

ANIKA THERAPEUTICS INC
Form 10-K
March 13, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

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
(State or Other Jurisdiction of Incorporation or
Organization)

04-3145961
(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 No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the
Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of

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the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

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

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

The aggregate market value of voting and non-voting equity held by non-affiliates of the Registrant as of June 30, 2013, the last day of the Registrant's most recently completed second fiscal quarter, was \$228,892,947 based on the close price per share of Common Stock of \$17.00 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 10, 2014, there were issued and outstanding 14,324,920 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, 2013. 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, 2013

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, 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 expectations regarding our joint health products, including existing products and 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 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;

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- Our ability to license our aesthetics product to new distribution partners domestically and outside the United States;
- Our ability, and the ability of our distribution partners, to market our aesthetics dermatology product; and our expectations regarding the distribution and sales of our ELEVESSTM product and the timing thereof;
- Our expectations regarding development of aesthetics product line extensions;
- Our expectations regarding HYVISC® sales;
- Our expectations regarding product gross margin;
- Our expectations regarding CINGALTM, including the expense associated therewith, and our ability to obtain regulatory approvals for this product;
- Our expectation for changes 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;
- Possible negotiations or re-negotiations with existing or new distribution or collaboration partners;
- Our ability to continue streamlining operations and improving our manufacturing capabilities;
- 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 ability to manage the operations of Anika Therapeutics S.r.l. (“Anika S.r.l.”) from one with losses, into a company generating continued profits;
- The strength of the economies in which the Company operates or will operate, as well as the political stability of any of those geographic areas;
- Our ability to effectively prioritize the many research and development projects underway;
- Our ability to obtain U.S. approval for orthopedic and other product franchises 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; and
- Our ability to successfully defend the Company against lawsuits and claims 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 in 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 a strategic shift which involved 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 became effective January 1, 2013. In 2013, the Company completed a restructuring plan which included a reduction-in-force of 12 people and provided for severance payments, disposals of related supplies, equipment, and other assets. This plan was 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.

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 about 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 pain relief from 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 the U.S., Turkey and Canada. ORTHOVISC mini and MONOVISC are our joint health viscosupplementation products which became available in certain international markets since the second quarter of 2008. Our most recent product approval was received in February 2014 for MONOVISC in the U.S. The related commercial introduction is planned for March 2014.

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 Synthes, Mitek Sports Medicine (“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 Asia. 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 TM, 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, with the 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.

Dermal

Our dermal products consist of advanced wound care products, based on the HYAFF technology, and aesthetic dermal fillers, based on Anika’s proprietary chemically modified cross-linked HA technology, BCDI. Our HYAFF technology offers 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 to aid healing and scaffolds used in connection with skin substitutes. Leading products include Hyalomatrix and Hyalofill, for treatment of complex wounds such as burns and ulcers. The dermal products are commercialized through a network of distributors, primarily in Europe, Latin America and the Middle East. Several of the products are also approved for sale in the United States including Hyalomatrix, Hyalofill, and Hyalogran. 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, and Chile.

Our aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and is commercialized in Europe, Canada, the U.S., Korea and selected countries in South America. Internationally, this product is marketed under the ELEVESS name. In the U.S., the trade name is HYDRELLETM, 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 ENT 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 three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes through 2014.

B&L accounted for 5% of product revenue for the year ended December 31, 2013; based on contractual minimums, product revenue is expected to be modestly lower in 2014. Operating margins under the 2004 B&L Agreement were low and will remain at a similar level under the current 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 and selected countries in the Middle East.

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 for our existing and new products. Our development focus includes products for tissue protection, healing and repair. For the years ended December 31, 2013, 2012 and 2011, these expenses were \$7.1 million, \$5.4 million, and \$6.2 million, respectively. We anticipate that our research and development efforts, including clinical trials, will increase significantly in the near future over historical levels.

Our first next generation osteoarthritis product is MONOVISC, which received FDA approval in February 2014. MONOVISC is a single-injection treatment product that uses a non-animal sourced HA, and is our first osteoarthritis product based on our proprietary cross-linked HA technology. Our second single-injection osteoarthritis product, currently under development, is CINGAL, which is based on our hyaluronic acid material with an added active therapeutic molecule designed to provide broad pain relief and for a longer period of time. We have completed the formulation and biocompatibility studies of the product. During the second quarter of 2013, we commenced a phase III clinical trial to obtain the needed clinical data for CE Mark submission and approval, and to support other product registrations, including in the United States.

The technologies obtained through our acquisition of Anika S.r.l. have enhanced our research and development capabilities, and our pipeline of product candidates. 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 and Hyalospine, an adhesion prevention gel for use after spinal surgery. 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. 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 2013, we were granted 7 new patents in the U.S., Japan and Canada. The patents covered regenerative technologies and products such as Hyalofast, among others. 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 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 Mitek an exclusive and non-transferable royalty bearing license to develop, commercialize and sell ORTHOVISC, and other products developed pursuant to the JNJ Agreement, in the U.S. This includes a license to manufacture, and have manufactured, such products in the event that we are unable to supply them with ORTHOVISC in accordance with the terms of the JNJ Agreement. We have also granted Mitek the exclusive, royalty free right to use the trademark ORTHOVISC in connection with the marketing, distribution and sale of the licensed product within the U.S.

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On December 21, 2011, the Company entered into a license, supply and distribution agreement (the “Mitek MONOVISC Agreement”) with Mitek for an exclusive, multi-year U.S. 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, 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 cleared in the U.S. as Class II devices through premarket notification (510(k)): Hyalomatrix, Hyalofill-R, and Hyalofill-F. Anika S.r.l. also has an advanced wound care product in the U.S., Hyalogran, which is classified under 510(k) as Class I exempt. 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.

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.

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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.

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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 a 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, was licensed in Canada in 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, in Canada in August 2009, and in the U.S. in February 2014. In addition, Anika has received approval for several of its products in Latin America, Korea, Turkey, the Middle East, including the United Arab Emirates and Saudi Arabia, and several markets in Asia.

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, South Korea, Malaysia, Singapore, Mexico, Argentina, Chile, Saudi Arabia, 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 we have. 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:

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- 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

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- The availability of 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 orthopedics, surgical adhesion prevention, advanced wound care, ENT, cosmetic dermal fillers and in ophthalmic surgery. There is a risk that we will be unable to compete effectively against our current or future competitors. See also the section captioned "Risk Factors—Substantial competition could materially affect our financial performance."

Employees

As of December 31, 2013, we had 102 employees, 22 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, but 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 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 that if material claims arise in the future, our insurance will be adequate to cover all situations. Moreover, we cannot assure 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. 20549. 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, 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, collection of non-U.S. accounts receivable, 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, including line extensions, 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.

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. During the second quarter of 2013, we commenced the clinical trial to obtain the needed clinical data for a CE Mark submission and approval, and to support other product registrations, including in the United States.

In addition, we cannot assure that:

- We will begin or successfully complete U.S. clinical trials for next generation products and new 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 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 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 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.

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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 require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. We have hired experienced clinical development and regulatory staff to develop and supervise our clinical trials and regulatory processes. However, we will remain dependent upon third party contract research organizations to carry out some of our clinical and preclinical research studies for the foreseeable future. As a result, we have had and will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trials than would be the case if we were relying entirely on our own staff. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may also experience unexpected cost increases that are beyond our control. Furthermore, 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.

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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 and countries 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 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.

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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 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, we cannot be certain that the supply of key raw materials, specifically HA, will continue be available at current levels or will be sufficient to meet our future needs. Any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We also rely on a single supplier for certain finished products, and if such manufacturer fails to meet production and delivery schedules, it could have an adverse impact on our ability to sell such products. 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 and maintain the necessary manufacturing capabilities;
- Obtain the assistance of additional marketing partners;

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- 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 we may never realize the anticipated benefits of such acquisitions or strategic alliances.

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 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, 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 In-Process Research and Development ("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 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 not fully realize the intended benefits of our restructuring plan.

On December 28, 2012, the Company announced a strategic shift involving 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 became effective January 1, 2013. The restructuring plan adopted included a reduction-in-force of 12 people, and the disposal of related supplies, equipment, and other assets. We completed the restructuring plan within the first six months of 2013. The restructuring plan was 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 will produce the expected future savings.

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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. 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.

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 obtaining coverage for MONOVISC in the U.S., and change of classification by Centers for Medicare and Medicaid Services (“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 \$63.3 million at December 31, 2013. 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;
- 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; 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 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 product liability 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, 2013, 2012 and 2011, approximately, 23%, 19%, and 25%, 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;

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- 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 9% of our business during fiscal year 2013 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.

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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, 2013, five customers accounted for approximately 79% of product revenue. We expect to continue to be dependent on a small number of large customers for the majority of our revenues. 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.

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 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 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. In 2013, 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.

The impact of United States healthcare reform legislation on us remains uncertain.

In 2010, federal legislation to reform the United States healthcare system was enacted into law in the Affordable Care Act. The legislation is far-reaching and is intended to expand access to health insurance coverage, improve quality and reduce costs over time. We expect the new law will impact certain aspects of our business. However, it is unclear how the new law will impact patient access to new technologies or reimbursement rates under the Medicare program. Many of the details of the new law will be included in new and revised regulations, which have not yet been promulgated, and require additional guidance to be provided by the Department of Health and Human Services, Department of Labor and Department of the Treasury. We are completing our assessment of the new law on our business. The legislation could have a material adverse effect on our business, cash flows, financial condition and results of operations.

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if we are excluded from being a supplier by a group purchasing organization or similar entity.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators and third-party payers to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This may result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions. If a group purchasing organization excludes us from being one of their suppliers, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Bedford, Massachusetts (“Bedford facility”), 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 28,000 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 years. For the year ended December 31, 2013, we had aggregate facility lease expenses of approximately \$1,400,000.

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 District 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 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 assessed and determined that contingent losses related to this matter were not probable. Therefore, pursuant to Accounting Standards Codification (“ASC”) 450, Contingencies, an accrual was not recorded for this loss contingency. Pursuant to the terms of the licensing and supply agreement entered into with DePuy Mitek, Inc., currently DePuy Synthes, Mitek Sports Medicine or Mitek, in December 2011, 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 District Court stay Genzyme’s lawsuit against the Company pending 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 September 2013, the District Court in the Seikagaku/Zimmer lawsuit issued an order denying all the post-trial motions in that case, except for Seikagaku/Zimmer’s motion for damages against Genzyme. On October 14, 2013, Genzyme filed a notice of appeal to the United States Court of Appeals for the Federal Circuit challenging the District Court’s judgment of invalidity and non-infringement. That appeal was dismissed by the Court of Appeals on January 13, 2014 pursuant to a request made by Genzyme. On January 27, 2014, the District Court granted a joint motion filed by the parties to dismiss with prejudice all claims in the Seikagaku/Zimmer lawsuit and the case was terminated. On March 7, 2014 Genzyme and the Company filed a joint motion to lift the stay in Genzyme’s lawsuit against the Company and to dismiss with prejudice all of Genzyme’s claims. On March 10, 2014, the District Court granted the motion dismissing with prejudice all of Genzyme’s claims against the Company and the case was terminated.

In 2011, Merogel Injectable was voluntarily withdrawn from the market due to a labeling error on the product's packaging. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error related to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. ("Fidia") and, as a result, we made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia maintained that it did not have liability for this matter, and 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. The Company reached agreement with Fidia in October 2013 to settle this matter without admission of liability by either party in return for a payment made by Fidia to the Company. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and shares previously held in escrow have been released.

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.

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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, 2013	High	Low
First Quarter	\$14.58	\$10.00
Second Quarter	18.07	12.26
Third Quarter	27.80	17.02
Fourth Quarter	38.68	23.26
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

At December 31, 2013, the closing price per share of our common stock was \$38.16 as reported on the NASDAQ Global Select Market and there were 174 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, 2008 in the Company's Common Stock and each of the indices.

	Dec-08	Dec-09	Dec-10	Dec-11	Dec-12	Dec-13
Anika Therapeutics, Inc.	\$ 100.00	\$ 250.99	\$ 219.41	\$ 322.37	\$ 326.97	\$ 1,255.26
NASDAQ Composite Index	\$ 100.00	\$ 143.89	\$ 168.22	\$ 165.19	\$ 191.47	\$ 270.55
NASDAQ Biotechnology Index	\$ 100.00	\$ 115.63	\$ 132.98	\$ 148.69	\$ 196.12	\$ 324.80

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, 2013 and 2012 and the Statement of Operations Data for each of the three years ended December 31, 2013, 2012 and 2011 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, 2011, 2010 and 2009, and the Statement of Operations Data for each of the two years in the period ended December 31, 2010 and 2009 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,				
	2013	2012	2011	2010	2009
Product revenue	\$71,774	\$68,010	\$61,956	\$52,736	\$37,321
Licensing, milestone and contract revenue	3,307	3,348	2,822	2,821	2,815
Total revenue	75,081	71,358	64,778	55,557	40,136
Cost of product revenue	22,765	28,989	26,784	23,827	13,670
Product gross profit	49,008	39,021	35,172	28,909	23,651
Product gross margin	68 %	57 %	57 %	55 %	63 %
Total operating expenses	42,474	51,643	50,811	48,019	34,549
Net income	20,575	11,757	8,467	4,316	3,688
Diluted net income per common share	\$1.39	\$0.82	\$0.62	\$0.32	\$0.32
Diluted common shares outstanding	14,826	14,345	13,748	13,647	11,562

Balance Sheet Data
(In thousands)

	Years ended December 31,				
	2013	2012	2011	2010	2009
Cash and cash equivalents	\$63,333	\$44,067	\$35,777	\$28,202	\$24,427
Working capital	85,309	62,932	49,600	36,952	33,307
Total assets	156,042	142,069	132,844	128,937	129,431
Long term obligations	-	9,600	11,200	12,800	14,400
Retained earnings	66,584	46,010	34,252	25,786	21,470
Stockholders' equity	135,634	108,925	94,763	85,190	82,144

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
Aesthetic dermatology	X	
Ophthalmic	X	
Surgical		
Anti-adhesion	X	X
Ear, nose and throat care (“ENT”)		X
Veterinary	X	

Orthobiologics

Anika’s orthobiologics business contributed 78% to our product revenue for the year ended December 31, 2013. 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 the U.S., Turkey and Canada. ORTHOVISC mini, and MONOVISC are two viscosupplementation products which became available in certain international markets during the second quarter of 2008. Our most recent product approval was received in February 2014 for MONOVISC in the U.S. The related commercial introduction is planned for March 2014.

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 8% of product revenue

for the year ended December 31, 2013.

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 orthobiologics area has been the fastest growing area for the Company, growing from 57% of our product revenue in 2008 to 78% of our product revenue in 2013. We continue to seek new distribution partnerships around the world and we expect total orthobiologics product sales to increase in 2014 compared to 2013, based on sales from existing and new partners.

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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 that 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 3% to our product revenue for the year ended December 31, 2013, and consist of advanced wound care products based on the HYAFF technology, and aesthetic dermal fillers. Anika S.r.l. offers 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, Latin America and the Middle East. Several of the products are also approved for sale in the United States including Hyalomatrix, Hyalofill and Hyalogran. Currently, the Company is actively seeking a commercial partner in the United States. 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 and Chile.

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., South Korea and certain countries in South America. Internationally, this product is marketed under the ELEVESS trade name. In the U.S., the trade name is HYDRELLE, although the product is not currently marketed in the U.S.

Surgical

Our surgical group consists of products used to prevent surgical adhesions, and to treat ENT disorders. For the year ended December 31, 2013, sales of surgical products contributed 8% 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 distribution of these products.

In 2011, Merogel Injectable was voluntarily withdrawn from the market due to a labeling error on the product's packaging. We settled the matter related to this dispute with Medtronic in August, 2012. This labeling error related to conduct that initially occurred prior to our acquisition of Anika S.r.l. from Fidia Farmaceutici S.p.A. ("Fidia") and, as a result, we made claims against Fidia for indemnification for Anika's losses related to this issue. Fidia maintained that it did not have liability for this matter, and 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. The Company reached agreement

with Fidia in October 2013 to settle this matter without admission of liability by either party in return for a payment made by Fidia to the Company. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and shares previously held in escrow have been released.

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2013, sales of ophthalmic products contributed 6% 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 three year contract for Anika to continue to supply these products to B&L as a second supplier with committed annual volumes for 2012, and with lower committed volumes in 2013 and 2014.

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B&L accounted for 5% of product revenue for the year ended 2013, and is expected to be lower in 2014 under the current contract. Operating margins under the 2004 B&L Agreement were low and will remain at a similar level under the current contract. See Item 1A. "Risk Factors."

Veterinary

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 5% to product revenue for the year ended December 31, 2013. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Research and Development

Anika's research and development efforts primarily consisted 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 related 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.

In February 2014 we received FDA approval for MONOVISC. MONOVISC is our first FDA approved single-injection treatment of osteoarthritis that uses a non-animal sourced HA. It 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.

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. During the second quarter of 2013, we commenced a phase III clinical trial to obtain the needed clinical data for a CE Mark submission and approval, and to support other product registrations including in the United States.

With the acquisition of Anika S.r.l., we have enhanced our research and development capabilities, our technology base, and our pipeline of product candidates. Anika S.r.l. has research and development programs for new products including Hyalofast, an innovative product for cartilage tissue repair, Hyalospine, an adhesion prevention gel for use after spinal surgery, and Hyalobone, a bone tissue filler.

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 became effective January 1, 2013. The restructuring plan primarily involved 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 was related to the noncash disposal of assets. The remaining \$0.9 million related to cash payments anticipated to occur in 2013, primarily for employee termination costs. The restructuring plan was completed in 2013, with a \$286,843 benefit to the statement of operations for the year ended December 31, 2013, based on actual expenses and payment settlements.

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, 2013.

Foreign Currency Translation

The functional currency of our wholly-owned 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 \$259,275 and \$200,452 during the years ended December 31, 2013, and 2012, respectively and losses from foreign currency transactions of \$623,093 in 2011.

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.

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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.

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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.

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

Revenue 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 is 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 quarterly unaudited or annual audited financial statements.

Pursuant to the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act, a medical device excise tax ("MDET") became effective on January 1, 2013 for sales of certain medical devices. Some of our product sales are subject to the provisions of the MDET. The Company has elected to recognize any amounts related to the MDET under the gross method as allowed under ASC 605-45. For the period ending December 31, 2013, amounts included in revenue and cost of goods sold for the MDET were immaterial.

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 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.

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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, while 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 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, 2013 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. Our annual assessment for impairment of IPR&D indicated that the fair value of our IPR&D as of November 30, 2013 exceeded their respective carrying values.

Through December 31, 2013 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 excess of the fair value of the equity of the Anika S.r.l. reporting unit over its carrying value at November 30, 2013 increased 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.

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.

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Restructuring and Impairment 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.

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, 2013 and 2012, 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.

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Results of Operations

Year ended December 31, 2013 compared to year ended December 31, 2012
Statement of Operations Detail

	Year Ended December 31,		Inc/(Dec)	Inc/(Dec)	
	2013	2012			
Product revenue	\$71,773,730	\$68,010,169	\$3,763,561	6	%
Licensing, milestone and contract revenue	3,307,424	3,348,336	(40,912)	(1)	%
Total revenue	75,081,154	71,358,505	3,722,649	5	%
Operating expenses:					
Cost of product revenue	22,765,404	28,988,621	(6,223,217)	(21)	%
Research & development	7,059,875	5,388,036	1,671,839	31	%
Selling, general & administrative	12,936,001	14,728,662	(1,792,661)	(12)	%
Restructuring charges	(286,843)	2,537,988	(2,824,831)	-	
Total operating expenses	42,474,437	51,643,307	(9,168,870)	(18)	%
Income from operations	32,606,717	19,715,198	12,891,519	65	%
Interest income (expense), net	(127,186)	(187,777)	60,591	(32)	%
Income before income taxes	32,479,531	19,527,421	12,952,110	66	%
Provision for income taxes	11,905,010	7,769,961	4,135,049	53	%
Net income	\$20,574,521	\$11,757,460	\$8,817,061	75	%
Product gross profit	\$49,008,326	\$39,021,548	\$9,986,778	26	%
Product gross margin	68	% 57	%		

Total Revenue. Total revenue for the year ended December 31, 2013 increased by \$3,722,649 to \$75,081,154. The increase in total revenue was primarily due to increased orthobiologics product revenue in 2013 as compared to 2012.

Product revenue by product line. Product revenue for the year ended December 31, 2013 was \$71,773,730, an increase of \$3,763,561, or 6%, compared to the prior year.

	Year Ended December 31,		Inc/(Dec)	Inc/(Dec)	
	2013	2012			
Orthobiologics	\$55,956,068	\$49,954,112	\$6,001,956	12	%
Dermal	1,816,602	1,384,403	432,199	31	%
Surgical	5,445,715	5,022,456	423,259	8	%
Ophthalmic	4,656,560	8,784,011	(4,127,451)	(47)	%
Veterinary	3,898,785	2,865,187	1,033,598	36	%
	\$71,773,730	\$68,010,169	\$3,763,561	6	%

Revenue from orthobiologics increased \$6,001,956, or 12%, in 2013 compared to 2012. The improvement in orthobiologics product revenue was due primarily to increases in domestic and international ORTHOVISC sales. Our U.S. ORTHOVISC product revenue for 2013 increased 9% compared to 2012. This increase reflects Mitek's continued market penetration. International viscosupplementation product revenue in 2013 increased 34% compared to 2012. The increase in international revenue was driven primarily by growth from existing partners, as well as geographic expansion. We expect orthobiologics revenue will continue to increase in 2014, both domestically and internationally.

Dermal revenue increased \$432,199, or 31%, in 2013 compared to 2012. The increase was primarily due to Anika S.r.l.'s advanced wound care products revenue which totaled \$1,647,396 in 2013, as compared to \$976,388 in 2012. This increase was driven by expansion of advanced wound care revenue from existing distributors as well as product

launches in South America. We expect advanced wound care revenue to increase in 2014 compared to 2013 primarily due to geographic expansion.

Sales of our surgical products increased \$423,259, or 8%, as compared to 2012. 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 distribution of its ENT products. We expect surgical product revenue to increase in 2014 compared to 2013.

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Revenue from ophthalmic products in 2013 decreased \$4,127,451, or 47%, compared to revenue for these products in 2012. The decrease was primarily attributable to B&L's plan to shift manufacturing to an alternative supplier. B&L accounted for 5% of product revenue for the year ended 2013, and is expected to be lower in 2014 due to the lower minimum purchase requirements under the current three year contract. Operating margins under the expired 2004 B&L Agreement were low, and remain at a similar level under the current contract.

Veterinary revenue increased \$1,033,598, or 36%, in 2013 as compared to 2012. Sales of HYVISC are made to a single customer under an exclusive agreement which expires December 31, 2014. We expect HYVISC revenue to be at a similar level in 2014 as compared to 2013.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the year ended December 31, 2013 was \$3,307,424, compared to \$3,348,336 for 2012. 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 was the last year for the recognition of these milestone payments related to ORTHOVISC under the initial term of the agreement. 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 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 received FDA PMA approval for MONOVISC in February 2014, and is entitled to receive additional payments from Mitek, following FDA approval and commercial launch of 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, 2013 was \$49,008,326, or 68% of product revenue, compared with \$39,021,548, or 57% of product revenue, for the year ended December 31, 2012. The increase in product gross profit was primarily due to the elimination of duplicate manufacturing facility costs for a full year in 2013, improved manufacturing efficiencies, as well as improvements in overall product sales mix, compared to the prior year, with increasing sales of our higher-margin orthobiologics products as a percent of our total product sales being the primary driver.

Research and development. Research and development ("R&D") expenses for the year ended December 31, 2013 increased by \$1,671,839, or 31%, 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 9% and 8% for the years ended 2013 and 2012, respectively. We expect research and development expenses will increase in 2014 and thereafter compared to 2013 with our continued efforts for CINGAL, the development efforts for tissue regenerative products, line extension products, new products, and early-stage development projects.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2013 decreased by \$1,792,661, or 12%, as compared to 2012. This decrease was primarily due to a legal dispute settlement payment received in 2013, as well as on-going cost saving initiatives. We expect general and administrative expenses for 2014 will increase reflective of the support required to grow our business both domestically and internationally.

Restructuring charges. On December 28, 2012 the Company announced a strategic shift involving 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 became effective January 1, 2013. As a result of the plan, the Company recorded restructuring and associated impairment charges in the fourth quarter 2012 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 related to cash payments anticipated to occur in 2013, primarily for employee termination costs. The restructuring plan was completed in 2013, with a \$286,843 benefit to the statement of operations for the year ended December 31, 2013, based on actual expenses and payment settlements.

Interest income (expense), net. Net interest expense was \$127,186 for the year ended December 31, 2013, as compared to \$187,777 in the same period ended 2012. The decrease is the result of the lower balance on our outstanding variable interest rate debt during 2013. On November 29, 2013, the Company terminated the Credit Agreement entered into on January 31, 2008 among the Company, as borrower, Anika Securities, Inc., a wholly owned subsidiary of the Company, as guarantor, each of the lenders from time to time party thereto, and Bank of America, N.A., as administrative agent. In connection with the termination, the Company pre-paid in full its entire outstanding debt under the Agreement plus accrued interest. The outstanding debt balance of \$8,400,000 was pre-paid and we did not incur any pre-payment penalties.

Income taxes. Provisions for income taxes were \$11,905,010 and \$7,769,961 for the years ended December 31, 2013 and 2012, respectively. The decrease in the effective tax rate in 2013 of 3.1%, as compared to 2012, is primarily due to increased R&D tax credits, increased deductible stock option expenses resulting from increased exercise activity, and a favorable foreign tax rate differential.

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,			
	2013		2012	
Statutory federal income tax rate	35.0	%	35.0	%
State tax expense, net of federal benefit	4.8	%	6.4	%
Permanent items, including nondeductible expenses	(0.2)	%	0.9	%
State investment tax credit	(0.1)	%	(0.2)	%
Federal, state and foreign research and development credits	(0.5)	%	(1.2)	%
Foreign rate differential	0.1	%	2.5	%
Domestic production deduction	(2.4)	%	(3.6)	%
Effective income tax rate	36.7	%	39.8	%

As of December 31, 2013, the Company had net operating losses (“NOL”) for federal income tax purposes in Italy of \$9,353,750 with no expiration date.

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. We have concluded that the positive evidence outweighs the negative evidence and, thus, that the deferred tax asset 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, 2013, and 2012, respectively.

The 2010 through 2013 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 2013 tax years remain subject to examination by the applicable governmental authorities in Italy.

Net income. For the year ended December 31, 2013, net income was \$20,574,521, or \$1.39 per diluted share, compared to \$11,757,460, or \$0.82 per diluted share, for the same period last year. The primary drivers for this increase in net income were an increase in product gross profit due to improvements in operating efficiencies and streamlining of manufacturing operations with the consolidation into one facility, a more favorable product mix, and lower general and administrative expenses.

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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	10 %
Licensing, milestone and contract revenue	3,348,336	2,822,249	526,087	19 %
Total revenue	71,358,505	64,778,635	6,579,870	10 %
Operating expenses:				
Cost of product revenue	28,988,621	26,783,738	2,204,883	8 %
Research & development	5,388,036	6,168,937	(780,901)	(13 %)
Selling, general & administrative	14,728,662	17,858,558	(3,129,896)	(18 %)
Restructuring charges	2,537,988	-	2,537,988	-
Total operating expenses	51,643,307	50,811,233	832,074	2 %
Income from operations	19,715,198	13,967,402	5,747,796	41 %
Interest income (expense), net	(187,777)	(182,388)	(5,389)	3 %
Income before income taxes	19,527,421	13,785,014	5,742,407	42 %
Provision for income taxes	7,769,961	5,318,334	2,451,627	46 %
Net income	\$11,757,460	\$8,466,680	\$3,290,780	39 %
Product gross profit	\$39,021,548	\$35,172,648	\$3,848,900	11 %
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 orthobiologics 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 %)
Surgical	5,022,456	4,976,261	46,195	1 %
Ophthalmic	8,784,011	10,963,822	(2,179,811)	(20 %)
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 an increase 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. orthobiologics product revenue for 2012 increased 42% compared to 2011. This increase reflected 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.

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 \$3,331,618 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.

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.

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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.

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.

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 is 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 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 Mitek, following FDA approval and commercial launch of 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. outsourced manufacturing of its medical devices to its former parent company, Fidia Farmaceutici, contributing to its then current lower gross margins. The Company continued 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.

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.

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 facility, and lower legal and professional fees, offset by exit costs associated with the closing of our Woburn facility.

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 became 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.

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 was 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, was 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 NOL's 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 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 did not record a valuation allowance at December 31, 2012, and 2011, respectively.

The 2010 through 2012 tax years remain subject to examination by the 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.

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 \$63.3 million and \$44.1 million, and working capital totaled approximately \$85.3 million and \$62.9 million, at December 31, 2013 and December 31, 2012, respectively. The Company believes it has adequate financial resources to support its business for at least the next twelve months.

Cash provided by operating activities was \$25,165,001, \$10,548,677 and \$10,173,134 for 2013, 2012, and 2011, respectively. Cash provided by operating activities increased by \$14,616,324 in 2013, as compared to the same period ended 2012. The increase was primarily attributable to increased net income in the current year combined with improvements in accounts receivable collections and the positive effect of deferred income taxes. These were partially offset by the building of inventories to meet anticipated demand.

Cash used in investing activities was \$253,155, \$1,504,707 and \$1,400,348 in 2013, 2012 and 2011, respectively. The decrease in cash used in investing activities in 2013, as compared to the same period in the prior year, is a result of fewer capital purchases associated with our Bedford facility during the current year.

Cash used in financing activities was \$5,689,229, \$758,854, and \$1,165,340 for 2013, 2012, and 2011, respectively. Cash used in financing activities for 2013 of \$9.6 million was due to the pre-payment of long-term debt of \$8.4 million in November 2013, and quarterly payment of principle of \$0.4 million in each of the first three quarters of 2013. This cash decrease is partially offset by \$3.1 million of proceeds from exercises of stock options.

Concentration of Risk

A 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, 2013, the Company's accounts receivable from all Italian customers totaled approximately \$1.2 million of which public hospital and agency receivables were approximately \$0.2 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.

Accounting for Off-Balance Sheet Arrangements

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

In February 2013, the Financial Accounting Standards Board ("FASB") issued ASU No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income. The provisions of ASU 2013-02 are effective for annual and interim periods beginning after December 15, 2012. The objective of this update is to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments in this update seek to attain that objective by requiring an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. generally accepted accounting principles to be reclassified in its entirety to net income. The adoption of this amendment did not have a material impact on our consolidated financial position, results of operations, or cash flows.

In March 2013, the FASB issued ASU No. 2013-05, Foreign Currency Matters (Topic 830): Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity. The provisions of ASU 2013-05 are effective for annual and interim periods beginning after December 15, 2013. The objective of the amendments in this update is to resolve the diversity in practice about whether Subtopic 810-10, Consolidation—Overall, or Subtopic 830-30, Foreign Currency Matters—Translation of Financial Statements, applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. The adoption of this amendment will not have a material impact on our consolidated financial position, results of operations, or cash flows.

In July 2013, the FASB issued ASU 2013-11, Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. The provisions of ASU 2013-11 are effective for annual and interim periods beginning after December 15, 2013. The main provisions of ASU 2013-11 require an unrecognized tax benefit, or a portion of an unrecognized tax benefit, to be presented in the financial statements as a reduction to a deferred tax asset for the following; a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, with certain exceptions. 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 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; and
- The successful management 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 for at least 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.

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The table below summarizes our non-cancelable operating leases and contractual obligations at December 31, 2013:

	Total	Payments due by period			More than 5 years
		Less than 1 year	2 - 3 years	4 - 5 years	
Operating Leases (1)	\$10,505,956	\$1,627,388	\$3,211,485	\$1,943,000	\$3,724,083
Purchase Commitments	5,169,047	5,161,476	7,571	-	-
Total	\$15,675,003	\$6,788,864	\$3,219,056	\$1,943,000	\$3,724,083

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- (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 Bedford facility was fully validated and approved by applicable regulatory authorities in 2012. We completed the manufacturing space consolidation and moved all domestic operations into the Bedford facility during the second quarter of 2012. 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2013, 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.

Primary Market Risk Exposures

Our primary market risk exposures are in the area of 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 currency exchange rate fluctuation for the two contracts on our financial statements was immaterial in 2013. 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 is subject to interest rate fluctuations, changes in credit quality of the issuer, or otherwise.

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, 2013 and December 31, 2012 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2013 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, 2013, based on criteria established in Internal Control - Integrated Framework (1992) as 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, 2014

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	December 31,	
	2013	2012
Current assets:		
Cash and cash equivalents	\$63,333,160	\$44,067,477
Accounts receivable, net of reserves of \$593,023 and \$337,459 at December 31, 2013 and 2012, respectively	18,736,845	21,462,481
Inventories	10,996,785	8,283,472
Current portion deferred income taxes	659,040	2,031,583
Prepaid expenses and other	865,957	1,539,477
Total current assets	94,591,787	77,384,490
Property and equipment, at cost	52,413,423	52,376,013
Less: accumulated depreciation	(19,474,712)	(17,263,032)
	32,938,711	35,112,981
Long-term deposits and other	69,080	171,053
Intangible assets, net	18,998,409	20,334,636
Goodwill	9,443,894	9,065,891
Total Assets	\$156,041,881	\$142,069,051
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,793,911	\$2,341,838
Accrued expenses	5,537,881	5,837,044
Deferred revenue	180,433	2,875,067
Current portion of long-term debt	-	1,600,000
Income taxes payable	770,276	1,798,669
Total current liabilities	9,282,501	14,452,618
Other long-term liabilities	1,133,544	1,541,124
Long-term deferred revenue	2,054,941	2,152,778
Deferred tax liability	7,936,864	6,997,397
Long-term debt	-	8,000,000
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, 2013 and 2012, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 14,289,308 and 13,866,060 shares issued and outstanding at December 31, 2013 and 2012, respectively	142,893	138,659
Additional paid-in-capital	70,606,031	65,431,424
Accumulated currency translation adjustment	(1,699,095)	(2,654,630)
Retained earnings	66,584,202	46,009,681
Total stockholders' equity	135,634,031	108,925,134
Total Liabilities and Stockholders' Equity	\$156,041,881	\$142,069,051

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,		
	2013	2012	2011
Product revenue	\$71,773,730	\$68,010,169	\$61,956,386
Licensing, milestone and contract revenue	3,307,424	3,348,336	2,822,249
Total revenue	75,081,154	71,358,505	64,778,635
Operating expenses			
Cost of product revenue	22,765,404	28,988,621	26,783,738
Research & development	7,059,875	5,388,036	6,168,937
Selling, general & administrative	12,936,001	14,728,662	17,858,558
Restructuring charges	(286,843)	2,537,988	-
Total operating expenses	42,474,437	51,643,307	50,811,233
Income from operations	32,606,717	19,715,198	13,967,402
Interest income (expense), net	(127,186)	(187,777)	(182,388)
Income before income taxes	32,479,531	19,527,421	13,785,014
Provision for income taxes	11,905,010	7,769,961	5,318,334
Net income	\$20,574,521	\$11,757,460	\$8,466,680
Basic net income per share:			
Net income	\$1.46	\$0.89	\$0.65
Basic weighted average common shares outstanding	14,086,912	13,260,739	13,064,051
Diluted net income per share:			
Net income	\$1.39	\$0.82	\$0.62
Diluted weighted average common shares outstanding	14,825,599	14,344,577	13,747,813
Net income	\$20,574,521	\$11,757,460	\$8,466,680
Other comprehensive income (loss)			
Foreign currency translation adjustment	955,535	412,551	(519,405)
Comprehensive income	\$21,530,056	\$12,170,011	\$7,947,275

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

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

	Common Stock			Retained Earnings	Accumulated	Total
	Number of Shares	\$.01 Par Value	Additional Paid in Capital		Currency Translation Adjustment	
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 loss	-	-	-	-	-	-