Anika Therapeutics, Inc.
Form 10-K
March 13, 2015

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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

For the transition period from to

Commission File Number 000-21326

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

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

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

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

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

Preferred Stock Purchase Rights

Name of Each Exchange on Which Registered: NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

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

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

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

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

The aggregate market value of voting and non-voting equity held by non-affiliates of the Registrant as of June 30, 2014, the last day of the Registrant's most recently completed second fiscal quarter, was $682,060,021 based on the close price per share of common stock of $46.33 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 9, 2015, there were issued and outstanding 14,546,275 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, 2014. 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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References in this Annual Report on Form 10-K to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

ANIKA, ANIKA THERAPEUTICS, ANIKAVISC, CINGAL, HYAFF, HYDRELLE, HYVISC, INCERT, MONOVISC, and ORTHOVISC are our registered trademarks, and HYALOSS, OPTIVISC, and SHELLGEL are our trademarks. This Annual Report on Form 10-K also contains registered marks, trademarks, and trade names that are the property of other companies and licensed to us.

FORM 10-K
ANIKA THERAPEUTICS, INC.
For Fiscal Year Ended December 31, 2014

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 to 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 expectations regarding revenue from ophthalmic products, including our ability to commercialize ANIKAVISC and ANIKAVISC PLUS, and our expectations regarding such commercialization and the potential profits generated

thereby;

- 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 ELEVESS and the timing thereof;

- Our expectations regarding dermal, surgical, and veterinary sales;

- Our expectations regarding product gross margin;

- Our expectations regarding CINGAL, including the expense associated therewith, and our ability to obtain regulatory approvals for this product;

- Our expectations 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 expectations 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 manage the operations of Anika Therapeutics S.r.l. ("Anika S.r.l."), our wholly owned Italian subsidiary, as a company generating continued profits;

- The strength of the economies in which we operate 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 United States, including the impact such efforts may have on our revenue; and

- Our ability to successfully manage the transfer of manufacturing responsibilities related to Anika S.r.l.'s HYAFF products from the current contract manufacturer to Anika's Bedford facility, and our ability to achieve planned results from this transfer.

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

Forward-looking statements 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

We develop, manufacture, and commercialize 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.

Our wholly-owned subsidiary, Anika S.r.l., has over 20 products currently commercialized, primarily in Europe. These products are also all made from HA, 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.

Our 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	

In December 2012, we announced a strategic shift which involved the closure of our 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, we 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 our Italian operations by reducing costs and focusing on products and technology with strong commercial potential. In connection with the plan, we 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 related to the abandonment of the HYALOGRAFT C autograft in-process research and development ("IPR&D") project.

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 MONOVISC. ORTHOVISC is available in the United States, Canada, and other international markets for the treatment of osteoarthritis of the knee, and in Europe and certain international markets for the treatment of osteoarthritis in all joints. In the U.S. market, ORTHOVISC is the lead product in the multi-injection segment, and the number two viscosupplementation product overall. ORTHOVISC mini is available in Europe, and it is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment indicated for all joints in Europe and certain international markets, and for the knee in the United States, Turkey, and Canada. ORTHOVISC has been marketed by us internationally since 1996. ORTHOVISC mini and MONOVISC are our joint health viscosupplementation products which became available in certain international markets in the second quarter of 2008. Our most recent U.S. product approval was received from the FDA in February 2014 for MONOVISC, and the related commercial introduction in the United States occurred in April 2014.

In the United States, 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. ORTHOVISC is a sterile, clear, viscous 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 United States on March 1, 2004, and it 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 and was extended for an additional 5 years in November 2012 (the “Mitek ORTHOVISC Agreement”). 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 key markets. See the sections captioned “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Management Overview” and “Risk Factors.”

In the United States, MONOVISC is also 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. MONOVISC is a sterile, clear, viscous solution of partially cross-linked sodium hyaluronate in a phosphate buffered saline solution. A treatment of MONOVISC is comprised of one injection of the product delivered directly into the affected joint. MONOVISC became available for sale in the United States in April 2014, and it is also marketed by Mitek under the terms of a fifteen-year licensing, distribution, supply, and marketing agreement, which was entered into on December 21, 2011 (the “Mitek MONOVISC Agreement”). Outside of the United States, we have a number of distribution relationships servicing international markets including Canada, Europe, Latin America, Asia, and certain other international countries. We continue to seek to establish distribution relationships in other key markets. 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, South America, and Asia. They include HYALOFAST, a biodegradable support for human bone marrow mesenchymal stem cells used for cartilage regeneration and as an adjunct for microfracture surgery; HYALONECT, a woven gauze used as a graft wrap; and HYALOSS MATRIX, 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 for use in the shoulder for prevention of 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 our proprietary chemically modified cross-linked HA technology, BCDI. Products utilizing our HYAFF technology are used 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 as skin substitutes. Leading products include HYALOMATRIX and HYALOFILL, for the 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 cleared for sale in the United States including HYALOMATRIX, HYALOFILL, HYALOGRAN, and HYALOMATRIX 3D. In 2012, we entered into a distribution agreement for sales of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, and Chile. In July 2014, we entered into an agreement with Medline Industries, Inc. to commercialize HYALOMATRIX in the United States on an exclusive basis through 2019.

Our aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA, and it is commercialized in Europe, Canada, the United States, and Korea. Internationally, this product is marketed under the ELEVESS name. In the United States, the trade name is HYDRELLE, although the product is not currently marketed in the United States,

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 it is not approved for sale in the United States. HYALOSPINE, a product designed to prevent post-surgical adhesions following spinal surgery, was CE Mark approved in January 2015 for sale in Europe. 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 United States. We co-own 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 STAARVISC-II, OPTIVISC (formerly ShellGel), ANIKAVISC, and NUVISC. 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 they function to maintain the shape of the eye, thereby facilitating ophthalmic surgical procedures.

We 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 us to continue to supply these products to B&L as a second supplier with committed annual volumes through year-end 2014, and the contract was not renewed upon expiration.

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 in selected countries in the Middle East.

See Note 15 “Revenue by Product Group, by Significant Customer and by Geographic Region; Geographic Information” to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a discussion regarding our segments and geographic sales.

See also the section captioned “Risk Factors—Risks Related to Our Business and Industry—We experience quarterly sales volume variation, which makes our future results difficult to predict and makes period-to-period comparisons potentially not meaningful” for a discussion regarding the effect that quarterly sales volume variation could have on our business and financial performance.

See also the section captioned “Risk Factors —Risks Related to Our Business and Industry—A significant portion of 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” for a discussion regarding our dependence on large-volume customers and the effects that the loss of any such customer could have on our business and financial performance.

Research and Development of Potential Products

Our 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, repair, and regeneration. For the years ended December 31, 2014, 2013 and 2012, these expenses were $8.1 million, $7.1 million, and $5.4 million, respectively. We anticipate that our research and development efforts, including pre-clinical studies and clinical trials, will increase significantly in the near future over historical levels.

Our second single-injection osteoarthritis product, which is currently under development, is CINGAL, a product based on our hyaluronic acid material with an added active therapeutic molecule designed to provide broad pain relief for a longer period of time. During the second quarter of 2013, we commenced a multinational phase III clinical trial to obtain the clinical data necessary for a CE Mark submission and approval, and to support other product registrations including in the United States. We completed the clinical study and the associated statistical analysis in the fourth quarter of 2014. We submitted our CE Mark application in December 2014 and a pre-market approval application (“PMA”) with the FDA in February 2015.

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 hyaluronic acid matrix for human bone marrow mesenchymal stem cells used to regenerate soft tissue. HYALOFAST received CE Mark approval in September 2009, and it is currently commercially available in Europe and certain international countries. During the second quarter of 2014, we submitted a proposed investigational device protocol to the FDA. Our current plan is to begin a phase III clinical trial in 2015. HYALOSPINE is an adhesion prevention gel for use after spinal surgery. We completed a pilot clinical study in 2012, submitted the CE Mark application in September 2013, and received the CE Mark approval in January 2015.

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.

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, and 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. In the United States, we own 28 patents, co-own 2 patents, license 25 patents, and have 2 patent applications currently pending. These U.S. patents have expiration dates through 2030. Internationally, we own 218 patents, co-own 9 patents, license 133 patents, and have 11 patent applications currently pending. Outside of the United States, we own, co-own, license, or have filed for patents in 38 jurisdictions. Our international patents have expiration dates through 2032. Many of these patents, including all licensed patents, belong to the Anika S.r.l. patent estate, which is extensive and partly intertwined with its former parent company, Fidia Farmaceutici S.p.A., through a patent licensing agreement that provides Anika S.r.l. with access to certain of Fidia's patents to the extent required to support Anika S.r.l.'s 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 interests and when the cost of seeking such protection is not inordinate relative to the potential benefits.

In 2014, we were granted 5 new patents in the United States and Canada. The patents covered regenerative technologies and products and our HYALOSPINE product, 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.

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—Risks Related to Our Intellectual Property.”

We have granted Mitek an exclusive and non-transferable royalty bearing license to develop, commercialize, and sell ORTHOVISC and MONOVISC, in the United States pursuant to the Mitek ORTHOVISC Agreement and the Mitek MONOVISC Agreement. These agreements include a license to manufacture, and have manufactured, such products in the event that we are unable to supply Mitek with ORTHOVISC or MONOVISC in accordance with the terms of the relevant agreement. We have also granted Mitek the exclusive, royalty free right to use the trademarks ORTHOVISC and MONOVISC in connection with the marketing, distribution, and sale of the licensed products within the United States.

Government Regulation

U.S. Regulation

Our research (including clinical research), development, manufacture, and marketing of products are subject to regulation by numerous governmental authorities in the United States 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 connected 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, refusal 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, which include, 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, which include, among other requirements, 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 a PMA from the FDA.

OPTIVISC (formerly SHELLGEL), STAARVISC, ANIKAVISC, and NUVISC are approved as Class III medical devices in the United States for intraocular ophthalmic surgical procedures used in humans. ORTHOVISC and MONOVISC are approved as Class III medical devices in the United States for treatment of pain resulting from osteoarthritis of the knee in humans. HYDRELLE is approved as a Class III medical device in the United States 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 four advanced wound care products cleared in the United States through premarket notification (510(k)) as unclassified devices: HYALOMATRIX, HYALOFILL-F/R, LASERSKIN/HYALOMATRIX KC, and HYALOSAFE/JALOSKIN. Anika S.r.l. also has two 510(k) Class I exempt advanced wound care products in the United States: HYALOGRAN and HYALOMATRIX 3D. Anika S.r.l also has a 510(k)-cleared Class II ENT product, HYALOMATRIX CO. All other Anika S.r.l. ENT products are 510(k) cleared as Class II devices, and were submitted for FDA approval by Medtronic. Not all of our 510(k)-cleared products are currently being marketed in the United States. 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 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 will accept submissions related to our products, or that once accepted, review of our submissions will result in product approval on a timely basis, if at all. The PMA approval process is lengthy and expensive, and it typically requires, among other things, valid scientific evidence, which generally includes extensive data such as pre-clinical and clinical trial data to demonstrate a reasonable assurance of safety and effectiveness.

Human clinical trials in the United States for significant risk devices must be conducted under Good Clinical Practice ("GCP") regulations through an 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 in the future approval of the product. In addition, the IDE approval process can 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) data generated suggesting that: the risks to clinical subjects are not outweighed by the anticipated benefits to the clinical subjects or 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 PMA applicant must submit other information relevant to the safety and efficacy of the device, including, among other things, the results of non-clinical tests, a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling of the product. 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 to any 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 New Drug Application ("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 the product, and proposed labeling of the product. 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, or the use of a different facility for manufacturing the product, 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, labeling and promotion. The FDC Act requires medical product manufacturers to comply with QSR for medical devices and cGMP regulations for pharmaceuticals. The FDA enforces these requirements through periodic inspections of manufacturing facilities. To ensure full compliance with the 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 facilities as well.

Another 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. Reporting obligations are also triggered when a medical device malfunctions, and such malfunction, if it were to recur, would be likely to cause or contribute to a death or serious injury. Reporting of these events is mandatory, and any report could adversely affect our ability to continue to market our products in the United States and in other countries.

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 United States and in other countries.

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

Foreign Regulation

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

The CE Mark for ORTHOVISC, achieved in 1996, allows the product to be marketed without further approvals in most of the EU nations as well as other countries that recognize EU device regulations. ORTHOVISC mini, our treatment for osteoarthritis that targets small joints, is available in Europe under a CE Mark authorization received in 2008. MONOVISC achieved CE Mark approval in 2007. In August 2004, we received a CE Design Examination Certificate, which entitles us to affix a CE Mark to INCERT as a barrier to adhesion formation following surgery. In May 2005, we received a CE Design Examination Certificate, which entitles us to affix a CE Mark to OPTIVISC (formerly SHELLGEL) as an ophthalmic viscoelastic surgical device. We also received a CE Mark for ANIKAVISC Plus in October 2011 and CE Mark approval for ELEVESS during the second quarter of 2007.

In addition, we have received approval for several of our products in Latin America, Korea, Turkey, the Middle East, including Israel, the United Arab Emirates, and Saudi Arabia, and several markets in Asia, including the Philippines and Malaysia.

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 its products in Taiwan, Egypt, South Korea, Malaysia, Singapore, Mexico, Argentina, Chile, Peru, Venezuela, Israel, 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 processes than we have. We also compete with academic institutions, government agencies, and other research organizations, which may be involved in the research and 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.

We compete with other market participants primarily on the efficacy of our products, our products' reputation for safety, our focus solely on HA-based products, and the breadth of our HA-based product portfolio. Other factors that impact competition in our industry are the timing and scope of regulatory approvals, the availability of raw material and finished product 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 the HA development and commercialization markets include:

- The quality and breadth of our continued development of our technology portfolio;
- Our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors;
- The successful execution of our commercial strategies;
- Our ability to recruit and retain skilled employees; and
- 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 United States or in certain foreign countries. All of our 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 dermatology, and ophthalmic surgery. There is a risk that we will be unable to compete effectively against our current or future competitors. Additionally, legislation and regulation aimed at curbing rising healthcare costs has resulted in a consolidation trend in the healthcare industry to create larger companies, including hospitals, with greater market power. In turn, this has led to greater and more intense competition in the provision of products and services to market participants. Important market makers, like group purchasing organizations, have increased their negotiating leverage, and if these market makers demand significant prices concessions or if we are excluded as a supplier by these market makers, our net sales could be adversely impacted. See also the sections captioned "Risk Factors— Risks Related to Our Business and Industry—Substantial competition could materially affect our financial performance" and "Risk Factors—Risks Related to Our Business and Industry—Our business may be adversely affected in 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" for additional discussion of the impact competition could have on our business and financial results.

Employees

As of December 31, 2014, we had 105 employees, 21 of whom were located outside the United States. 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 entails 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 vary significantly in the future depending on a number of factors. You should consider carefully the risks and uncertainties described below, in addition to the other information contained in this Annual Report on Form 10-K, before deciding whether to purchase our common stock. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business and Industry

Failure to obtain, or any delay in obtaining, 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.

Several of our current products, including CINGAL and HYALOFAST, and any future products we may develop, will require clinical trials to determine their safety and efficacy for United States and international marketing approval by regulatory bodies, including the FDA. 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 accept submissions related to our new products, and, even if submissions are accepted, there can be no guarantee that the FDA will grant approval for our new products, including CINGAL or other line extensions, on a timely basis, if at all. In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local, and foreign regulations applicable to product approval, which may vary significantly across jurisdictions. Additional approval of existing products may be required when changes to such products may affect the safety and effectiveness, including for 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. Failure to obtain regulatory approvals of our products, including any changes to existing products, could have an adverse material impact on our business, financial condition, and results of operations.

Even if granted, FDA and international regulatory approvals may be subject to significant, unanticipated delays throughout the regulatory approval process. Internally, we make assumptions regarding product approval timelines, both in the United States and internationally, in our business planning, and any delay in approval could materially affect our competitive position in the relevant product market and our projections related to future business results.

We cannot be certain that product approvals, both in the United States and internationally, will not include significant limitations on the product indications, and other claims sought for use, under which the products may be marketed. The relevant approval or clearance may also include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements. Any of these factors could significantly impact our competitive position in relation to such products and could have a negative impact on the sales of such products.

Once obtained, we cannot guarantee that FDA or international product approvals will not be withdrawn or that relevant agencies will not require other corrective action, and any withdrawal or corrective action could materially affect our business and financial results.

Once obtained, marketing approval can be withdrawn by the FDA or comparable foreign regulatory agencies for a number of reasons, including the failure to comply with ongoing regulatory requirements or the occurrence of unforeseen problems following initial approval. Regulatory authorities could also limit or prevent the manufacture or distribution of our products. Any regulatory limitations on the use of our products or any withdrawal or suspension of approval or rescission of approval by the FDA or a comparable foreign regulatory agency could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and products are subject to extensive regulation, compliance with which is costly and time consuming, and our failure to comply may result in substantial penalties, including recalls of our products.

The FDA and foreign regulatory bodies impose extensive regulations applicable to our operations and products, including 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 maintain compliance required for FDA, CE marking, or other foreign regulatory approvals for any or all of our operations and products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements.

Failure to comply with applicable regulatory requirements could result in substantial penalties, including warning letters, fines, injunctions, civil penalties, seizure of products, total or partial suspension of production, refusal to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals, and criminal prosecution. Additionally, regulatory authorities have the power to require the recall of our products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per regulatory requirements of one or several of our products. The imposition of any of the foregoing penalties, whether voluntarily or involuntary, could have a material negative impact on our business, financial condition, and results of operations.

Any changes in FDA or international regulations related to product approval, including those that apply retroactively, could adversely affect our competitive position and materially affect our business and financial results.

FDA and foreign regulations depend heavily on administrative interpretation, and we cannot assure you that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. Additionally, any changes, whether in interpretation or substance, in existing regulations or policies, or any future adoption of new regulations or policies by relevant regulatory bodies, could prevent or delay approval of our products. In the event our future, or current, products, including HA generally, are classified, or re-classified, as human drugs, combination products, or biologics by the FDA or an applicable international regulatory body, the applicable review process related to such products is typically substantially longer and substantially more expensive than the review process to which they are currently subject as medical devices, which could materially impact our competitive position, business, and financial results.

Substantial competition could materially affect our financial performance.

We compete with many companies, including 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, government agencies, and other research organizations that may be involved in research, development, and commercialization of products similar to our own. 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 United States 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 United States 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 may rely on third parties to support certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval or commercialize our products and our business could be substantially harmed.

We have hired experienced clinical development and regulatory staff, and we have also retained the services of knowledgeable external service providers, including consultants and clinical research organizations, to develop and supervise our clinical trials and regulatory processes. Despite our internal investment in staffing, we will remain dependent upon these third party contract research organizations to carry out portions 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. Failure by these third parties to comply with regulatory requirements or to meet timing expectations may require us to repeat clinical or preclinical trials, which would delay the regulatory approval process, or require substantial unexpected expenditures.

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. One partner, DePuy Synthes Mitek Sports Medicine (“Mitek”), accounted for 72% of our product revenue in fiscal year 2014. We cannot assure you that our partners, including Mitek, will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. A failure to renew these partnerships on terms satisfactory to us, or at all, could result in a material adverse effect on our operating results.

We continue to seek to establish long-term distribution relationships in regions and countries not covered by existing agreements, and 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. 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. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms and within our planned timeframes could have a material adverse effect on our business, financial condition, and results of operations.

We must achieve market acceptance of our products in order to be successful in the future.

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 or viable commercial strategies 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.

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 or 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.

We use raw materials derived from animal sources to produce certain of our products, and there is no guarantee that we will be able to continue to utilize this source of material in the future.

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 a qualified vendor, who controls for contamination and has 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 and beyond.

Our financial performance depends on the continued sales growth and increasing 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, 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 or develop appropriate alternative sales strategies;
- 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, which exposes us to a variety of risks that could adversely affect our business operations.

Our business strategy includes the acquisition of businesses, technologies, services, or products that we believe are a strategic fit with our business. We may fund these acquisitions by utilizing our cash, incurring debt, issuing additional shares of our common stock, or by other means. Completed acquisitions may expose us to a number of risks and expenses, including unanticipated liabilities, amortization expenses related to intangible assets with definite lives, or risks associated with entering new markets with which we have limited experience or where commercial alliances with experienced partners or existing sales channels are not available. Whether or not completed, acquisitions may result in diversion of management resources otherwise available for ongoing development of our business and significant expenditures.

We may not be able to realize the expected benefits of any completed acquisitions, including synergies and cost savings from the integration of acquired businesses or assets with our existing operations and technologies, as rapidly as expected, or at all. In addition, the integration and reorganization processes for our acquisitions may be complex, costly, and time consuming and include unanticipated issues, expenses, and liabilities. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company in a manner that enhances the performance of our combined businesses or product lines and allows us to realize value from expected synergies. Moreover, we may lose key clients or employees of acquired businesses as a result of the change in ownership to us. 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, which could adversely affect our operating results. The failure to achieve the expected benefits of any acquisition may harm our business, financial condition, and results of operations.

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

On December 28, 2012, we announced a strategic shift involving the closure of our 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 our 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.

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

As of December 31, 2014, we had long-lived assets, including goodwill, of $55 million. 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 or future outlook, we may be required to record an impairment charge on such assets.

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 distract 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 locate suitable acquisition targets or have the opportunity to make acquisitions of such targets 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 United States and other foreign 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 generally depend upon the distributors of our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payers, both in the United States and internationally, 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, or the applicable foreign regulatory agency, has granted marketing approval. Also, the U.S. Congress, certain state legislatures, and certain foreign governments and regulatory agencies 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 United States, 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 continuing coverage for MONOVISC and ORTHOVISC in the United States, and any change of classification by the Centers for Medicare and Medicaid Services for ORTHOVISC and MONOVISC, 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, cash equivalents, and investments of $106.9 million at December 31, 2014. 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;

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The success and sales of our products under various distributor agreements, including the ability of our partners to achieve third party reimbursement for our products;

- 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 demand.

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, through strategic alliances with corporate partners and others or through other sources. The terms of any future equity financings may be dilutive to our investors 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 at the time we seek financing. 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, and 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, and 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 technical and highly skilled managerial and manufacturing personnel. We face significant competition for such personnel from competitive 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, 2014, 2013, and 2012, 13%, 23%, and 19%, 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;
- Instability of foreign economic, political, and labor conditions;
- Unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non-competition agreements in the European Union;
- The impact of strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, or other collective bargaining disputes;
- Difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs, or other trade barriers or by U.S. export laws;
- Imposition of government controls limiting the volume of international sales;
- Longer accounts receivable payment cycles;
- Potentially adverse tax consequences, including, if required or applicable, difficulties transferring funds generated in non-U.S. jurisdictions to the United States in a tax efficient manner;
- Difficulties in protecting intellectual property, especially in international jurisdictions;
- 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 7% of our business during fiscal year 2014 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.

A significant portion of 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, 2014, five customers accounted for 85% of product revenue, with Mitek alone accounting for 72% of product revenue. We expect to continue to be dependent on a small number of large customers, especially Mitek, for the majority of our revenues for the foreseeable future. The failure of these customers to purchase our products in the amounts they historically have or in amounts that we expect 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 agreements, 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, or develop alternative commercial strategies, 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, it 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. While we have not previously experienced a material information security breach caused by illegal hacking, computer viruses, or acts of vandalism or terrorism, we may in the future be subject to such a breach. 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 exposure to litigation, any of which could harm our business and operating results.

The impact of U.S. healthcare reform legislation on us remains uncertain but could be significant.

In 2010, federal legislation to reform the U.S. healthcare system was enacted into law in the Patient Protection and Affordable Care Act. The legislation 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 remains unclear how the new law will impact patient access to new technologies or reimbursement rates under the Medicare program as such access or rates pertain to us. Many of the details of the new law will be included in new and revised regulations, the totality of which have not yet been promulgated, and will 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.

We experience quarterly sales volume variation, which makes our future results difficult to predict and makes period-to-period comparisons potentially not meaningful.

We experience quarterly fluctuations in our products sales as a result of multiple factors, many of which are outside of our control. These quarterly fluctuations create uncertainty as to the volume of sales that we may achieve in a given period. As a result, comparing our operating results on a period-to-period basis might not be meaningful. You should not rely on our past results as an indication of our future performance. Our operating results could be disproportionately affected by a reduction in revenue because a proportionately smaller amount of our expenses varies with our revenue. As a result, our quarterly operating results are difficult to predict, even in the near term.

Risks Related to Our Intellectual Property

We may be unable to adequately protect our intellectual property rights, which could have a material impact on our business and future financial results.

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 and trademarks, to protect trade secrets, to obtain licenses to technology owned by third parties when necessary, and to conduct our business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical product, 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, that 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 U.S. Patent and Trademark Office to determine priority of invention, which could result in the 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, including, but not limited to, the diversion of management's attention away from our other 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, 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 in order to continue production of the products. 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.

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.

There can be no assurance that we will not infringe upon the intellectual property rights of others, which could have a significant impact on our business and financial results.

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. The cost of defending infringement suits is typically large, and there is no guarantee that any future defense would be successful. In addition, infringement could lead to substantial damages payouts or our inability to produce or market certain of our current or future products. As a result, any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Ownership of Our Common Stock

Our stock price may be 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, government 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.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they adversely change their recommendations regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. No person is under any obligation to publish research or reports on us, and any person publishing research or reports on us may discontinue doing so at any time without notice. If adequate research coverage is not maintained on our company or if any of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business or provide relatively more favorable recommendations about our competitors, our stock price would likely decline. If any analysts who cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We do not intend to pay dividends on our common stock in the foreseeable future.

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. Accordingly, investors are not likely to receive any dividends on their common stock in the foreseeable future, and their ability to achieve a return on their investment will therefore depend on appreciation in the price of our common stock.

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

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, and 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 adopted a ten-year 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 becomes an interested stockholder. All of these

provisions, policies, and plans are reviewed periodically by our Board of Directors. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

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, 2014, we had aggregate facility lease expenses of approximately $1,401,000. We believe that the capacity of each of the properties we currently occupy is sufficient to satisfy our current needs, as well as our needs for the foreseeable future.

ITEM 3. LEGAL PROCEEDINGS

On July 7, 2010, Genzyme Corporation filed a complaint against our company in the U.S. District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The complaint alleged that we infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and would infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if we manufactured and sold MONOVISC in the United States. On March 7, 2014, we filed a joint motion with Genzyme to lift the stay in Genzyme's lawsuit against us and to dismiss with prejudice all of Genzyme's claims. On March 10, 2014, the District Court granted the motion to dismiss all of Genzyme's claims against us with prejudice 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 the product's distributor, 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 it asserted a counterclaim against us for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. We reached an 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 us. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration has been withdrawn, and the 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.

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 they may not necessarily represent actual transactions.

Year Ended December 31, 2014	High	Low
First Quarter	$52.49	$28.79
Second Quarter	51.40	35.62
Third Quarter	50.89	35.39
Fourth Quarter	43.24	34.16

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

At December 31, 2014, the closing price per share of our common stock was $40.74 as reported on the NASDAQ Global Select Market, and there were 151 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

Set forth below is a graph comparing the total returns of our company, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index. The graph assumes $100 is invested on December 31, 2009 in our common stock and each of the indices. Past performance is not indicative of future results.

	Dec-09	Dec-10	Dec-11	Dec-12	Dec-13	Dec-14
Anika Therapeutics, Inc.	$100.00	$87.42	$128.44	$130.28	$500.13	$533.94
NASDAQ Composite Index	$100.00	$116.91	$114.81	$133.07	$184.06	$208.71
NASDAQ Biotechnology Index	$100.00	$115.01	$128.59	$169.61	$280.89	$376.68

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 the section captioned “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, 2014 and 2013 and the Statement of Operations Data for each of the three years ended December 31, 2014, 2013, and 2012 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, 2012, 2011, and 2010, and the Statement of Operations Data for each of the two years in the period ended December 31, 2011 and 2010 have been derived from 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,				
	2014	2013	2012	2011	2010
Product revenue	$75,474	$71,774	$68,010	$61,956	$52,736
Licensing, milestone and contract revenue	30,121	3,307	3,348	2,822	2,821
Total revenue	105,595	75,081	71,358	64,778	55,557
Cost of product revenue	20,930	22,765	28,989	26,784	23,827
Product gross profit	54,544	49,009	39,021	35,172	28,909
Product gross margin	72%	68%	57%	57%	55%
Total operating expenses	44,148	42,474	51,643	50,811	48,019
Net income	38,319	20,575	11,757	8,467	4,316
Diluted net income per common share	$2.51	$1.39	$0.82	$0.62	$0.32
Diluted common shares outstanding	15,269	14,826	14,345	13,748	13,647

Balance Sheet Data
(In thousands)

	Years ended December 31,				
	2014	2013	2012	2011	2010
Cash, cash equivalents and investments	$106,906	$63,333	$44,067	$35,777	$28,202
Working capital	133,052	85,309	62,932	49,600	36,952
Total assets	193,996	156,042	142,069	132,844	128,937
Long term debt	-	-	9,600	11,200	12,800
Retained earnings	104,904	66,584	46,010	34,252	25,786
Stockholders' equity	178,097	135,634	108,925	94,763	85,190

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

The following section 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 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 the sections captioned “Business” and “Risk Factors.” The following discussion should also be read in

conjunction with the consolidated financial statements and the Notes thereto appearing elsewhere in this Annual Report on Form 10-K.

Management Overview

We develop, manufacture, and commercialize 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. We offer therapeutic products in the following areas:

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

Orthobiologics

Our orthobiologics business contributed 82% to our product revenue for the year ended December 31, 2014. Our orthobiologics products consist of joint health and orthopedic products. Joint health products include ORTHOVISC, ORTHOVISC mini, and MONOVISC. ORTHOVISC, the lead product in this franchise, is available in the United States, Canada, and some international markets for the treatment of osteoarthritis of the knee, and in Europe and other international markets for the treatment of osteoarthritis in all joints, and it has been marketed by us internationally since 1996 through various distribution agreements. 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 certain international markets, and for the knee in the United States, Turkey, and Canada. ORTHOVISC mini and MONOVISC both became available in certain international markets during the second quarter of 2008. Our most recent product approval was received in February 2014 for MONOVISC when it was approved by the FDA for sale in the United States. The related commercial introduction of MONOVISC in the United States occurred in April 2014.

We currently offer several orthopedic products used in connection with regenerative medicine. The products currently available in Europe and certain international markets include HYALOFAST, a biodegradable support for human bone marrow mesenchymal stem cells used for cartilage regeneration and as an adjunct for microfracture surgery; HYALONECT, a woven gauze used as a bone 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 for the treatment of adhesive capsulitis prevention in the shoulder. These products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea. We believe that the U.S. market offers excellent expansion potential to increase revenue for these products, and this will continue to be a focus area for us moving forward.

Our strategy is to continue to add new products, to expand the indications for usage of both our current and any new products, and to expand our commercial reach. The orthobiologics area has been our fastest growing area, growing from 58% of our product revenue in 2010 to 82% of our product revenue in 2014. We continue to seek new

distribution partnerships around the world, in concert with entering new markets with other appropriate sales strategies, and we expect total orthobiologics product sales to increase in 2015 compared to 2014 based on sales from existing and new partners.

Dermal

Our dermal products contributed 2% to our product revenue for the year ended December 31, 2014 and consist of advanced wound care products, which are 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 as skin substitutes. Leading products include HYALOMATRIX and HYALOFILL for the treatment of complex wounds, such as burns and ulcers, and 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 cleared for sale in the United States including HYALOMATRIX, HYALOFILL, HYALOGRAN, and HYALOMATRIX 3D. In 2012, we entered into a distribution agreement for sales of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, and Chile. In July 2014, we entered into a new agreement with Medline Industries, Inc. to commercialize HYALOMATRIX in the United States on an exclusive basis through 2019.

Our initial aesthetic dermatology product is a dermal filler based on our proprietary, chemically modified, cross-linked HA, and it is approved in Europe, Canada, the United States, South Korea, and certain countries in South America. Internationally, this product is marketed under the ELEVESS trade name. In the United States, the trade name is HYDRELLE, although the product is not currently marketed in the United States.

Surgical

Our surgical group consists of products used to prevent surgical adhesions and to treat ENT disorders. For the year ended December 31, 2014, 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 it is not approved in the United States. INCERT, approved for sale in Europe, Turkey, and Malaysia, is a chemically modified, cross-linked HA product used for the prevention of post-surgical spinal adhesions. There are no plans at this time to distribute INCERT in the United States. We co-own 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 HA, a biocompatible agent that creates a moist wound-healing environment. Anika S.r.l. is partnered with Medtronic for the worldwide 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 and, as a result, we made claims against Fidia for indemnification for our losses related to this issue. Fidia maintained that it did not have liability for this matter, and asserted a counterclaim against us for failing to consent to the release of the remaining shares held in escrow upon the closing of the Anika S.r.l. acquisition. We reached an 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 us. As a result of the settlement, the arbitration with Fidia pending before the London Court of International Arbitration was withdrawn, and the shares previously held in escrow were released.

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2014, sales of ophthalmic products contributed 4% of our product revenue. We previously manufactured the AMVISC product line for B&L 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 us 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. Operating margins under the B&L agreement were low, and B&L accounted for 3% of product revenue for the year ended 2014. Our contractual arrangement with B&L expired on December 31, 2014, and it was not renewed. Given that the ophthalmic franchise is not part of our core business, and that it has been steadily diminishing for the past few years, we do not expect this event to have a material impact on our results going forward.

Veterinary

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 4% to product revenue for the year ended December 31, 2014. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Research and Development

Our research and development efforts in 2014 primarily consisted of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, including CINGAL and HYALOFAST, 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 research and development has been important over the years, and it has varied 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 in relation to clinical trials, in the future. With the acquisition of Anika S.r.l., we enhanced our research and development capabilities, our technology base and our pipeline of product candidates. Anika S.r.l. has research and development programs underway for new products including HYALOFAST, an innovative product for cartilage tissue repair, HYALOBONE, a bone void filler and other early stage regenerative medicine development programs.

In February 2014, we received FDA approval for MONOVISC, and Mitek began selling the product in the United States in the second quarter of 2014. MONOVISC is the first FDA-approved, single-injection treatment for osteoarthritis that uses non-animal sourced HA. It is also our first osteoarthritis product based on our proprietary, cross-linked HA technology. We received CE Mark approval for MONOVISC in October 2007, and we began selling in Europe through our distribution network during the second quarter of 2008.

Our second single-injection osteoarthritis product under development is CINGAL, which is based on our HA material with an added active therapeutic molecule designed to provide broad pain relief over a longer period of time. 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. We completed the CINGAL clinical trial during the fourth quarter of 2014. In December 2014, we submitted an application for CE Mark approval of the product, and we submitted a PMA to the FDA for U.S. marketing approval in February 2015. We are also currently conducting a reinjection study related to CINGAL with patients who participated in the initial clinical trial.

Restructuring Plan

On December 28, 2012 we announced the closure of our 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 IPR&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 that occurred 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 included elsewhere in this Annual Report on Form 10-K, which consolidated financial statements 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 the 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 are discussed throughout this section captioned "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 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Fair Value Measurements

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

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

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

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

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

Allowance for Doubtful Accounts

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

Inventories

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

Our policy is to write-down inventory when conditions exist that suggest inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for our products and market conditions. We regularly evaluate our 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 is 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, we evaluate both the contractual terms and conditions of our distribution and supply agreements as well as our 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.

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. We adopted Accounting Standards Update ("ASU") 2009-13, Revenue Recognition, in January 2011, which amends ASC 605-25, Multiple Element Arrangements 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 we complete our performance obligations.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Equipment and software are typically amortized over two to ten 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. 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 as income or loss.

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 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, the risk free rate of return on an investment, the 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, 2014 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit. Our goodwill balance relates entirely to the 2009 acquisition of Anika S.r.l. and has been assigned to the Anika S.r.l. reporting unit.

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, estimates of the timing of and expected costs to complete the in-process projects, projections related to regulatory approvals timelines, estimated future cash flows from product sales resulting from completed projects and in-process projects, and estimates of appropriate discount rates. Our annual assessment for impairment of IPR&D indicated that the fair value of our IPR&D as of November 30, 2014 exceeded their respective carrying values.

Through December 31, 2014 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. We continue 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. Our intangible assets are comprised of purchased developed technologies, distributor relationships, patents, and trade names. These intangible assets are carried at cost, net of accumulated amortization. Amortization is recorded on a straight-line basis over the intangible assets' useful lives, which range from approximately 5 to 16 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.

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.

Stock-Based Compensation

We measure the compensation cost of award recipients' 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. For performance based awards with financial achievement targets, we recognize expense using the graded vesting methodology based on the number of shares expected to vest. Compensation expense associated with these performance based awards is adjusted to reflect

subsequent changes in the estimated outcome of performance-related conditions until the date the results are determined. Changes to the probability assessment and the estimated shares expected to vest will result in adjustments to the related share-based compensation expense that will be recorded in the period of the change. If the performance targets are not achieved, no compensation cost is recognized and any previously recognized compensation cost is reversed. See Note 12 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K 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 16 to such consolidated financial statements for details related 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.

Results of Operations

Year ended December 31, 2014 compared to year ended December 31, 2013

Statement of Operations Detail

	Years Ended December 31,				
	2014	2013	Inc/(Dec)	Inc/(Dec)	
Product revenue	$75,473,998	$71,773,730	$3,700,268	5	%
Licensing, milestone and contract revenue	30,120,841	3,307,424	26,813,417	811	%
Total revenue	105,594,839	75,081,154	30,513,685	41	%
Operating expenses:					
Cost of product revenue	20,930,318	22,765,404	(1,835,086)	(8	%)
Research & development	8,144,152	7,059,875	1,084,277	15	%
Selling, general & administrative	15,073,485	12,936,001	2,137,484	17	%
Restructuring credits	-	(286,843)	286,843	-	
Total operating expenses	44,147,955	42,474,437	1,673,518	4	%
Income from operations	61,446,884	32,606,717	28,840,167	88	%
Interest income (expense), net	58,137	(127,186)	185,323	(146	%)
Income before income taxes	61,505,021	32,479,531	29,025,490	89	%
Provision for income taxes	23,185,542	11,905,010	11,280,532	95	%
Net income	$38,319,479	$20,574,521	$17,744,958	86	%
Product gross profit	$54,543,680	$49,008,326	$5,535,354	11	%
Product gross margin	72%	68%			

Total revenue. Total revenue for the year ended December 31, 2014 increased by $30,513,685 to $105,594,839. The increase in product and total revenue was primarily due to the U.S. MONOVISC commercial launch in April 2014 and milestone revenue from our U.S. distributor for MONOVISC, resulting from the product's FDA approval, patent litigation resolution, and commercial launch in 2014.

Product revenue by product line. Product revenue for the year ended December 31, 2014 was $75,473,998, an increase of $3,700,268 or 5%, compared to the prior year.

	Years Ended December 31,			
	2014	2013	Inc/(Dec)	Inc/(Dec)
Orthobiologics	$61,956,870	$55,956,068	$6,000,802	11 %
Dermal	1,334,295	1,816,602	(482,307)	(27 %)
Surgical	5,854,876	5,445,715	409,161	8 %
Ophthalmic	3,153,435	4,656,560	(1,503,125)	(32 %)
Veterinary	3,174,522	3,898,785	(724,263)	(19 %)
	$75,473,998	$71,773,730	$3,700,268	5 %

Revenue from our orthobiologics franchises increased $6,000,802, or 11%, in 2014 compared to 2013. The improvement in orthobiologics product revenue was due primarily to increases in domestic MONOVISC and ORTHOVISC revenue. This increase reflects MONOVISC U.S. product launch in April 2014 and Mitek's continued market penetration. International viscosupplementation product revenue in 2014 decreased 23% compared to 2013. The decrease in international revenue was driven primarily by decreased sales of ORTHOVISC in 2014, as compared to 2013, resulting from increased price competition. We expect orthobiologics revenue to grow in 2015, led by increased MONOVISC revenue in the United States, as well as overall revenue growth from our viscosupplementation products both domestically and internationally.

Dermal revenue decreased $482,307, or 27%, in 2014 compared to 2013. The decrease was primarily due to Anika S.r.l.'s advanced wound care products revenue, which totaled $1,241,453 in 2014, as compared to $1,647,396 in 2013. This decrease was driven by order timing and lower revenue in Argentina as a result of the country's recent financial crisis. We expect advanced wound care revenue to increase in 2015 compared to 2014 primarily as a result of geographic expansion, particularly in the U.S. market.

Sales of our surgical products increased $409,161, or 8%, in 2014 as compared to 2013. The increase was primarily due to the addition of line extension products in Korea to utilize an expanded treatment indication. Our Surgical franchise consists primarily of Anika S.r.l.'s anti-adhesion and ENT products. Our anti-adhesion products include INCERT and HYALOBARRIER. Our leading ENT product is MEROGEL. Anika S.r.l. is partnered with Medtronic for worldwide distribution of these ENT products. We expect surgical product revenue to increase in 2015 compared to 2014 due to continued growth in the European and Asian markets.

Revenue from ophthalmic products in 2014 decreased $1,503,125, or 32%, compared to revenue for these products in 2013. The decrease was primarily attributable to the reduced contractual minimum purchase commitment in the latest B&L supply agreement, which expired as expected at the end of 2014. As a result, we expect that ophthalmic product revenue will decrease in 2015 as compared to 2014. Operating margins under the B&L agreement were low, and given that the ophthalmic franchise is not part of our core business, and that it has been steadily diminishing for the past few years, we do not expect this event to have a material impact on our results going forward.

Veterinary revenue decreased $724,263, or 19%, in 2014 as compared to 2013. The decrease was primarily due to order timing by our distributors. Sales of HYVISC are made to a single customer under an exclusive agreement which expires December 31, 2016. We expect veterinary revenue to increase in 2015 as compared to 2014, due to increased demand for the product in the United States.

Licensing, milestone and contract revenue. Licensing, milestone, and contract revenue for the year ended December 31, 2014 was $30,120,841, compared to $3,307,424 for 2013. Licensing and milestone included a $17,500,000 milestone payment resulting from the resolution of the patent litigation with Genzyme and the FDA approval of MONOVISC, and it also included the recognition of approximately $2,200,000 remaining in the unamortized upfront payment previously received in December 2011. These payments were related to our development obligations under the Mitek MONOVISC Agreement. The FDA's approval of our MONOVISC product during the quarter ended March 31, 2014 completed the delivery of our development obligations under the Mitek

MONOVISC Agreement, and resulted in the immediate recognition of the $17,500,000 milestone payment, as well as the full recognition of prior deferred revenue in the first quarter of 2014. During the second quarter of 2014, a $5,000,000 milestone payment associated with the first commercial sale of MONOVISC in the United States was earned, received, and recognized as revenue. We also received a unique J-Code from the Centers for Medicare and Medicaid Services (“CMS”) for MONOVISC during the fourth quarter of 2014 and, as a result, we collected a milestone payment of $5,000,000, which was fully earned and recognized as revenue. For the year ended December 31, 2014, we recognized a total of $29.7 million in milestone revenue related to MONOVISC.

Product gross profit and margin. Product gross profit for the year ended December 31, 2014 was $54,543,680, or 72% of product revenue, compared with $49,008,326, or 68% of product revenue, for the year ended December 31, 2013. The increase in product gross profit was primarily due to improved manufacturing efficiencies, as well as improvements in the overall product sales mix compared to the prior year, with increased sales of our higher-margin orthobiologics products as a percentage of our total product sales.

Research and development. Research and development expenses for the year ended December 31, 2014 increased by $1,084,277, or 15%, as compared to the prior year, mainly due to the progression of certain clinical trials. Research and development expense as a percentage of total revenue was 8% and 9% for the years ended 2014 and 2013, respectively. We expect research and development expenses will increase in 2015 and thereafter compared to 2014 with our continued efforts related to CINGAL and HYALOFAST, our development efforts for tissue regenerating 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, 2014 increased by $2,137,484, or 17%, as compared to 2013. This increase was primarily due to a legal dispute settlement payment received in 2013, increases in external professional fees, and increased headcount related expenses in 2014. We expect selling, general, and administrative expenses for 2015 will increase to reflect the support required to grow our business both domestically and internationally.

Restructuring credits. On December 28, 2012, we announced a strategic shift involving the closure of our 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, we 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 that occurred 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 income was $58,137 for the year ended December 31, 2014, as compared to interest expense of $127,186 in the same period ended 2013. On November 29, 2013, we terminated our credit agreement entered into on January 31, 2008 with lenders for which Bank of America, N.A. served as administrative agent. In connection with the termination, we pre-paid in full the entire outstanding debt balance of $8,400,000, and we did not incur any pre-payment penalties. This termination resulted in the change from net interest expense in 2013 to net interest income in 2014. Interest income is primarily from our short-term investment holdings.

Income taxes. Provisions for income taxes were $23,185,542 and $11,905,010 for the years ended December 31, 2014 and 2013, respectively. The increase in the effective tax rate in 2014 of 1.0%, as compared to 2013, is primarily due to a decreased benefit from domestic production activities.

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

	Years ended December 31,			
	2014		2013	
Statutory federal income tax rate	35.0	%	35.0	%
State tax expense, net of federal benefit	4.9	%	4.8	%
Permanent items, including nondeductible expenses	0.1	%	(0.2	%)
State investment tax credit	(0.1	%)	(0.1	%)
Federal, state and foreign research and development credits	(0.7	%)	(0.5	%)
Foreign rate differential	0.2	%	0.1	%

Domestic production deduction	(1.7	%)	(2.4	%)
Effective income tax rate	37.7	%	36.7	%

As of December 31, 2014, we had net operating losses (“NOL”) for income tax purposes in Italy of $8,334,628 with no expiration date.

In connection with the preparation of the financial statements, we performed an analysis to ascertain if it was more likely than not that we would be able to utilize, in future periods, the net deferred tax assets associated with our NOL carry-forward. We have concluded that the positive evidence outweighs the negative evidence and, thus, that the deferred tax assets not otherwise subject to a valuation allowance are realizable on a "more likely than not" basis. As such, we have not recorded a valuation allowance at December 31, 2014 or 2013.

The 2011 through 2014 tax years remain subject to examination by the Internal Revenue Service ("IRS") and other taxing authorities for U.S. federal and state purposes. The 2010 through 2014 tax years remain subject to examination by the applicable governmental authorities in Italy.

Net income. For the year ended December 31, 2014, net income was $38,319,479, or $2.51 per diluted share, compared to $20,574,521, or $1.39 per diluted share, for the same period in the prior year. The primary drivers for this increase in net income were an increase in gross profit due to increased milestone and licensing revenue, a more favorable product mix, and the improved manufacturing efficiencies at our Bedford, Massachusetts manufacturing facility.

Year ended December 31, 2013 compared to year ended December 31, 2012

Statement of Operations Detail

	Years Ended December 31,			
	2013	2012	Inc/(Dec)	Inc/(Dec)
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 (credits) 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.

	Years Ended December 31,			
	2013	2012	Inc/(Dec)	Inc/(Dec)
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 reflected 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.

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.

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.

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. Operating margins under the expired B&L agreements were relatively low.

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.

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 included the ratable recognition of $27,000,000 in up-front and milestone payments related to the Mitek ORTHOVISC Agreement. These amounts were 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 Mitek ORTHOVISC Agreement for an additional five years through December 2018.

In December 2011, we entered into a fifteen-year licensing and supply agreement with Mitek, Inc. to market MONOVISC in the United States. We received an initial payment of $2,500,000 in December 2011, which is also being recognized ratably over the development obligation period. We received a PMA from the FDA for MONOVISC in February 2014, and were entitled to receive additional payments from Mitek, following achievement of the PMA 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 increased 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 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. Research and development as a percentage of revenue was 9% and 8% for the years ended 2013 and 2012, respectively.

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.

Restructuring charges. On December 28, 2012 we announced a strategic shift involving the closure of our 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, we 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 was the result of the lower balance on our outstanding variable interest rate debt during 2013. On November 29, 2013, we terminated our credit agreement entered into on January 31, 2008 with lenders for which Bank of America, N.A. served as administrative agent. In connection with the termination, we pre-paid in full the outstanding debt balance of $8,400,000, 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, was 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:

	Years 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, we had 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, we performed an analysis to ascertain if it was more likely than not that we would be able to utilize, in future periods, the net deferred tax assets associated with our NOL carry-forward. We concluded that the positive evidence outweighs the negative evidence and, thus, that the deferred tax asset not otherwise subject to a valuation allowance were realizable on a “more likely than not” basis. As such, we did not record a valuation allowance at either December 31, 2013 or 2012.

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.

Concentration of Risk

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, 2014, five customers accounted for 85% of product revenue, with Mitek alone accounting for 72% of product revenue. We expect to continue to be dependent on a small number of large customers, especially Mitek, for the majority of our revenues for the foreseeable future. The failure of these customers to purchase our products in the amounts they historically have or in amounts that we expect 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 agreements, 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, it could seriously harm our business, financial condition, and results of operations.

See Note 15, Revenue by Product Group, by Significant Customer and by Geographic region; Geographic Information, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information regarding significant customers.

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, investments and debt, have met our cash requirements. Cash, cash equivalents and investments totaled $106.9 million and $63.3 million, and working capital totaled $133.1 million and $85.3 million, at December 31, 2014 and December 31, 2013, respectively. We believe that we have adequate financial resources to support our business for at least the next twelve months.

Cash provided by operating activities was $39,978,375, $25,165,001 and $10,548,677 for 2014, 2013, and 2012, respectively. Cash provided by operating activities increased by $14,813,374 in 2014, as compared to the same period ended 2013. The increase was primarily attributable to a total of $29.7 million milestone payments recognized under the Mitek MONOVISC Agreement, which was partially offset by an increase in inventory due to anticipated future sales demand.

Cash used in investing activities was $8,302,922, $253,155 and $1,504,707 in 2014, 2013, and 2012, respectively. The increase in cash used in investing activities in 2014, as compared to the same period in the prior year, is a result of purchases of investments and increased capital purchases associated with our Bedford facility during 2014. We expect an increase in investing activities in 2015 as a result of our decision to establish additional manufacturing capabilities at the Bedford, Massachusetts facility. We expect to spend approximately $8 million in 2015 related to this activity.

Cash provided by financing activities was $5,331,871 for 2014, whereas cash used in financing activities was $5,689,229, and $758,854 in 2013 and 2012, respectively. Cash provided by financing activities for 2014 was due to primarily to proceeds from the exercise of stock options of $2.1 million, and the related tax benefit from the exercise of stock options of $9.6 million. This increase was partially offset by $6.3 million of minimum tax withholdings on share-based awards.

Contractual Obligations and Other Commercial Commitments

We incurred significant capital investments related to the build-out of our manufacturing 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 marketing, license, and 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 of 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 or other appropriate commercial strategies 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 demand.

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. 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 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.

The table below summarizes our non-cancelable operating leases and contractual obligations at December 31, 2014:

		Payments due by period			
	Total	Less than 1 year	1 - 3 years	4 - 5 years	More than 5 years
Operating Leases (1)	$8,185,997	$1,547,414	$1,943,000	$1,943,000	$2,752,583
Purchase Commitments	983,190	728,230	187,712	67,248	-
Total	$9,169,187	$2,275,644	$2,130,712	$2,010,248	$2,752,583

(1) Included in this line is a lease we entered into on January 4, 2007, pursuant to which we lease our corporate headquarters facility, which consists of approximately 134,000 square feet of general office, research and development, 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, ranging in length from 5 to 6 years, 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. Also included in this line is a lease entered into pursuant to which Anika S.r.l. leases its Italian facility, which consists of approximately 28,000 square feet of space. The lease commenced on December 30, 2009 for a period of six years with certain extension options. See the section captioned “Properties” for additional information

regarding these leases.

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 above, 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 May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers." ASU 2014-09 supersedes the revenue recognition requirements in "Topic 605, Revenue Recognition" and requires entities to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Effective for the Company beginning on January 1, 2017, the amendment allows for two methods of adoption, a full retrospective method or a modified retrospective approach with the cumulative effect recognized at the date of initial application. Early adoption is not permitted. We are in the process of determining the method of adoption and the impact of this amendment on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Primary Market Risk Exposures

We manage our investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain a high degree of liquidity to meet operating and other needs, and obtain competitive returns subject to prevailing market conditions without significantly increasing risk. To achieve this objective, we maintain our portfolio of cash equivalents and investments in a variety of high quality securities, including money market funds and bank certificates of deposits. The investments are classified as available-for-sale and consequently are recorded at fair value with unrealized gains or losses reported as a separate component of accumulated other comprehensive income. Our portfolio of cash equivalents and investments is subject to interest rate fluctuations, changes in credit quality of the issuer and other factors.

Foreign Exchange Risk

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 2014. 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.

A significant portion of Anika S.r.l.’s revenue, and all operating expenses, are denominated in Euros, which leaves us 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, 2014 and December 31, 2013 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 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, 2014, based on criteria established in Internal Control - Integrated Framework (2013) 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, 2015

Anika Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets

ASSETS	December 31, 2014	2013
Current assets:		
Cash and cash equivalents	$100,155,864	$63,333,160
Investments	6,750,000	-
Accounts receivable, net of reserves of $146,618 and $593,023 at December 31, 2014 and 2013, respectively	17,152,028	18,736,845
Inventories	12,406,776	10,996,785
Prepaid income taxes	412,301	-
Current portion deferred income taxes	1,188,768	659,040
Prepaid expenses and other	959,305	865,957
Total current assets	139,025,042	94,591,787
Property and equipment, at cost	53,619,589	52,413,423
Less: accumulated depreciation	(21,950,706)	(19,474,712)
	31,668,883	32,938,711
Long-term deposits and other	69,042	69,080
Intangible assets, net	14,894,710	18,998,409
Goodwill	8,338,699	9,443,894
Total Assets	$193,996,376	$156,041,881
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,201,226	$2,793,911
Accrued expenses	4,747,526	5,537,881
Deferred revenue	24,510	180,433
Income taxes payable	-	770,276
Total current liabilities	5,973,262	9,282,501
Other long-term liabilities	893,935	1,133,544
Long-term deferred revenue	102,192	2,054,941
Deferred tax liabilities	8,929,890	