Unit Award Agreement for Non-Employee Directors under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File no. 001-14027), filed with the Securities and Exchange Commission on March 9, 2009.
†10.24	Letter Agreement, dated April 27, 2009, by and between the Company and Frank J. Luppino, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on May 29, 2009.
†10.25	Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on June 11, 2009.
†10.26	Employment Agreement, dated September 10, 2009, between the Company and Frank J. Luppino, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
†10.27	Employment Agreement, dated September 10, 2009, between the Company and William J. Mrachek, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
10.28	Registration Rights Agreement, dated December 30, 2009, between the Company and Fidia Farmaceutici S.p.A., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.

10.29	Lease Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l., incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
10.30	Tolling Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l., incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
10.31	Consent and First Amendment to the Credit Agreement, dated as of December 30, 2009, by and among the Company, Anika Securities, Inc., Bank of America, N.A. and each lender signatory thereto, incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
10.32	Pledge Agreement on a Quota of Fidia Advanced Biopolymers S.r.l., dated March 12, 2010, dated March 12, 2010, by the Company in favor of Bank of America, N.A., incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File no. 001-14027), filed with the Securities and Exchange Commission on May 10, 2010.
†10.33	Amendment No. 1 to Employment Agreement by and between the Company and Charles H. Sherwood, Ph.D., dated December 18, 2010, incorporated herein by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2011.
†10.34	Amendment No. 1 to Employment Agreement by and between the Company and Kevin W. Quinlan, dated December 18, 2010, incorporated herein by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2011.
†10.35	Amendment No. 1 to Employment Agreement by and between the Company and Frank J. Luppino, dated December 18, 2010, incorporated herein by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2011.
†10.36	Amendment No. 1 to Employment Agreement by and between the Company and William J. Mrachek, dated December 18, 2010, incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (file no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2011.
†10.37	1993 Stock Option Plan, as amended, incorporated herein by reference to the Company's Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 28, 2000.
†10.38	Second Amended and Restated 2003 Stock option and incentive Plan, incorporated herein by reference to Appendix A to the Company's Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 28, 2011.
**10.39	License Agreement, dated as of December 21, 2011, by and between Anika Therapeutics, Inc. and DePuy Mitek, Inc., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on December 22, 2011.
†10.40	Separation Agreement by and between the Company and Kevin W. Quinlan, dated February 1, 2013, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (file no. 001-14027), filed with the Securities and Exchange Commission on February 28, 2013.

(11) Statement Regarding the Computation of Per Share Earnings

11.1	See Note 3 to the Financial Statements included herewith.

(21) Subsidiaries of the Registrant

*21.1	List of Subsidiaries of the Registrant.
(23) Consent of Experts	
*23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
(31) Rule 13a-14(a) / 15d-14(a) Certifications	
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Kevin W. Quinlan pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32) Section 1350 Certification	
***32.1	Certification of Charles H. Sherwood, Ph.D. and Kevin W. Quinlan, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(101) xBRL

^101 The following materials from the Company's Annual Report on Form 10-K for the period ended December 31, 2012, formatted in xBRL: (i) Consolidated Balance Sheets as of December 31, 2012 and December 31, 2011; (ii) Consolidated Statements of Operations for the Years Ended December 31, 2012, December 31, 2011, and December 31, 2010; (iii) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2012, December 31, 2011, and December 31, 2010; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2012, December 31, 2011, and December 31, 2010; and (v) Notes to Consolidated Financial Statements.

** Filed herewith.

** Certain portions of this document have been omitted pursuant to a confidential treatment request filed with the Commission. The omitted portions have been filed separately with the Commission.

*** Furnished herewith.

† Denotes compensatory plan or arrangement.

^ Pursuant to Rule 406T of Regulation S-T, the xBRL related information in Exhibit 101 to this Annual Report on Form 10-K is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

SIGNATURES

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

ANIKA THERAPEUTICS, INC.

Date: March 13, 2013 By: /s/ CHARLES H. SHERWOOD, PH.D.

Charles H. Sherwood, Ph.D.
Chief Executive Officer

SIGNATURES

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.

Signature	Title	Date
/s/ CHARLES H. SHERWOOD, PH.D. Charles H. Sherwood, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2013
/s/ KEVIN W. QUINLAN Kevin W. Quinlan	Chief Financial Officer (Principal Accounting Officer)	March 13, 2013
/s/ JOSEPH L. BOWER Joseph L. Bower	Director	March 13, 2013
/s/ RAYMOND J. LAND Raymond J. Land	Director	March 13, 2013
/s/ JOHN C. MORAN John C. Moran	Director	March 13, 2013
/s/ JEFFERY S. THOMPSON Jeffery S. Thompson	Director	March 13, 2013
/s/ STEVEN E. WHEELER Steven E. Wheeler	Director	March 13, 2013