

Anika Therapeutics, Inc.  
Form 10-K  
March 10, 2016

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-K**

(Mark  
One)

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

**For the fiscal year ended December 31, 2015**

☐ **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 ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

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

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

Non-accelerated filer ☐

Large accelerated filer ☐ Accelerated filer ☒ (Do not check if a smaller reporting company) ☐  
reporting company)

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

The aggregate market value of voting and non-voting equity held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) as of June 30, 2015, the last day of the Registrant’s most recently completed second fiscal quarter, was \$483,203,467 based on the close price per share of common stock of \$33.03 as of such date as reported on the NASDAQ Global Select Market. At March 4, 2016, there were issued and outstanding 14,330,207 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, 2015. 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, 2015**

**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 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 orthobiologics products, including expectations related to our existing products, our new products, including CINGAL, expanded uses of existing products, new distribution and sales models and partnerships, and revenue growth;

Our intention to increase our market share for orthobiologics 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 product development, clinical trials, regulatory approvals, and commercial launches;

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

Our expectations regarding product gross margin;

Our expectations regarding CINGAL, including our ability to obtain regulatory approvals and commercialize this product ourselves in the United States and with distribution partners in other territories;

Our expectations regarding HYALOFAST, including the expenses associated therewith, and our ability to obtain regulatory approvals for the product in the United States and other international markets outside of the European Union;

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;

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 our orthopedic and other product franchises, 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;

Our ability to successfully manage the implementation of our direct sales model for CINGAL, and other future products, in the United States initially through a contract sales organization, and our ability to successfully transition the direct sales function into our organization as part of a broader buildout of our commercial capabilities;

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, Massachusetts facility, and our ability to achieve planned results from this transfer; and



Our expectations related to, and our ability to manage, the physical move of our Italian subsidiary from its current facility to its newly-leased facility.

*Furthermore, statements identified by words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “intend,” “s,” “designed,” “develop,” “would,” “future,” “can,” “could,” and other expressions that are predictions of or indicate future e and 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 are a global, integrated orthopedic medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. We have over two decades of expertise developing, manufacturing and commercializing more than 20 products, in markets across the globe, based on our proprietary hyaluronic acid (“HA”) technology. Our orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration.

Our therapeutic offerings consist of products in the following areas: Orthobiologics, Dermal, Surgical, Ophthalmic, and Veterinary. All of our products are based on 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 proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies HA to allow for longer residence time in the body. We also offer products made from HA based on two other technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Our technologies are protected by an extensive portfolio of owned and licensed patents.

Since our inception in 1992, we have utilized a commercial partnership model for the distribution of our products to end users. Our strong, worldwide network of distributors has historically provided, and continues to provide, a solid foundation for our revenue growth and territorial expansion. In 2015, we made the strategic decision to commercialize our next generation viscosupplementation product, CINGAL, in the United States by utilizing a direct sales model, initially through the engagement of a contract sales organization. Ultimately, we intend to transition the direct sales function into our company as part of a broader buildout of our commercial capabilities. We believe that the combination of the direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio.

We began a strategic project in 2015 to move the manufacturing of our HYAFF-based products, which currently are manufactured by a third party in Italy, to our Bedford, Massachusetts facility. Our main purposes behind this strategic move are to improve the efficiency of our manufacturing process and to enhance our research and development capabilities, with the aim of accelerating future product development. We expect to expend approximately \$15 million on this project over the course of the next 12 to 18 months.

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

### *Orthobiologics*

Our orthobiologics products primarily consist of viscosupplementation and regenerative orthopedics 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 results 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 viscosupplementation franchise includes ORTHOVISC, ORTHOVISC *mini*, MONOVISC, and CINGAL. 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 became available in certain international markets in the second quarter of 2008. MONOVISC was approved by the FDA for sale in the United States in February 2014, and the related U.S. commercial introduction of the product occurred in April 2014. CINGAL, our second single-injection osteoarthritis product, received regulatory approval from Health Canada in November 2015, and we expect the related commercial introduction of CINGAL in Canada to occur in the second quarter of 2016. We are currently seeking regulatory approval of CINGAL in the United States and the European Union. Upon achievement, if any, of such regulatory approval in the United States, we plan to commercialize the product through a direct sales model, initially through the engagement of a contract sales organization, with the ultimate goal of transitioning the direct sales function into our company as part of a broader buildout of our commercial capabilities.

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 four 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. In total, orthobiologics products accounted for 84%, 82%, and 78% of our product revenue in 2015, 2014, and 2013 respectively.

### *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 the United States, 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. We previously entered into a distribution agreement for the sale of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, and Chile, on an exclusive basis through 2018. We have also 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 certain European Union countries, 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 post-surgical adhesions after abdominal-pelvic, spinal, and ear, nose, and throat (“ENT”) surgeries. HYALOBARRIER is a clinically proven post-operative adhesion barrier for use in the abdominopelvic area. The product is currently commercialized 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 and commercialized through a network of distributors 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.

We offer 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. We have partnered with Medtronic Xomed, Inc. (“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. (“Boehringer”) in the United States and in selected countries in the Middle East.

See Note 16 “*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.

See also the section captioned “*Risk Factors—Risks Related to Our Business and Industry—Our manufacturing processes involve inherent risks, and disruption could materially adversely affect our business, financial condition and results of operations*” for a discussion of the sources and availability of raw materials related to the manufacture of our products.

**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, 2015, 2014 and 2013, these expenses were \$9.0 million, \$8.1 million, and \$7.1 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including in relation to clinical trials, in the future.



Our second single-injection osteoarthritis product under development is CINGAL, which is composed of our proprietary cross-linked HA material combined with an approved steroid and is designed to provide both short- and long-term pain relief to patients. We completed the CINGAL phase III clinical trial and associated statistical analysis during the fourth quarter of 2014. During the first half of 2015, we completed a CINGAL retreatment study with patients who had participated in the phase III clinical trial and reported safety data related to the retreatment study. On the regulatory front, we submitted an application for CE Mark approval of the product in December 2014, and we expect to achieve approval by the end of April 2016. In May 2015, we also submitted an application for regulatory approval of CINGAL to Health Canada, and we received notification of approval for CINGAL from Health Canada in early November 2015. After discussion with the FDA related to the regulatory pathway for CINGAL in the United States, we conducted a formal meeting with the FDA's Office of Combination Products ("OCP") to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to the Center for Drug Evaluation and Research ("CDER") as the lead agency center for premarket review and regulation. Since then, we have been in ongoing discussions with CDER to understand the requirements for submitting a New Drug Application ("NDA") for CINGAL, and preliminary indications from the FDA suggest that additional clinical work may be required. We will meet with the FDA to collaboratively discuss this topic.

We have research and development programs underway for new products including for HYALOFAST, an innovative product for cartilage tissue repair, HYALOBONE, a bone void filler, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption ("IDE") to the FDA, which was approved in July 2015. We are in the early stages of the phase III clinical trial for HYALOFAST, and we enrolled our first patient in December 2015. Another of our products, HYALOSPINE, is an innovative adhesion prevention gel for use after spinal surgery. We completed a HYALOSPINE pilot clinical study in 2012, submitted the CE Mark application in September 2013, and received the CE Mark approval in January 2015.

In June 2015, we entered into an agreement with the Institute for Applied Life Sciences at the University of Massachusetts Amherst to collaborate on research to develop a therapy for rheumatoid arthritis. The purpose of this research is to develop a novel modality for the treatment of rheumatoid arthritis, and if successful, it is expected to yield a potential product candidate that we could begin to move towards commercialization as early as 2017.

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 26 patents, 2 of which are co-owned with other parties, license 18 patents, and have 2 patent applications currently pending. These U.S. patents have expiration dates through 2030. Internationally, we own 190 patents, 7 of which are co-owned with other parties, license 88 patents, and have 10 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. (“Fidia”), 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.

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**

The clinical development, manufacturing, and marketing of our products are subject to governmental regulation in the United States, the European Union and other territories worldwide. Various statutes, regulations, directives, and guidelines, including the Food, Drug, and Cosmetics Act in the United States, govern the development, design, non-clinical and clinical research, testing, manufacture, safety, efficacy, labeling, packaging, storage, record keeping, premarket clearance or approval, adverse event reporting, advertising, and promotion of our products. Product development and approval within these various regulatory frameworks takes a number of years and involves the expenditure of substantial resources. Pharmaceutical and medical device manufacturers are also inspected regularly by the FDA and other applicable regulatory bodies.

Medical products regulated by the FDA are generally classified as drugs, biologics, 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 effectiveness. Class II devices are cleared for marketing under the premarket notification 510(k) regulatory pathway, which may include clinical testing. Class III devices require pre-market approval based on valid scientific evidence of safety and effectiveness, including evidence elicited through appropriate clinical testing. Drugs and biologic products undergo rigorous preclinical testing prior to beginning clinical trials. Clinical trials for new drugs or biologic products include Phase I trials in healthy volunteers to understand safety, dosage tolerance, and pharmacokinetics, Phase II trials in a limited patient population to identify initial efficacy and side effects, and Phase III pivotal trials to statistically evaluate the safety and efficacy of the product. The failure to demonstrate adequately the quality, safety, and efficacy of a product under development can delay or prevent regulatory approval of the product. In order to gain marketing approval, we must submit to the relevant regulatory authority for review information on the quality aspects of the product as well as the non-clinical and clinical data. The FDA undertakes this review in the United States.

In the European Union, medical devices must be CE Marked in order to be marketed. CE marking a device involves working with a Notified Body, and in some cases a Competent Authority, to demonstrate that the device meets all applicable requirements of the Medical Devices Directive and that our Quality Management System is compliant. Drug approval in the European Union follows one of several possible processes: (i) a centralized procedure involving members of the European Medicines Agency's Committee for Medicinal Products for Human Use; (ii) a "mutual recognition procedure" in which an individual country's regulatory agency approves the product followed by "mutual recognition" of this review by regulatory agencies of other countries; or (iii) a decentralized procedure in which the approval is sought through the regulatory agencies of multiple countries at the same time.

Approval timelines can range from several months to several years, or applications can be denied entirely. The approval process can be affected by a number of factors. For example, additional studies or clinical trials may be requested during the review, which may delay marketing approval and involve unbudgeted costs. As a condition of approval, the regulatory agency may require post-marketing surveillance to monitor for adverse effects, and may require other additional studies, as it deems appropriate. After approval for an initial indication, further clinical studies are generally necessary to gain approval for any additional indications. The terms of any approval, including labeling content, may be more restrictive than expected and could affect the marketability of a product.

As a condition of approval, the relevant regulatory agency requires that the product continues to meet applicable regulatory requirements related to quality, safety, and efficacy, and it requires strict procedures to monitor and report any adverse effects. Where adverse effects occur or may occur, the regulatory agency may require additional studies or changes to the labeling. Compelling new "adverse" data may result in a product approval being withdrawn at any stage following review by an agency and discussion with product manufacturer.

The branch of the FDA responsible for product marketing oversight routinely reviews company marketing practices and also may impose pre-clearance requirements on materials intended for use in marketing of approved drug products. We are also subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Similar review and regulation of advertising and marketing practices exists in the other geographic areas where the company operates.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, such as issuing an FDA Form 483 notice of inspectional observations, a warning letter, an untitled letter, imposing civil money penalties, suspending or delaying issuance of approvals, requiring product recall, imposing a total or partial shutdown of production, withdrawal of approvals or clearances already granted, pursuing product seizures, consent decrees or other injunctive relief, or criminal prosecution through the Department of Justice. The FDA can also require us to repair, replace or refund the cost of products that we manufactured or distributed. Outside the US, regulatory agencies may exert a range of similar powers.

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## 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 strategic activities related to the significant expansion of our business or product portfolio.

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 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 price concessions or if we are excluded as a supplier by these market makers, our product revenue 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 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*” for additional discussion of the impact competition could have on our business and financial results.

## **Employees**

As of December 31, 2015, we had 107 employees, 20 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 \$5.0 million per occurrence and \$5.0 million 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](http://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, 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.

***We are implementing a direct sales model to commercialize our CINGAL product, as well as certain other future products, in the United States and we may face unforeseen difficulties and delays in implementing this new model, which could affect our business and financial results.***

For the first time, we are implementing a direct sales model to market and promote one of our products, CINGAL, in the United States, initially through a contract sales organization, with the ultimate goal of transitioning the direct sales function into our company as part of a broader buildout of our commercial capabilities. We may also use this direct model to commercialize other of our products in the United States in the future. Our success in utilizing this sales model will initially depend in part on our ability to successfully develop and implement the necessary internal and external resources to manage the contract sales organization and the sales of the product. Our longer term success will depend on our ability to transition the direct sales function into our company and to manage all resources associated with this function. We cannot assure you that there will not be unforeseen roadblocks or delays in finalizing the contracts related to, and implementing, the relationship with the contract sales organization, nor we can we assure you that we will not face setbacks in transitioning the direct sales function into our organization. The initial implementation timeline of this direct sales model is also dependent on CINGAL obtaining FDA approval in a timely manner, of which there is no guarantee. Failure to timely implement our direct sales model or to successfully manage the implementation or transition process 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 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, Mitek accounted for 72% of our product revenue in fiscal year 2015. 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 are in the process of transferring the manufacturing of our HYAFF products from Italy to our Bedford, MA facility, which carries inherent risks of supply interruption.***

We are currently in the process of transferring the manufacturing responsibilities for our HYAFF products from our current contract manufacturer in Italy to our facility in Bedford, MA. This process requires us to take several steps including, but not limited to, building excess inventory of the products, finishing the necessary construction at our Bedford facility to allow the transfer of equipment, removing our equipment from our contract manufacturer's facility, properly packaging and storing the manufacturing equipment for transportation to the United States from Italy, installing the equipment in the Bedford facility, and validating the equipment and achieving regulatory approval of the manufacturing processes in accordance with all applicable law and regulations. There is no guarantee that any of these activities will not become delayed or otherwise disrupted, which could lead to a supply interruption for the HYAFF products. Such an interruption could ultimately have a material adverse effect on our business, financial condition, and results of operations.

***Our Italian subsidiary, Anika Therapeutics S.r.l. (“Anika S.r.l.”) is moving from its current facility in Abano Terme, Italy to a new facility in Padova, Italy, and there is no guarantee that this facility move will not result in an interruption of our business.***

Anika S.r.l. currently occupies warehousing, research and development, and administrative space in Abano Terme, Italy. In October 2015, Anika S.r.l. entered into a build-to-suit lease agreement to lease a new warehousing, research and development, and administrative facility in Padova, Italy. We expect that we will move into this new facility in at the end of 2016. There is no guarantee that this move will be completed smoothly and in a timely manner due to, among other things, unexpected construction delays or unexpected difficulties related to the lessor achieving necessary permitting, and any delay has the potential to cause a disruption to our business activities. If there is a business disruption or the move is delayed, this could ultimately have a material adverse effect on our business, financial condition, and results of operations.

***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 may face circumstances in the future that will result in impairment charges, including, but not limited to, goodwill impairment and In-Process Research and Development (“IPR&D”) charges.***

As of December 31, 2015, we had long-lived assets, including goodwill, of \$59 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.

***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.

***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 \$138.5 million at December 31, 2015. Our future capital requirements and the adequacy of available funds will depend, however, on numerous factors, including:

- Market acceptance of our existing and future products;

The success and sales of our products under various distributor agreements and other appropriate commercial strategies, 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 \$5.0 million per occurrence and \$5.0 million in the aggregate to cover such product liability claims should they arise, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operations.

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

We are highly dependent on the members of our management and technical staff, the loss of one or more of whom could have a material adverse effect on us. We have experienced a number of management changes in recent years, 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, 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, 2015, 2014, and 2013, 18%, 13%, and 23%, 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 10% of our business during fiscal year 2015 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 who resell our products to end-users, and most of these customers are significantly larger companies than us. For the year ended December 31, 2015, five customers accounted for 84% 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.

***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.

Anika S.r.l. currently leases 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, with the current lease being a six year lease that Anika may terminate at any time by providing six months' notice. On October 9, 2015, Anika S.r.l. entered into a build-to-suit lease agreement for a new European headquarters facility, consisting of approximately 33,000 square feet of general office, research and development, training, and warehousing space located in Padova, Italy. The lease has an initial term of fifteen years, which is expected to commence during the fourth quarter of 2016. The lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The Company has the ability to early withdraw from this lease subject to certain financial penalties after six years and with no penalties after the ninth year. The lease provides for an initial yearly rent of approximately \$0.4 million.

For the year ended December 31, 2015, we had aggregate facility lease expenses of approximately \$1.3 million. 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. Upon Anika S.r.l.'s move into its new facility, we believe that the property will be sufficient to satisfy its then-current needs, as well as its 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.

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, 2015	High	Low
First Quarter	\$45.35	\$37.05
Second Quarter	41.30	31.36
Third Quarter	39.24	30.93
Fourth Quarter	43.82	30.94

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

At December 31, 2015, the closing price per share of our common stock was \$38.16 as reported on the NASDAQ Global Select Market, and there were 146 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, due to shares being held by intermediaries.

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.

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## 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, 2010 in our common stock and each of the indices. Past performance is not indicative of future results.

	Dec-10	Dec-11	Dec-12	Dec-13	Dec-14	Dec-15
Anika Therapeutics, Inc.	\$100.00	\$146.93	\$149.03	\$572.11	\$610.79	\$572.11
NASDAQ Composite Index	\$100.00	\$98.20	\$113.82	\$157.44	\$178.53	\$188.75
NASDAQ Biotechnology Index	\$100.00	\$111.81	\$147.48	\$244.24	\$327.52	\$364.93

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**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, 2015 and 2014 and the Statement of Operations Data for each of the three years ended December 31, 2015, 2014, and 2013 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, 2013, 2012, and 2011, and the Statement of Operations Data for each of the two years in the period ended December 31, 2012 and 2011 have been derived from audited consolidated financial statements for such years not included in this Annual Report on Form 10-K.

	Years ended December 31,				
	2015	2014	2013	2012	2011
Statements of Operations Data:	(in thousands, except per share data)				
Product revenue	\$87,696	\$75,474	\$71,774	\$68,010	\$61,956
Licensing, milestone and contract revenue	5,303	30,121	3,307	3,348	2,822
Total revenue	92,999	105,595	75,081	71,358	64,778
Cost of product revenue	21,053	20,930	22,765	28,989	26,784
Product gross profit	66,643	54,544	49,009	39,021	35,172
Product gross margin	76%	72%	68%	57%	57%
Total operating expenses	44,865	44,148	42,474	51,643	50,811
Net income	30,758	38,319	20,575	11,757	8,467
Diluted net income per common share	\$2.01	\$2.51	\$1.39	\$0.82	\$0.62
Diluted common shares outstanding	15,321	15,269	14,826	14,345	13,748

	Years ended December 31,				
	2015	2014	2013	2012	2011
Balance Sheet Data:	(in thousands)				
Cash, cash equivalents and investments	\$138,458	\$106,906	\$63,333	\$44,067	\$35,777
Working capital*	159,155	131,863	84,650	60,900	47,680
Total assets	235,748	192,808	156,042	142,069	132,844
Long term debt	-	-	-	9,600	11,200
Retained earnings	135,662	104,904	66,584	46,010	34,252
Stockholders' equity	210,848	178,098	135,634	108,925	94,763

\* In 2015, the Company adopted new accounting guidance related to the presentation of deferred income taxes, which has been applied above retrospectively. Current deferred tax assets and liabilities have been reclassified as non-current deferred tax assets and liabilities.

**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 are a global, integrated orthopedic medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. We have over two decades of expertise developing, manufacturing, and commercializing our products, in markets across the globe, based on our proprietary hyaluronic acid (“HA”) technology. Our orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration.

Our therapeutic offerings consist of products in the following areas: Orthobiologics, Dermal, Surgical, Ophthalmic, and Veterinary. All of our products are based on 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 proprietary technologies for modifying the HA molecule allow product properties to be tailored specifically to therapeutic use. Our patented technology chemically modifies HA to allow for longer residence time in the body. We also offer products made from HA based on two other technologies: HYAFF, which is a solid form of HA, and ACP gel, an autocross-linked polymer of HA. Our technologies are protected by an extensive portfolio of owned and licensed patents.

Since our inception in 1992, we have utilized a commercial partnership model for the distribution of our products to end users. Our strong, worldwide network of distributors has historically provided, and continues to provide, a solid foundation for our revenue growth and territorial expansion. In 2015, we made the strategic decision to commercialize our next generation viscosupplementation product, CINGAL, in the United States ourselves, initially through the engagement of a contract sales organization. Ultimately, we intend to transition the entirety of the direct sales function into our company as part of a broader buildout of our commercial capabilities. We believe that the combination of the direct and distribution commercial models will maximize the revenue potential from our current and future product portfolio.

We began a strategic project in 2015 to move the manufacturing of our HYAFF-based products, which currently are manufactured by a third party in Italy, to our Bedford, Massachusetts facility. Our main purposes behind this strategic move are to improve the efficiency of our manufacturing process and to enhance our research and development capabilities, with the aim of accelerating future product development. We expect to expend approximately \$15 million on this project over the course of the next 12 to 18 months.

The following sections provide more information about our products:

### *Orthobiologics*

Our orthobiologics business contributed 84% of our product revenue for the year ended December 31, 2015. Our orthobiologics products primarily consist of viscosupplementation and regenerative orthopedic products. Viscosupplementation products include ORTHOVISC, ORTHOVISC *mini*, and MONOVISC, each of which is commercialized in various territories worldwide, and CINGAL, which we plan to launch internationally in Canada and Europe in 2016. ORTHOVISC 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. It has been marketed by us in the United States since 2004 and 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 through our network of distributors during the second quarter of 2008, and the commercial introduction of MONOVISC in the United States occurred in April 2014. CINGAL, our second single-injection osteoarthritis product, received regulatory approval from Health Canada in November 2015, and we expect the related commercial introduction of CINGAL in Canada to occur in the second quarter of 2016. We are currently seeking regulatory approval of CINGAL in the United States and the European Union, and we expect to receive CE Mark approval in the European Union by the end of April 2016.

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 use 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 84% of our product revenue in 2015. 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 2016 compared to 2015 based on sales to existing and new partners, as well as CINGAL international product launches, including in Canada and Europe. Additionally, if we achieve FDA approval of CINGAL, we plan to utilize a direct sales model to commercialize the product in the United States initially through the engagement of a contract sales organization with the ultimate goal of transitioning the direct sales function to our company as part of a broader buildout of our commercial capabilities.

### *Dermal*

Our dermal products contributed 2% to our product revenue for the year ended December 31, 2015 and consist of advanced wound care products, which are based on the HYAFF technology, and aesthetic dermal fillers. We offer 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. Our 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, HYALOGAN, and HYALOMATRIX 3D. We have a commercial partnership 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 certain European Union countries, 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, 2015, sales of surgical products contributed 7% of our product revenue. HYALOBARRIER is a clinically proven post-operative adhesion barrier for use in the abdomino-pelvic area. The product is currently commercialized in Europe, the Middle East, and certain Asian countries through a distribution network, but 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 also offer 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. We partner with Medtronic for the worldwide distribution of these products.

#### *Ophthalmic*

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2015, sales of ophthalmic products contributed 2% 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, 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. Operating margins under the B&L agreement were low, and B&L accounted for 3% of product revenue for the year ended 2014.

#### *Veterinary*

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 5% to product revenue for the year ended December 31, 2015. We continue to look at other veterinary applications and opportunities to expand geographic territories.



*Research and Development*

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, 2015, 2014 and 2013, these expenses were \$9.0 million, \$8.1 million, and \$7.1 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including in relation to clinical trials, in the future.

Our second single-injection osteoarthritis product under development is CINGAL, which is composed of our proprietary cross-linked HA material combined with an approved steroid and is designed to provide both short- and long-term pain relief to patients. We completed the CINGAL phase III clinical trial and associated statistical analysis during the fourth quarter of 2014. During the first half of 2015, we completed a CINGAL retreatment study with patients who had participated in the phase III clinical trial and reported safety data related to the retreatment study. On the regulatory front, we submitted an application for CE Mark approval of the product in December 2014, and we expect to receive such approval by the end of April 2016. In May 2015, we also submitted an application for regulatory approval of CINGAL to Health Canada, and we received notification of approval for CINGAL from Health Canada in early November 2015. After discussion with the FDA related to the regulatory pathway for CINGAL, we conducted a formal meeting with the FDA's Office of Combination Products to present and discuss our data in September 2015, and we submitted a formal request for designation with OCP a month later. In its response to our formal request for designation, OCP assigned the product to CDER as the lead agency center for premarket review and regulation. Since then, we have been in ongoing discussions with CDER to understand the requirements for submitting an NDA for CINGAL, and preliminary indications from the FDA suggest that additional clinical work may be required. We will meet with the FDA to collaboratively discuss this topic.

We have research and development programs underway for new products including for HYALOFAST, an innovative product for cartilage tissue repair, HYALOBONE, a bone void filler, and other early stage regenerative medicine development programs. HYALOFAST received CE Mark approval in September 2009, and it is commercially available in Europe and certain international countries. During the first quarter of 2015, we submitted an Investigational Device Exemption ("IDE") to the FDA, which was approved in July 2015. We are in the early stages of the phase III clinical trial for HYALOFAST, and we enrolled our first patient in December 2015. Another of our products, HYALOSPINE, is an innovative adhesion prevention gel for use after spinal surgery. We completed a HYALOSPINE pilot clinical study in 2012, submitted the CE Mark application in September 2013, and received the CE Mark approval in January 2015.

In June 2015, we entered into an agreement with the Institute for Applied Life Sciences at the University of Massachusetts Amherst to collaborate on research to develop a therapy for rheumatoid arthritis. The purpose of this research is to develop a novel modality for the treatment of rheumatoid arthritis, and if successful, it is expected to yield a potential product candidate that we could begin to move towards commercialization as early as 2017.

## **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. 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.

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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.

#### *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 estimated or reported sales results 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. Our business strategy includes entering into collaborative license, development, and/or supply agreements with partners for the development and commercialization of our 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.

### *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. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if we believe there is probable future commercial use and future economic benefit.

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.

### *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 our reporting unit 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, 2015 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D project is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. We estimate the fair value for IPR&D projects using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. During the fourth quarter of 2015 we performed an impairment review of our IPR&D projects as we reassessed our R&D strategy. We recorded an impairment charge of \$0.7 million due to the decision to discontinue further development efforts needed to commercialize this technology. Our annual assessment for impairment of IPR&D indicated that the fair value of our other IPR&D assets as of November 30, 2015 exceeded their respective carrying values.

Through December 31, 2015 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 our 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.

### *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 cost associated with performance grants is estimated using the Black-Scholes valuation method multiplied by the expected number of shares to be issued, which is adjusted based on the estimated probabilities of achieving the performance goals. 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 13 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 17 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, 2015 compared to year ended December 31, 2014***

## Statement of Operations Detail

	Years Ended December 31,				
	2015	2014	\$	%	
			Inc/(Dec)	Inc/(Dec)	
	(in thousands, except percentages)				
Product revenue	\$87,696	\$75,474	\$12,222	16	%
Licensing, milestone and contract revenue	5,303	30,121	(24,818)	(82	%)
Total revenue	92,999	105,595	(12,596)	(12	%)
Operating expenses:					
Cost of product revenue	21,053	20,930	123	1	%
Research & development	8,987	8,144	843	10	%
Selling, general & administrative	14,825	15,074	(249 )	(2	%)
Total operating expenses	44,865	44,148	717	2	%
Income from operations	48,134	61,447	(13,313)	(22	%)
Interest income, net	120	58	62	107	%
Income before income taxes	48,254	61,505	(13,251)	(22	%)
Provision for income taxes	17,496	23,186	(5,690 )	(25	%)
Net income	\$30,758	\$38,319	\$(7,561 )	(20	%)
Product gross profit	\$66,643	\$54,544	\$12,099	22	%
Product gross margin	76%	72%			

*Total revenue.* Total revenue for the year ended December 31, 2015 decreased by \$12.6 million to \$93.0 million compared to the prior year. Total revenue decreased primarily due to the recognition of approximately \$29.7 million in milestone and contract revenue recognized in the year ended December 31, 2014 associated with the Mitek MONOVISC Agreement, which was partially offset by \$5 million of milestone revenue received in 2015 for the achievement of a target MONOVISC U.S. end user sales threshold.

*Product revenue by product line.* Product revenue for the year ended December 31, 2015 was \$87.7 million, an increase of \$12.2 million, or 16%, compared to the prior year. Product revenue increases in our Orthobiologics, Dermal, and Veterinary franchises were partially offset by moderate decreases in revenue as a result of the unfavorable impact from foreign currency exchange rate fluctuations. The increases were also offset by decreases related to the B&L supply agreement, which expired as expected at the end of 2014. Included in product revenue for the year ended December 31, 2015 was approximately \$1.8 million and \$0.5 million of non-recurring revenue recorded in the second and third quarter of 2015, respectively, related to a high end-user average selling price for MONOVISC products sold to our U.S. partner, Mitek, prior to the fourth quarter of 2014. Products sold to Mitek after the third quarter of 2014 are not impacted by this arrangement, which will not result in additional related revenue.



	Years Ended December 31,			
	2015	2014	\$	%
			Inc/(Dec)	Inc/(Dec)
	(in thousands, except percentages)			
Orthobiologics	\$73,247	\$61,957	\$11,290	18 %
Dermal	2,266	1,334	932	70 %
Surgical	5,812	5,855	(43 )	(1 %)
Other	6,371	6,328	43	1 %
	\$87,696	\$75,474	\$12,222	16 %

Revenue from our orthobiologics franchises increased \$11.3 million, or 18%, in 2015 compared to 2014. The growth in 2015 reflected a growing end-user demand, continued market penetration, increased revenue from worldwide ORTHOVISC and worldwide MONOVISC sales, as well as the non-recurring product revenue discussed in the prior section. Domestic ORTHOVISC and MONOVISC end user sales increased 24% in 2015 compared to 2014. These increases were partially offset by decreases in product sales to Mitek as a result of its planned reduction in inventory, which was completed during the third quarter of 2015. International viscosupplementation product revenue in 2015 increased 42% compared to 2014. The increase in international revenue was driven primarily by increased sales of MONOVISC and ORTHOVISC in 2015, as compared to 2014, resulting from growing end-user demand. We expect orthobiologics revenue to continue to grow in 2016, led by increased MONOVISC revenue in the United States, the expected commercial launch of CINGAL in Canada and Europe, as well as overall revenue growth from our viscosupplementation products both domestically and internationally.

Dermal revenue increased \$0.9 million, or 70%, in 2015 compared to 2014. The increase as compared to 2014 primarily reflects revenue from the agreement we entered into in July 2014 with Medline Industries, Inc. to commercialize HYALOMATRIX in the United States on an exclusive basis through 2019. We expect advanced wound care revenue to increase in 2016 compared to 2015 primarily due increased end user demand and geographic expansion, particularly in the U.S., European, and Latin American markets.

Sales of our surgical products decreased slightly in 2015 as compared to 2014. The decrease of surgical product revenue was primarily due to the unfavorable impact from foreign currency exchange rate fluctuations compared with the same periods in the prior year. Our Surgical franchise consists primarily of our anti-adhesion and ENT products. Our anti-adhesion products include INCERT and HYALOBARRIER. Our leading ENT product is MEROGEL. We are partnered with Medtronic for worldwide distribution of these ENT products. We expect surgical product revenue to decrease moderately in 2016 compared to 2015 primarily due to continued unfavorable foreign currency exchange rates and releveing of inventory by our U.S. ENT commercial partner.

Other product revenue includes revenues from ophthalmic and veterinary products. The other product revenue decreased in 2015 from 2014 due to an increase in veterinary revenue, partially offset by a decrease in ophthalmic revenue. We expect other revenue to decrease in 2016 as compared to 2015, primarily driven by lower veterinary revenue.

*Licensing, milestone, and contract revenue.* Licensing, milestone, and contract revenue for the year ended December 31, 2015 was \$5.3 million, compared to \$30.1 million for 2014. The year over year decrease was primarily the result of the recognition of licensing and milestone revenue for the year ended December 31, 2014 of \$27.5 million for milestone payments related to development obligations under the Mitek MONOVISC Agreement. It also included the recognition of approximately \$2.2 million unamortized upfront payments previously received in December 2011. The FDA's approval of our MONOVISC product during the first quarter in 2014 completed the delivery of development obligations under the Mitek MONOVISC Agreement, and it resulted in the immediate recognition of a \$17.5 million milestone payment, as well as the full recognition of prior deferred revenue in that quarter. During the second quarter of 2014, a \$5.0 million milestone payment associated with the first commercial sale of MONOVISC in the United States was also earned, received, and recognized as revenue. We also received a unique J-Code from the Centers for Medicare and Medicaid Services for MONOVISC during the fourth quarter of 2014 and, as a result, we collected a milestone payment of \$5.0 million 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. During the fourth quarter of 2015, we collected and fully recognized revenue for a milestone payment of \$5.0 million as a result of U.S. MONOVISC annual end-user sales exceeding \$50 million. We expect that our licensing, milestone, and contract revenue will decrease in 2016 compared to 2015 in large part due to milestone achievements by us in 2015 in relation to our commercial agreement with Mitek for MONOVISC in the United States.

*Product gross profit and margin.* Product gross profit for the year ended December 31, 2015 was \$66.6 million, or 76% of product revenue, compared with \$54.5 million, or 72% of product revenue, for the year ended December 31, 2014. 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, 2015 increased by \$0.8 million, or 10%, as compared to the prior year, mainly due to a \$0.7 million expense resulting from an impairment charge related to IPR&D that was recorded in connection with our acquisition of Anika S.r.l. The charge resulted from a decision to discontinue development of the acquired Hemostatic Patch in-process development project. Research and development expense as a percentage of total revenue was 10% and 8% for the years ended 2015 and 2014, respectively. Research and development spending is expected to increase in 2016 and thereafter compared to 2015 as we further develop new products and initiate new clinical trials based on our existing technology assets, including HYALOFAST, as well as increased development activities for other products in the pipeline.

*Selling, general, and administrative.* Selling, general, and administrative expenses for the year ended December 31, 2015 decreased by \$249 thousand, or 2%, as compared to 2014. The decrease was primarily a result of the full amortization of certain intangible assets on December 31, 2014, certain former employee termination and related expenses in 2014, as well as beneficial impact from foreign currency exchange rate fluctuations. We expect selling, general, and administrative expenses for 2016 will increase to reflect the support required to grow our business both domestically and internationally.

*Income taxes.* Provisions for income taxes were \$17.5 million and \$23.2 million for the years ended December 31, 2015 and 2014, respectively. The decrease in the effective tax rate in 2015 of 1.4%, as compared to 2014, is primarily due to an increased 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,	
	2015	2014
Statutory federal income tax rate	35.0 %	35.0 %
State tax expense, net of federal benefit	4.8 %	4.9 %
Permanent items, including nondeductible expenses	(0.3 %)	0.1 %
State investment tax credit	0.0 %	(0.1 %)
Federal, state and foreign research and development credits	(0.4 %)	(0.7 %)
Foreign rate differential	0.1 %	0.2 %
Domestic production deduction	(2.9 %)	(1.7 %)
Effective income tax rate	36.3 %	37.7 %

As of December 31, 2015, we had net operating losses (“NOL”) for income tax purposes in Italy of \$6.3 million 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, 2015 or 2014.

The 2012 through 2015 tax years remain subject to examination by the Internal Revenue Service (“IRS”) and other taxing authorities for U.S. federal and state purposes. The 2011 through 2015 tax years remain subject to examination by the applicable governmental authorities in Italy.

*Net income.* For the year ended December 31, 2015, net income was \$30.8 million, or \$2.01 per diluted share, compared to \$38.3, or \$2.51 per diluted share, for the same period in the prior year. The decrease in net income and diluted earnings per share was primarily a result of the approximately \$29.7 million in milestone and contract revenue recognized for the year ended December 31, 2014 associated with our U.S. license agreement for MONOVISC.

***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)	
	(in thousands, except percentages)				
Product revenue	\$75,474	\$71,774	\$3,700	5	%
Licensing, milestone and contract revenue	30,121	3,307	26,814	811	%
Total revenue	105,595	75,081	30,514	41	%
Operating expenses:					
Cost of product revenue	20,930	22,765	(1,835 )	(8	%)
Research & development	8,144	7,060	1,084	15	%
Selling, general & administrative	15,074	12,936	2,138	17	%
Restructuring credits	-	(287 )	287	(100	%)
Total operating expenses	44,148	42,474	1,674	4	%
Income from operations	61,447	32,607	28,840	88	%
Interest income (expense), net	58	(127 )	185	(146	%)
Income before income taxes	61,505	32,480	29,025	89	%
Provision for income taxes	23,186	11,905	11,281	95	%
Net income	\$38,319	\$20,575	\$17,744	86	%
Product gross profit	\$54,544	\$49,009	\$5,535	11	%
Product gross margin	72%	68%			

*Total revenue.* Total revenue for the year ended December 31, 2014 increased by \$30.5 million to \$105.6 million. 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, commercial launch, and the achievement of a unique reimbursement code from the Centers for Medicare and Medicaid Services in 2014.

*Product revenue by product line.* Product revenue for the year ended December 31, 2014 was \$75.5 million, an increase of \$3.7 million, or 5%, compared to the prior year.

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	Years Ended December 31,			
	2014	2013	\$	%
			Inc/(Dec)	Inc/(Dec)
	(in thousands, except percentages)			
Orthobiologics	\$61,957	\$55,956	\$6,001	11 %
Dermal	1,334	1,817	(483 )	(27 %)
Surgical	5,855	5,446	409	8 %
Other	6,328	8,555	(2,227 )	(26 %)
	\$75,474	\$71,774	\$3,700	5 %

Revenue from our orthobiologics franchises increased \$6.0 million, 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.

Dermal revenue decreased \$0.5 million, or 27%, in 2014 compared to 2013. The decrease was primarily due to decreases in advanced wound care products revenue, which totaled \$1.2 million in 2014, as compared to \$1.6 million in 2013. This decrease was driven by order timing and lower revenue in Argentina as a result of the country's recent financial crisis.

Sales of our surgical products increased \$0.4 million, 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 anti-adhesion and ENT products. Our anti-adhesion products include INCERT and HYALOBARRIER. Our leading ENT product is MEROGEL. We are partnered with Medtronic for worldwide distribution of these ENT products.

Other revenue decreased \$2.2 million, or 26%, compared to other revenue 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.

*Licensing, milestone, and contract revenue.* Licensing, milestone, and contract revenue for the year ended December 31, 2014 was \$30.1 million, compared to \$3.3 million for 2013. Licensing and milestone included a \$17.5 million 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 \$2.2 million 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 \$17.5 million 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 \$5.0 million 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 CMS for MONOVISC during the fourth quarter of 2014 and, as a result, we collected a milestone payment of \$5.0 million, 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 \$54.5 million, or 72% of product revenue, compared with \$49.0 million, or 68% of product revenue, for the year ended December 31, 2013. The increase in product gross profit was primarily due to favorable revenue mix, 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 \$1.1 million, or 15%, as compared to the prior year, mainly due to the CINGAL phase III clinical trial. Research and development expense as a percentage of total revenue was 8% and 9% for the years ended 2014 and 2013, respectively.

*Selling, general, and administrative.* Selling, general, and administrative expenses for the year ended December 31, 2014 increased by \$2.1 million, 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.

*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 \$0.3 million 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 thousand for the year ended December 31, 2014, as compared to interest expense of \$127 thousand 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 \$8.4 million, 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 \$23.2 million and \$11.9 million 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 \$8.3 million 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.

*Net income.* For the year ended December 31, 2014, net income was \$38.3 million, or \$2.51 per diluted share, compared to \$20.6 million, 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.

## 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, 2015, five customers accounted for 84% 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, even with our implementation of a direct sales model for CINGAL in the United States. 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 16, *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 \$138.5 million and \$106.9 million, and working capital totaled \$159.2 million and \$131.9 million, at December 31, 2015 and December 31, 2014, 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 \$39.1 million, \$40.0 million and \$25.2 million for 2015, 2014, and 2013, respectively. The decrease in cash provided by operations was due primarily to decreased net income compared to the same period last year, which reflected \$29.7 million in milestone and contract revenue associated with our U.S. license agreement for MONOVISC. Cash provided by operations was also impacted by an increase in net working capital requirements as compared to the same period in 2014 related to higher accounts receivable, inventory purchases and the timing of sales during the year, which was partially offset by higher levels of accounts payable at December 31, 2015.

Cash used in investing activities was \$30.2 million, \$8.3 million, and \$253 thousand for 2015, 2014, and 2013, respectively. The increase in cash used in investing activities in 2015, 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, Massachusetts headquarters and manufacturing facility. We expect an increase in investing activities in 2016 as a result of our on-going project to establish additional manufacturing capabilities at the Bedford, Massachusetts facility to manufacture our HYAFF-based products, which currently are manufactured by a third party in Italy. At December 31, 2015, we expended approximately \$9 million for this project. We expect to expend approximately \$15.0 million on this project over the course of the next twelve to eighteen months.

Cash provided by financing activities was \$1.9 million and \$5.3 million for 2015 and 2014, respectively, whereas cash used in financing activities was \$5.7 million in 2013. The decrease in cash provided by financing activities compared to the same period in the prior year was attributable to the lower tax benefits and cash received in regards to employees' exercise of equity awards.

## *Contractual Obligations and Other Commercial Commitments*

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The table below summarizes our non-cancelable operating leases, purchase commitments and contractual obligations related to future periods which are not reflected in our consolidated balance sheet at December 31, 2015. Purchase commitments relate primarily to non-cancellable inventory commitments and capital expenditures entered in the normal course of business:

	Payments due by period (in thousands)				
		Less than	1 - 3 years	3 - 5 years	More than 5 years
Operating Leases <sup>(1)</sup>	\$10,403	\$1,540	\$2,618	\$2,668	\$3,577
Purchase Commitments <sup>(2)</sup>	16,601	16,249	318	34	-
Total	\$27,004	\$17,789	\$2,936	\$2,702	\$3,577

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

- (1) 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. On October 9, 2015, Anika S.r.l. entered into a build-to-suit lease agreement for a new European headquarters facility consisting of approximately 33,000 square feet of general office, research and development, training, and warehousing space located in Padova, Italy. This lease has an initial term of fifteen years, which is expected to commence during the fourth quarter of 2016. The lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The lease provides for an initial yearly rent of approximately \$0.4 million. See the section captioned “*Item 2—Properties*” in this Annual Report on Form 10-K for additional discussion regarding these leases.
- (2) Included in this line is approximately \$15 million related to our on-going project to establish additional manufacturing capabilities at the Bedford, Massachusetts facility.

## **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**

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements in this Annual Report.

## **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, corporate bonds 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 2015. 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.

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## 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, 2015 and December 31, 2014 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 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, 2015, 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.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes in 2015 and 2014 due to the adoption of Accounting Standards Update 2015-17, Balance Sheet Classification of Deferred Taxes.

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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 10, 2016

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## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Balance Sheets

(in thousands, except share data and per share data)

	December 31,	
	2015	2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$110,707	\$100,156
Investments	27,751	6,750
Accounts receivable, net of reserves of \$167 and \$147 at December 31, 2015 and December 31, 2014, respectively	21,652	17,152
Inventories	14,938	12,407
Prepaid expenses and other current assets	1,385	1,371
Total current assets	176,433	137,836
Property and equipment, net	40,108	31,669
Long-term deposits and other	69	69
Intangible assets, net	11,656	14,895
Goodwill	7,482	8,339
Total assets	\$235,748	\$192,808
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$8,302	\$1,201
Accrued expenses and other current liabilities	4,778	4,772
Income taxes payable	4,198	-
Total current liabilities	17,278	5,973
Other long-term liabilities	781	894
Long-term deferred revenue	66	102
Deferred tax liability	6,775	7,741
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	-	-
Common stock, \$.01 par value; 30,000,000 shares authorized, 15,036,808 and 14,851,703 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	150	149
Additional paid-in-capital	81,685	77,540
Accumulated other comprehensive loss	(6,649 )	(4,495 )
Retained earnings	135,662	104,904
Total stockholders' equity	210,848	178,098
Total Liabilities and Stockholders' Equity	\$235,748	\$192,808

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



## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Operations and Comprehensive Income

(in thousands, except per share data)

	For the Years Ended December 31,		
	2015	2014	2013
Product revenue	\$87,696	\$75,474	\$71,774
Licensing, milestone and contract revenue	5,303	30,121	3,307
Total revenue	92,999	105,595	75,081
Operating expenses:			
Cost of product revenue	21,053	20,930	22,765
Research & development	8,987	8,144	7,060
Selling, general & administrative	14,825	15,074	12,936
Restructuring credits	-	-	(287 )
Total operating expenses	44,865	44,148	42,474
Income from operations	48,134	61,447	32,607
Interest income (expense), net	120	58	(127 )
Income before income taxes	48,254	61,505	32,480
Provision for income taxes	17,496	23,186	11,905
Net income	\$30,758	\$38,319	\$20,575
Basic net income per share:			
Net income	\$2.06	\$2.61	\$1.46
Basic weighted average common shares outstanding	14,934	14,678	14,087
Diluted net income per share:			
Net income	\$2.01	\$2.51	\$1.39
Diluted weighted average common shares outstanding	15,321	15,269	14,826
Net income	\$30,758	\$38,319	\$20,575
Other comprehensive income (loss):			
Foreign currency translation adjustment	(2,154 )	(2,796 )	956
Comprehensive income	\$28,604	\$35,523	\$21,531

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

## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

	Common Stock			Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Number of Shares	\$.01 Par Value	Additional Paid in Capital			
Balance, December 31, 2012	13,866,060	139	65,431	46,010	(2,655 )	108,925
Issuance of common stock for equity awards	423,248	4	3,050	-	-	3,054
Tax benefit related to equity awards	-	-	857	-	-	857
Stock-based compensation expense	-	-	1,268	-	-	1,268
Net income	-	-	-	20,575	-	20,575
Other comprehensive income	-	-	-	-	956	956
Balance, December 31, 2013	14,289,308	\$ 143	\$ 70,606	\$66,585	\$ (1,699 )	\$ 135,635
Issuance of common stock for equity awards	696,169	7	2,048	-	-	2,055
Tax benefit related to equity awards	-	-	9,626	-	-	9,626
Stock-based compensation expense	-	-	1,607	-	-	1,607
Retirement of common stock for minimum tax withholdings	(133,774 )	(1 )	(6,347 )	-	-	(6,348 )
Net income	-	-	-	38,319	-	38,319
Other comprehensive loss	-	-	-	-	(2,796 )	(2,796 )
Balance, December 31, 2014	14,851,703	\$ 149	\$ 77,540	\$104,904	\$ (4,495 )	\$ 178,098
Issuance of common stock for equity awards	185,105	1	1,073	-	-	1,074
Tax benefit related to equity awards	-	-	847	-	-	847
Stock-based compensation expense	-	-	2,225	-	-	2,225
Net income	-	-	-	30,758	-	30,758
Other comprehensive loss	-	-	-	-	(2,154 )	(2,154 )
Balance, December 31, 2015	15,036,808	\$ 150	\$ 81,685	\$135,662	\$ (6,649 )	\$ 210,848

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

## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Cash Flows

(in thousands)

	For the years ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income	\$30,758	\$38,319	\$20,575
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	3,775	4,706	4,772
Stock-based compensation expense	2,225	1,607	1,268
Deferred income taxes	(747 )	815	2,206
Provision for doubtful accounts	38	-	238
Provision for inventory	210	378	171
Gain on sale of assets	-	-	(126 )
Tax benefit from equity awards	(847 )	(9,626 )	(857 )
Non-cash impairment charges for IPR&D	697	-	-
Restructuring credits	-	-	(161 )
Changes in operating assets and liabilities:			
Accounts receivable	(4,996 )	898	2,411
Inventories	(2,939 )	(1,974 )	(2,823 )
Prepaid expenses, other current and long-term assets	89	585	307
Accounts payable	5,625	(750 )	623
Accrued expenses	(199 )	(1,189 )	(377 )
Deferred revenue	(15 )	(2,014 )	(2,795 )
Income taxes payable	5,484	8,436	152
Other long-term liabilities	(94 )	(213 )	(419 )
Net cash provided by operating activities	39,064	39,978	25,165
Cash flows from investing activities:			
Proceeds from maturity of investments	24,250	20,000	-
Purchase of investments	(45,251 )	(26,750 )	-
Purchase of property and equipment	(9,225 )	(1,553 )	(441 )
Proceeds from sale of assets	-	-	188
Net cash used in investing activities	(30,226 )	(8,303 )	(253 )
Cash flows from financing activities:			
Principal payments on debt	-	-	(9,600 )
Proceeds from exercise of equity awards	1,074	2,055	3,054
Tax benefit from equity awards	847	9,626	857
Minimum tax withholdings on share-based awards	-	(6,349 )	-
Net cash provided by financing activities	1,921	5,332	(5,689 )
Exchange rate impact on cash	(208 )	(184 )	43

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Increase in cash and cash equivalents	10,551	36,823	19,266
Cash and cash equivalents at beginning of period	100,156	63,333	44,067
Cash and cash equivalents at end of period	\$110,707	\$100,156	\$63,333
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	\$12,724	\$13,778	\$9,842
Cash paid for interest	\$-	\$-	\$126
Non-cash Investing Activities:			
Purchases of property and equipment included in accounts payable and accrued expenses	\$1,949	\$52	\$364

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

## **Anika Therapeutics, Inc. and Subsidiaries**

### **Notes to Consolidated Financial Statements**

#### **1. Nature of Business**

Anika Therapeutics, Inc. is a global, integrated orthopedic medicines company committed to improving the lives of patients with degenerative orthopedic diseases and traumatic conditions by providing innovative and differentiated therapeutic pain management solutions along the continuum of care, from palliative care to regenerative medicine. The Company has over two decades of expertise developing, manufacturing and commercializing more than 20 products, in markets across the globe, based on the Company's proprietary hyaluronic acid technology. The Company's orthopedic medicine portfolio is comprised of marketed (ORTHOVISC and MONOVISC) and pipeline (CINGAL and HYALOFAST in the United States) products to alleviate pain and restore joint function by replenishing depleted HA and aiding cartilage repair and regeneration.

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

#### **2. Summary of Significant Accounting Policies**

##### *Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

##### *Principles of Consolidation*



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

#### *Foreign Currency Translation*

The functional currency of our foreign subsidiary is the Euro. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using the monthly average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as a component of accumulated currency translation adjustment which resulted in a loss from foreign currency translation of \$2.2 million and \$2.8 million for the years ended December 31, 2015 and 2014, respectively. The translation adjustments resulted in a gain from foreign currency translation of \$1.0 million for the year ended December 31, 2013.

The Company recognized a loss from foreign currency transactions of \$0.4 million and \$0.6 million during the years ended December 31, 2015 and 2014, respectively and a gain from foreign currency transactions of \$259 thousand during the year ended December 31, 2013.

#### *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, the Company considers the principal or most advantageous market in which it 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 non-performance. 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 directly 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 instrument.

The Company's financial assets have been classified as Level 2. The Company's financial assets (which include cash equivalents and investments) have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data.

#### *Allowance for Doubtful Accounts*

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, and are included in general and administrative expenses in the accompanying consolidated statements of operations. 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. A summary of activity in the allowance for doubtful accounts is as follows (in thousands):

	December 31,		
	2015	2014	2013
Balance, beginning of the year	\$147	\$593	\$337
Amounts provided	38	-	238
Amounts written off	(3 )	(377)	-
Translation adjustments	(15 )	(69 )	18
Balance, end of the year	\$167	\$147	\$593

#### *Revenue Recognition - General*

The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists, risk of loss has passed or services have been rendered, the seller's price to the buyer is fixed or determinable, and collection from the customer is reasonably assured.

*Product Revenue*

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

Product revenue also includes royalties. Royalty revenue is based on our distributors' sales and recognized in the same period our distributors record their sale of products manufactured by us. On a quarterly basis the Company records royalty revenue based upon sales provided to us by our distributor customers.

Pursuant to the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act, a medical device excise tax (“MDET”) became effective on January 1, 2013 for sales of certain medical devices. Some of our product sales are subject to the provisions of the MDET. The Company has elected to recognize any amounts related to the MDET under the gross method as allowed under ASC 605-45. For the periods ended December 31, 2015 and 2014, amounts included in revenues and costs of goods sold for the MDET were immaterial. On December 18, 2015, President Obama signed the Consolidated Appropriations Act of 2016, which suspends the 2.3 percent MDET beginning on January 1, 2016, with the suspension ending on December 31, 2017.

#### *Licensing, Milestone, and Contract Revenue*

Licensing, milestone, and contract revenue consist of revenue recognized on initial and milestone payments, as well as contractual amounts received from partners. The Company’s business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company’s products. Under the milestone method, the Company recognizes a consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

The consideration is commensurate with either the entity’s performance to achieve the milestone or the enhancement

1. of the value of the delivered item(s) as a result of a specific outcome resulting from the entity’s performance to achieve the milestone,

2. The consideration relates solely to past performance, and

3. The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity’s performance or on the occurrence of a specific outcome resulting from the entity’s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. Non substantive milestones are recognized when there are no further obligations by the Company.

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

arrangement as the Company completes its performance obligations.

#### *Cash and Cash Equivalents*

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. The Company's cash equivalents consist of money market funds and bank certificates of deposit with an original maturity of less than 90 days.

#### *Investments*

The Company's investments consist of bank certificates of deposit with an original maturity of more than 90 days. The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recorded in accumulated other comprehensive income. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest income (expense), net. Interest is recorded when earned. Investments with original maturities greater than approximately three months and remaining maturities less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments. The Company considers securities with maturities of three months or less from the purchase date to be cash equivalents.

All of the Company's investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the extent and length of time the investment's fair value has been lower than its cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security, and whether or not the Company will be required to sell the security prior the expected recovery of the investment's amortized cost basis. During the years ended December 31, 2015 and 2014, the Company did not record any other-than-temporary impairment charges on its available-for-sale securities because the Company does not intend to sell the securities and it is not more likely than not that the Company will be required to sell these securities before the recovery of their amortized cost basis.

#### *Concentration of Credit Risk and Significant Customers*

The Company has no significant off-balance sheet risks related to foreign exchange contracts, option contracts, or other foreign hedging arrangements. The Company's cash equivalents and investments are held with two major international financial institutions.

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

As of December 31, 2015 and 2014, DePuy Mitek, represented 60% and 52%, respectively, of the Company's accounts receivable balance, no other single customer accounted for more than 10% of accounts receivable in either period.

#### *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. Inventory costs associated with product candidates that have not yet received regulatory approval are capitalized if the Company believes there is probable future commercial use and future economic benefit.

The Company's 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 the Company's products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including, but not limited to, historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Purchasing requirements and alternative usage avenues are explored within these processes to mitigate inventory exposure.

When recorded, inventory write-downs are intended to reduce the carrying value of inventory to its net realizable value. Inventory of \$14.9 million and \$12.4 million as of December 31, 2015 and 2014, respectively, is stated net of inventory reserves of approximately \$0.9 million and \$0.9 million, respectively. If actual demand for the Company's products deteriorates, or market conditions are less favorable than those projected, additional inventory write-downs may be required.

#### *Property and Equipment*

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. 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; additions and improvements are capitalized. When an item is sold or retired, the cost and related accumulated depreciation is relieved, and the resulting gain or loss, if any, is recognized in income. Construction-in-process is stated at cost, which includes the cost of construction and other direct costs attributable to the construction. Construction-in-process is not depreciated until such time as the relevant assets are completed and put into use. Construction-in-process at December 31, 2015 and 2014 primarily represents the costs of building, leasehold improvements, machinery and equipment under installation.

### *Goodwill and Acquired Intangible Assets*

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired 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 the Company considers 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 the Company's use of the acquired assets or the strategy for its 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. The Company estimates the fair value for its reporting unit using discounted cash flow valuation models which require the use of significant estimates and assumptions, including but not limited to, risk free rate of return on an investment, weighted average cost of capital, future revenue, operating margin, working capital, and capital expenditure needs. The Company's annual assessment for impairment of goodwill as of November 30, 2015 indicated that the fair value of our reporting unit exceeded the carrying value of the reporting unit.

To conduct impairment tests of IPR&D, the fair value of the IPR&D project is compared to its carrying value. If the carrying value exceeds its fair value, the Company records an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. The Company estimates the fair value for IPR&D projects using discounted cash flow valuation models, which require the use of significant estimates and assumptions, including but not limited to, estimating the timing of and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in-process projects, and developing appropriate discount rates. During the fourth quarter of 2015 the Company performed an impairment review of its IPR&D projects as it reassessed its R&D strategy. The Company recorded an impairment charge of \$0.7 million due to the decision to discontinue further development efforts needed to commercialize this technology. The Company's annual assessment for impairment of IPR&D indicated that the fair value of our other IPR&D assets as of November 30, 2015 exceeded their respective carrying values.

### *Long-Lived Assets*



Long-lived assets primarily include property and equipment, and intangible assets with finite lives. The Company's 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. The Company reviews 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.

#### *Research and Development*

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

#### *Stock-Based Compensation*

The Company measures 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. See Note 13 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.

For performance based awards with financial achievement targets, the Company recognizes expense using the graded vesting methodology based on the number of shares expected to vest. Compensation cost associated with these grants was estimated using the Black-Scholes valuation method multiplied by the expected number of shares to be issued, which is adjusted based on the estimated probabilities of achieving the performance goals. 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. The Company recorded approximately \$0.4 million related to performance based awards in 2015. There was no expense recognized on performance based awards in 2014 as satisfaction of the performance conditions were not considered probable.

### *Income Taxes*

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

### *Comprehensive Income*

Comprehensive income consists of net income and other comprehensive income (loss), which includes foreign currency translation adjustments, and unrealized gains and losses on available-for-sale securities. For the purposes of comprehensive income disclosures, the Company does not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as it intends to indefinitely reinvest undistributed earnings of its foreign subsidiary. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity and, for the years ended December 31, 2015 and 2014, comprehensive income was comprised solely of cumulative translation adjustments.

### *Segment Information*

Operating segments, as defined under U.S. GAAP, are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group,

in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. Based on the criteria established by ASC 280, *Segment Reporting*, the Company has one reportable operating segment, the results of which are disclosed in the accompanying consolidated financial statements.

#### *Subsequent Events*

Events occurring subsequent to December 31, 2015 have been evaluated for potential recognition or disclosure in the consolidated financial statements. See Note 19 *Subsequent Events*, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information regarding subsequent events.

#### *Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. In July 2015, the FASB issued a deferral of ASU 2014-09 of one year making it effective for annual reporting periods beginning on or after December 15, 2017 while also providing for early adoption not to occur before the original effective date. The Company is assessing the appropriate method for implementing ASU 2014-09, as well as the impact the adoption of ASU 2014-09 will have on its consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330) “Simplifying the Measurement of Inventory.” ASU 2015-11 more closely aligns the measurement of inventory in US GAAP with the measurement of inventory in International Financial Reporting Standards by requiring companies using the first-in, first-out and average costs methods to measure inventory using the lower of cost and net realizable value, where net realizable value is the estimated selling prices in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The provisions of ASU 2015-11 are effective for annual and interim periods beginning after December 15, 2016. ASU 2015-11 should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of this amendment is not expected to have a material impact on the Company’s financial position or results of operations.

In November 2015 FASB issued ASU No. 2015-17, Income Taxes (Topic 740) Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires entities to present deferred tax assets and deferred tax liabilities as noncurrent in a classified balance sheet. The ASU simplifies the current guidance, which requires entities to separately present deferred tax assets and deferred tax liabilities as current and noncurrent in a classified balance sheet. The guidance in ASU 2015-17 is required for annual reporting periods beginning after December 15, 2016, including interim periods within the reporting period. We early adopted the provisions of this ASU during the fourth quarter of fiscal year 2015 and applied it retrospectively. The adoption of ASU 2015-17 resulted in the reclassification of \$2.3 million of current deferred tax assets to a reduction in noncurrent deferred tax liabilities as of December 31, 2015. We retrospectively adjusted the December 31, 2014 consolidated balance sheet and related disclosures to reflect the reclassification of \$1.2 million of current deferred tax assets to a reduction in noncurrent deferred tax liabilities. Adoption of this standard did not impact results of operations, retained earnings, or cash flows in the current or previous interim and annual reporting periods.

In February 2016, the FASB issued “Leases (Topic 842)” (ASU 2016-02). This new standard amends existing leasing accounting requirements. The most significant change will result in the recognition of lease assets and lease liabilities by lessees for virtually all leases. The new guidance will also require significant additional disclosures about the amount, timing and uncertainty of cash flows from leases. ASU 2016-02 is effective for fiscal years and interim periods beginning after December 15, 2018. Upon adoption, entities are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted, and a number of optional practical expedients may be elected to simplify the impact of adoption. We are currently evaluating the impact of adopting this guidance.

### **3. Investments**

All of the Company’s investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income, net of related income taxes. The Company held corporate debt securities of \$2.0 million at December 31, 2015 and bank certificates of deposits of \$25.8 million and \$6.8 million at December 31, 2015 and 2014, respectively. There were no unrealized gains or losses on the Company’s available-for-sale securities at December 31, 2015 or 2014.

#### **4. Fair Value Measurements**

The Company's investments are all classified within Level 2 of the fair value hierarchy. The Company's investments classified within Level 2 of the fair value hierarchy are valued based on matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk.

The fair value hierarchy of the Company's cash equivalents and investments at fair value is as follows (in thousands):

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		Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)			Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)	
	December 31, 2015							
Cash equivalents:								
Money market funds	\$ 61,385	\$-	\$ 61,385	\$	-			
Bank certificates of deposit	250	-	250		-			
Total cash equivalents	\$ 61,635	\$-	\$ 61,635	\$	-			
Investments:								
Corporate debt securities	\$ 2,001	\$-	\$ 2,001	\$	-			
Bank certificates of deposit	25,750	-	25,750		-			
Total investments	\$ 27,751	\$-	\$ 27,751	\$	-			

		Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)			Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)	
	December 31, 2014							
Cash equivalents:								
Money market funds	\$ 69,552	\$-	\$ 69,552	\$	-			
Bank certificates of deposit	3,000	-	3,000		-			
Total cash equivalents	\$ 72,552	\$-	\$ 72,552	\$	-			
Investments:								
Bank certificates of deposit	\$ 6,750	\$-	\$ 6,750	\$	-			

The Company did not have any transfers between Level 1 and Level 2 or transfers in or out of Level 3 of the fair value hierarchy during the years ended December 31, 2015 and 2014.

**5. Earnings per Share (“EPS”)**

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

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

	Years Ended December 31,		
	2015	2014	2013
Shares used in the calculation of basic earnings per share	14,934	14,678	14,087
Effect of dilutive securities:			
Stock options, SARs, and RSAs	387	591	739
Diluted shares used in the calculation of earnings per share	15,321	15,269	14,826

Stock options to purchase 197,691 shares, 129,540 shares, and 21,326 shares for 2015, 2014, and 2013, respectively, were excluded from the computation of diluted EPS as their effect would have been anti-dilutive.

At December 31, 2015, 2014, and 2013, 62,825 shares, 30,700 shares, and 52,339 shares of issued and outstanding unvested restricted stock, respectively, were excluded from the basic earnings per share.

**6. Inventories**

Inventories consist of the following (in thousands):

	December 31,	
	2015	2014
Raw materials	\$5,780	\$6,162
Work-in-process	5,656	3,041
Finished goods	3,502	3,204
Total	\$14,938	\$12,407

**7. Property and Equipment**

Property and equipment is stated at cost and consists of the following (in thousands):

	December 31,	
	2015	2014
Equipment and software	\$24,512	\$24,176
Furniture and fixtures	1,240	1,296
Leasehold improvements	27,622	27,589
Construction in progress	11,274	559
Subtotal	64,648	53,620
Less accumulated depreciation	(24,540)	(21,951)
Total	\$40,108	\$31,669

Depreciation expense was \$2.7 million, \$2.6 million, and \$2.7 million for the years ended December 31, 2015, 2014, and 2013, respectively.

**8. Acquired Intangible Assets, Net**

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



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

The Company recorded an impairment charge totaling \$0.7 million to write-off in-process research and development that was recorded in connection with our acquisition of Anika S.r.l. Subsequent to an evaluation in the fourth quarter of the ongoing research and development efforts surrounding the Hemostatic Patch IPR&D project, the Company determined it would discontinue further development efforts needed to commercialize this technology. As a result of this decision, an impairment charge was recorded. These amounts are included in research and development expenses on our consolidated statements of operations. Through December 31, 2015, there have not been any events or changes in circumstances that indicate that the carrying value of the other acquired intangible assets may not be recoverable. The Company continues to monitor and evaluate the financial performance of its 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.

In January 2015 the Company received CE Mark approval for HYALOSPINE which is an innovative adhesion prevention gel for use after spinal surgery, and was a component of the IPR&D intangible assets initially identified. As a result of this approval the Company has reclassified \$400 thousand from IPR&D to developed technology and began amortization on the HYALOSPINE asset.

Amortization expense was \$1.1 million, \$2.1 million, and \$2.1 million for the years ended December 31, 2015, 2014, and 2013, respectively. Amortization expense on intangible assets is expected to be approximately \$1.0 million in 2016, \$0.9 million annually through 2020 and approximately \$3.8 million in aggregate thereafter.

Intangible assets consist of the following (in thousands):

		December 31, 2015					December 31, 2014	
	Gross Value	Current Period Completed Projects	Abandonment	Currency Translation Adjustment	Accumulated Amortization	Net Book Value	Net Book Value	Useful Life
Developed technology	\$16,700	\$400	\$ -	\$ (3,215 )	\$ (5,926 )	\$7,959	\$9,410	15
In-process research & development	5,503	(400)	(697 )	(1,307 )	-	3,099	4,653	Indefinite
Distributor relationships	4,700	-	-	(415 )	(4,285 )	-	-	5
Patents	1,000	-	-	(194 )	(333 )	473	581	16
Eleves trade name	1,000	-	-	-	(875 )	125	251	9
Total	\$28,903	\$-	\$ (697 )	\$ (5,131 )	\$ (11,419 )	\$11,656	\$14,895	

## 9. Goodwill

The Company completed its annual impairment review as of November 30, 2015 and concluded that no impairment in the carrying value exists as of that date with respect to goodwill. Through December 31, 2015, there have not been any events or changes in circumstances that indicate that the carrying value of goodwill may not be recoverable. Changes in the carrying value of goodwill were as follows (in thousands):

	December 31,	
	2015	2014
Balance, beginning	\$8,339	\$9,444
Effect of foreign currency adjustments	(857 )	(1,105 )
Balance, ending	\$7,482	\$8,339

## 10. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2015	2014
Compensation and related expenses	\$3,082	\$2,792
Facility construction costs	415	-
Research grants	381	539
Clinical trial costs	252	508
Professional fees	210	554
Other	438	379
Total	\$4,778	\$4,772

## 11. Deferred Revenue

In December 2003, the Company entered into the Mitek ORTHOVISC Agreement with Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies, to market ORTHOVISC in the U.S. In mid-2005, the agreement was assigned to Mitek. Under the Mitek ORTHOVISC Agreement, Mitek performs sales, marketing, and distribution functions, and Mitek licenses the right to further develop and commercialize ORTHOVISC, as well as other new products for the treatment of pain associated with osteoarthritis based on the Company's viscosupplementation technology. In support of the license, the Mitek ORTHOVISC Agreement provides that Mitek will fund post-marketing clinical trials for new indications of ORTHOVISC. The Company received an initial payment of \$2.0 million upon entering into the Mitek ORTHOVISC Agreement, a milestone payment of \$20.0 million in February 2004 as a result of obtaining FDA approval of ORTHOVISC, and a milestone payment of \$5.0 million in December 2004 for planned upgrades to our manufacturing operations. The Company evaluated the terms of the Mitek ORTHOVISC Agreement and determined that the upfront fee and milestone payments did not meet the conditions to be recognized separately from the supply agreement. These payments were recognized into revenue as all of the performance obligations were met.

In December 2011, the Company entered into a fifteen-year licensing agreement (the "Mitek MONOVISC Agreement") with DePuy Synthes Mitek Sports Medicine, a division of DePuy Orthopaedics, Inc., to exclusively market MONOVISC in the U.S. The Company received an upfront payment of \$2.5 million in December 2011. This non-refundable upfront payment did not have standalone value without Anika's completion of development obligations, which included obtaining regulatory approval of the product and resolving the related patent litigation. As a result, the Company recognized the upfront payment over the development obligation period. During the first quarter of 2014, the Company received FDA approval of MONOVISC and resolved the patent lawsuit with Genzyme Corporation. As a result of the full delivery of its development obligations under this agreement, the Company recognized approximately \$2.2 million, which represented the remaining balance of deferred revenue relating to the initial \$2.5 million payment. In the first quarter of 2014, the Company also received a milestone payment of \$17.5 million as a result of achieving FDA approval for MONOVISC and resolving the patent litigation with Genzyme. This milestone payment was fully recognized as revenue during the three months ended March 31, 2014. On April 15, 2014 the first U.S. commercial sale of MONOVISC was made by our commercial partner, Mitek. Under the terms of the Mitek MONOVISC Agreement, the Company earned and collected a milestone payment of \$5 million, which was fully recognized as revenue in the second quarter of 2014. On November 10, 2014, the Center for Medicare & Medicaid Services ("CMS") assigned a unique Healthcare Common Procedure Coding System ("HCPCS") code, or J-Code, to MONOVISC. The issuance of this code by CMS set national Medicare reimbursement rates for the product. The new J-Code became effective on January 1, 2015. As a result of CMS assigning the J-Code, the Company collected a milestone payment of \$5.0 million, which was fully recognized as revenue in the fourth quarter of 2014. During the fourth quarter of 2015, the Company collected and fully recognized revenue for a milestone payment of \$5.0 million as a result of U.S. MONOVISC annual end-user sales exceeding \$50 million. For the year ended December 31, 2015 and 2014, the Company recognized a total of \$5.0 million and \$29.7 million in milestone revenue related to MONOVISC, respectively.

## 12. Commitments and Contingencies

### *Leasing Arrangements*

The Company's headquarters facility is located in Bedford, Massachusetts, where the Company leases approximately 134,000 square feet of administrative, manufacturing, and R&D space. This lease was entered into on January 4, 2007, and the lease commenced on May 1, 2007 for an initial term of ten and one-half years. The Company has an option under the lease to extend its terms for up to four additional periods beyond the original expiration date subject to the condition that the Company notify the landlord that the Company is 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, while the final renewal option extends the term by six years. The Company's administrative and R&D personnel moved into the Bedford facility in November of 2007. The Bedford facility was fully validated and approved by applicable regulatory authorities in 2012.

Anika S.r.l., leases 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 (6) years, with options to extend, which the Company has not exercised as of December 31, 2015 and is currently renting this facility under a six year lease that Anika may terminate at any time by providing six months' notice. The Company expects to exit this facility in late

2016.

On October 9, 2015, Anika S.r.l. entered into a build-to-suit lease agreement with Consorzio Zona Industriale E Porto Fluviale di Padova (“ZIP”), as landlord, pursuant to which Anika S.r.l. will lease a new European headquarters facility, consisting of approximately 33,000 square feet of general office, research and development, training, and warehousing space located in Padova, Italy. The Lease has an initial term of fifteen years, which is expected to commence during the fourth quarter of 2016 once construction of the facility is completed. The Lease will automatically renew for up to three additional six-year terms, subject to certain terms and conditions. The Company has the ability to withdraw from this lease subject to certain financial penalties after six years and with no penalties after the ninth year. Beginning on the commencement date, the Lease provides for an initial yearly rent of approximately \$0.4 million.

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Construction of the new facility is expected to begin in the first quarter of 2016 and is expected to be completed in late 2016. During the period of construction the Company is considered the deemed owner of the facility and as a result at December 31, 2015 has recorded a construction-in-process asset of approximately \$0.2 million, and an offsetting facility lease obligation of approximately \$30 thousand associated with the new facility.

Rental expense in connection with the various facility leases totaled \$1.3 million for the year ended December 31, 2015, and \$1.4 million, for the years ended December 31, 2014 and 2013, respectively.

The Company's future lease commitments as of December 31, 2015 are as follows (in thousands):

2016	\$1,540
2017	1,309
2018	1,309
2019	1,319
2020 and thereafter	4,926
Total	\$10,403

#### *Warranty and Guarantor Arrangements*

In certain of our contracts, the Company warrants to its customers that the products it manufactures conform to the product specifications as in effect at the time of delivery of the specific product. The Company may also warrant that the products it manufactures do not infringe, violate or breach any U.S. patent or intellectual property rights, trade secret, or other proprietary information of any third party. On occasion, the Company contractually indemnifies its customers against any and all losses arising out of, or in any way connected with, any claim or claims of breach of its warranties or any actual or alleged defect in any product caused by the negligence or acts or omissions of the Company. The Company maintains a products liability insurance policy that limits its exposure to these risks. Based on the Company's historical activity, in combination with its liability insurance coverage, the Company believes the estimated fair value of these indemnification agreements is immaterial. The Company has no accrued warranties at December 31, 2015 or 2014, respectively, and has no history of claims paid.

#### *Legal Proceedings*

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The complaint alleged that the Company 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 the Company manufactured and sold MONOVISC in the United States. On March 7, 2014, Genzyme and the Company filed a joint motion to lift the stay

in Genzyme's lawsuit against the Company and to dismiss with prejudice all of Genzyme's claims. On March 10, 2014, the District Court granted the motion to dismiss all of Genzyme's claims against the Company with prejudice, and the case was terminated.

The Company is 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, the Company does 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.

### **13. Equity Incentive Plan**

The Anika Therapeutics, Inc. Stock Option and Incentive Plan, as amended, (the "2003 Plan") provides for grants of nonqualified and incentive stock options, common stock, restricted stock, restricted stock units, and SAR's to employees, directors, officers, and consultants. The 2003 Plan was originally approved by the Board of Directors on April 4, 2003, approved by the Company's shareholders on June 4, 2003, and reserved 1,500,000 shares of common stock for grant pursuant to its terms. There are 1,251,635 shares available for future grant at December 31, 2015.

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

At the 2011 Annual Meeting of Stockholders on June 7, 2011, the shareholders of the Company approved the Anika Therapeutics, Inc. Second Amended and Restated Stock Option and Incentive Plan (the “2003 Plan”), which, among other things, increased the number of shares reserved for issuance under the Company’s predecessor stock option and incentive plan by 800,000 to 3,150,000 shares. Pursuant to this amendment and restatement to the 2003 Plan approved by our shareholders, each share award issued after June 7, 2011 other than options or stock appreciation rights will reduce the number of total shares available for grant by 1.9 shares.

At the 2013 Annual Meeting of Stockholders on June 18, 2013, the shareholders of the Company approved an additional amendment to the Amended 2003 Plan, which, among other things, increased the number of shares reserved for issuance under the Company’s stock option and incentive plan by 650,000 to 3,800,000 shares. Pursuant to this amendment and restatement to the 2003 Plan approved by our shareholders, each share award issued after June 18, 2013 other than options or stock appreciation rights will reduce the number of total shares available for grant by 1.5 shares

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

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

The Company uses historical data on the exercise of stock options and other factors to evaluate and estimate the expected term of share-based awards. The Company also evaluates actual forfeiture rates periodically and adjusts the expected forfeiture rate assumption within the model accordingly. The expected volatility assumption is evaluated against the historical volatility of the Company’s common stock over a four year average, and it is adjusted if there are material swings in historical volatility. The risk-free interest rate assumption is based on U.S. Treasury interest rates at the time of grant.

The fair value of each stock option and SAR award during 2015, 2014, and 2013 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

December 31,		
2015	2014	2013



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Risk free interest rate	1.15% -	1.46%	1.16% -	1.39%	0.61% -	1.02%
Expected volatility	53.15%-	54.65%	53.28%-	57.05%	53.60%-	57.60%
Expected life (years)	4.5		4.0		4.0	
Expected dividend yield	0.00%		0.00%		0.00%	

The Company recorded \$2.2 million, \$1.6 million, and \$1.3 million of share-based compensation expense for the years ended December 31, 2015, 2014, and 2013, respectively, for stock options, SAR's, and restricted stock awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to each of its employees.

Combined stock options and SAR's activity under our plans is summarized as follows for the years ended December 31, 2015 and 2014, respectively:

	2015	Weighted	2014	Weighted
	Number of	Average	Number of	Average
	Shares	Exercise	Shares	Exercise
		Price Per		Price Per
		Share		Share
Options and SAR's outstanding at beginning of year	851,287	\$ 14.85	1,513,326	\$ 9.14
Granted	111,625	\$ 39.25	179,240	\$ 35.62
Cancelled	(85,349 )	\$ 19.77	(53,325 )	\$ 23.73
Expired	(8,825 )	\$ 20.03	(24,292 )	\$ 9.87
Exercised	(106,478 )	\$ 10.96	(763,662 )	\$ 7.95
Options and SAR's outstanding at end of year	762,260	\$ 18.75	851,287	\$ 14.85

Of the 762,260 options and SAR's outstanding at December 31, 2015, 734,301 are vested or are expected to vest, with a weighted-average exercise price of approximately \$17.88 as well as an aggregate intrinsic value of approximately \$15 million related to these awards. The weighted average remaining contractual term of the vested and expected to vest options and SAR's was 6.7 years as of December 31, 2015.

As of December 31, 2015, total unrecognized compensation costs related to non-vested options and SAR's was approximately \$2.6 million and is expected to be recognized over a weighted average period of 2.5 years.

There were 140,023 incentive stock options exercisable at December 31, 2015 with a weighted-average exercise price of \$9.52 and a weighted-average remaining contractual term of 5.6 years for these awards.

There were 225,620 non-qualified stock options exercisable at December 31, 2015 with a weighted-average exercise price of \$12.27 and a weighted-average remaining contractual term of 6.3 years.

There were 56,220 SAR's exercisable at December 31, 2015 with a weighted-average exercise price of \$8.30 and a weighted-average remaining contractual term of 2.9 years for these awards.

The aggregate intrinsic value of stock options and SAR's fully vested at December 31, 2015 and 2014 was \$11.6 million and \$12.0 million, respectively. The aggregate intrinsic value of stock options and SAR's outstanding at December 31, 2015 and 2014 was \$15.2 million and \$21.7 million, respectively.

The total intrinsic value of options and SAR's exercised was \$3.1 million and \$26.7 million for the years ended December 31, 2015 and 2014, respectively. During the second quarter of 2014, the Company acquired, and subsequently retired, 133,774 common shares related to an employee SAR's exercise to meet minimum statutory tax withholding requirements.

The total fair value of options and SAR's vested during the years ended December 31, 2015 and 2014 was approximately \$1.1 million for both periods.

The Company received \$1.1 million and \$2.1 million for exercises of stock options during the years ended December 31, 2015 and 2014, respectively.

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The restricted stock activity for the years ended December 31, 2015 and 2014 is as follows:

	2015	Weighted	2014	Weighted
	Number	Average	Number	Average
	of	Grant	of	Grant
	Shares	Date	Shares	Date
		Fair		Fair
		Value		Value
Nonvested at Beginning of year	109,614	\$ 23.91	79,591	\$ 11.93
Granted	81,080	\$ 37.84	60,098	\$ 32.02
Cancelled	(10,635 )	\$ 32.02	(7,500 )	\$ 25.46
Expired	-	\$ -	-	\$ -
Vested/Released	(29,675 )	\$ 19.31	(22,575 )	\$ 10.01
Nonvested at end of year	150,384	\$ 34.29	109,614	\$ 23.91

The total fair value of restricted stock and restricted stock units vested during the year ended December 31, 2015 and 2014 was \$1.2 million and \$0.8 million.

#### 14. Shareholder Rights Plan

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

- (1) A person becomes an “Acquiring Person” by acquiring 15% or more of the Company’s common stock, or
- (2) A person commences a tender offer that would result in that person owning 15% or more of the Company’s common stock.

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

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

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

(2) The Expiration Date.

At any time after any person becomes an "Acquiring Person," the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of the Company's common stock at an exchange ratio specified in the 2008 Plan. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to affect such exchange at any time after any person becomes the beneficial owner of 50% or more of the Company's common stock.

In connection with the establishment of the 2008 Plan, the Board of Directors approved the creation of Preferred Stock of the Company designated as Series B Junior Participating Cumulative Preferred Stock with a par value of \$0.01 per share. The Board also reserved 175,000 shares of preferred stock for issuance upon exercise of the Rights. Until a Right is exercised, the holder will have no rights as a stockholder of the Company, beyond those as an existing stockholder, including the right to vote or to receive dividends.

## **15. Employee Benefit Plan**

U.S. employees are eligible to participate in the Company's 401(k) savings plan. Employees may elect to contribute a percentage of their compensation to the plan, and the Company will make matching contributions up to a limit of 5% of an employee's eligible compensation. In addition, the Company may make annual discretionary contributions. The Company made matching contributions of approximately \$350 thousand, \$350 thousand, and \$362 thousand, for the years ended December 31, 2015, 2014, and 2013, respectively.

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

Product revenue by product group is as follows (in thousands, except percentages):

	Years Ended December 31, 2015			2014			2013		
	Revenue	Percentage of Product Revenue		Revenue	Percentage of Product Revenue		Revenue	Percentage of Product Revenue	
Orthobiologics	\$73,247	84 %		\$61,957	82 %		\$55,956	78 %	
Dermal	2,266	2 %		1,334	2 %		1,817	3 %	
Surgical	5,812	7 %		5,855	8 %		5,446	8 %	
Other	6,371	7 %		6,328	8 %		8,555	11 %	
	\$87,696	100 %		\$75,474	100 %		\$71,774	100 %	

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

	Percentage of Product Revenue Years Ended December 31, 2015 2014 2013		
Mitek	72 %	72 %	63 %
Boehringer	5 %	4 %	5 %
Medtronic	3 %	4 %	3 %
Nordic Pharma	2 %	2 %	2 %
Pharmascience	2 %	2 %	3 %
	84 %	84 %	76 %

Total revenue by geographic location based on the location of the customer in total and as a percentage of total revenue are as follows (in thousands, except percentages):

	Years Ended December 31, 2015		2014		2013	
	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue	Total Revenue	Percentage of Revenue

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Geographic Location:

United States	\$76,621	82	%	\$92,259	87	%	\$58,490	78	%
Europe	8,756	9	%	6,215	6	%	7,412	10	%
Other	7,622	9	%	7,121	7	%	9,179	12	%
Total	\$92,999	100	%	\$105,595	100	%	\$75,081	100	%

The Company recorded licensing, milestone, and contract revenue of \$5.3 million, \$30.1 million and \$3.3 million for the years ended December 31, 2015, 2014, and 2013, respectively. Substantially all licensing, milestone, and contract revenue was derived in the United States for each year presented.

Net long-lived assets, consisting of net property and equipment, are subject to geographic risks because they are generally difficult to move and to effectively utilize in another geographic area in a reasonable time period and because they are relatively illiquid. Net tangible long-lived assets by principal geographic areas were as follows (in thousands):

	Years Ended	
	December 31,	
	2015	2014
United States	\$39,732	\$31,059
Italy	376	610
Total	\$40,108	\$31,669

**17. Income Taxes***Income Tax Expense*

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

	Years ended December 31,		
	2015	2014	2013
Income (loss) before income taxes			
Domestic	\$48,608	\$63,232	\$33,061
Foreign	(354 )	(1,727 )	(581 )
	\$48,254	\$61,505	\$32,480
	Years ended December 31,		
	2015	2014	2013
Provision for (benefit from) income taxes:			
Current provision:			
Federal	\$14,572	\$18,301	\$8,024
State	3,635	3,895	1,581
Foreign	249	192	94
	18,456	22,388	9,699
Deferred provision:			
Federal	(370 )	1,153	2,375
State	(33 )	122	115
Foreign	(557 )	(477 )	(284 )
	(960 )	798	2,206
Total provision	\$17,496	\$23,186	\$11,905

*Deferred Tax Assets and Liabilities*

Significant components of the Company's deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carry forward, foreign	\$1,567	\$2,292



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Stock-based compensation expense	1,043	755
Foreign currency exchange	762	353
Accrued expenses and other	510	527
Inventory reserve	547	334
Tax credit carry forward	-	46
Deferred tax assets	\$4,429	\$4,307

	December 31,	
	2015	2014
Deferred tax liabilities:		
Acquisition-related Intangibles	\$(3,738 )	\$(4,827 )
Depreciation	(7,466 )	(7,221 )
Deferred tax liabilities	\$(11,204)	\$(12,048)
Net deferred tax liabilities	\$(6,775 )	\$(7,741 )

*Tax Rate*

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

	Years ended December 31,		
	2015	2014	2013
Statutory federal income tax rate	35.0%	35.0%	35.0%
State tax expense, net of federal benefit	4.8 %	4.9 %	4.8 %
Permanent items, including nondeductible expenses	(0.3 %)	0.1 %	(0.2 %)
State investment tax credit	0.0 %	(0.1 %)	(0.1 %)
Federal, state and foreign research and development credits	(0.4 %)	(0.7 %)	(0.5 %)
Foreign rate differential	0.1 %	0.2 %	0.1 %
Domestic production deduction	(2.9 %)	(1.7 %)	(2.4 %)
Effective income tax rate	36.3%	37.7%	36.7%

As of December 31, 2015, the Company had NOL's for income tax purposes in Italy of \$6.3 million with no expiration date.

*Accounting for Uncertainty in Income Taxes*

The Company had no unrecognized tax benefits for the years ended December 31, 2015 and 2014, respectively. A reconciliation of the beginning and ending amount of our unrecognized tax benefits is summarized as follows (in thousands):

	Year ended December 31, 2013
Unrecognized tax benefit, beginning of year	\$ 56
Tax positions related to current year	-
Tax positions related to prior years	-
Statute expirations	(56 )
Unrecognized tax benefit, end of year	\$ -

In the normal course of business, Anika and its subsidiaries may be periodically examined by various taxing authorities. The Company files income tax returns in the U.S. federal jurisdiction, in certain U.S. states, and in Italy. The associated tax filings remain subject to examination by applicable tax authorities for a certain length of time following the tax year to which those filings relate. The 2012 through 2015 tax years remain subject to examination by the IRS and other taxing authorities for U.S. federal and state tax purposes. The 2011 through 2015 tax years remain subject to examination by the appropriate governmental authorities for Italy.

The Company does not anticipate experiencing any significant increases or decreases in our unrecognized tax benefits within the twelve months following December 31, 2015.

The Company incurred expenses related to stock-based compensation in 2015, 2014, and 2013 of \$2.2 million, \$1.6 million, and \$1.3 million, respectively. Accounting for the tax effects of certain stock-based awards requires that the Company establish a deferred tax asset as the compensation expense is recognized for financial reporting prior to recognizing the related tax deduction upon exercise of the awards. The gross tax benefit recognized in the consolidated statement of operations related to stock-based compensation totaled \$1.1 million, \$3.1 million, and \$2.0 million in 2015, 2014, and 2013, respectively.

Upon the settlement of certain stock-based awards (i.e., exercise, vesting, forfeiture, or cancellation), the actual tax deduction is compared with cumulative financial reporting compensation cost and any excess tax deduction related to these awards is considered a windfall tax benefit. Such benefits are tracked in a “windfall tax benefit pool” to offset any future tax deduction shortfalls, and they will be recorded as increases to additional paid-in capital in the period when the tax deduction reduces income taxes payable. The Company follows the with-and-without approach for the direct effects of windfall/shortfall items and to determine the timing of the recognition of any related benefits. The Company recorded a net windfall of \$0.9 million, \$9.6 million and \$0.9 million in 2015, 2014, and 2013, respectively.

**18. Quarterly Financial Data (Unaudited)**

<b>Year 2015</b>	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Product revenue	\$ 25,607	\$ 23,676	\$ 22,898	\$ 15,515
Total revenue	30,894	23,681	22,904	15,520
Cost of product revenue	6,290	5,176	5,274	4,313
Gross profit on product revenue	19,317	18,500	17,624	11,202
Net income	\$ 11,042	\$ 8,380	\$ 7,820	\$ 3,516
Per common share information:				
Basic net income per share	\$ 0.74	\$ 0.56	\$ 0.52	\$ 0.24
Basic common shares outstanding	14,965	14,967	14,961	14,905
Diluted net income per share	\$ 0.72	\$ 0.55	\$ 0.51	\$ 0.23
Diluted common shares outstanding	15,353	15,316	15,336	15,330

<b>Year 2014</b>	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Product revenue	\$ 17,880	\$ 21,975	\$ 21,267	\$ 14,352
Total revenue	23,255	22,055	26,275	34,010
Cost of product revenue	5,511	5,725	5,333	4,361
Gross profit on product revenue	12,369	16,250	15,934	9,991
Net income	\$ 7,816	\$ 6,171	\$ 9,302	\$ 15,030
Per common share information:				
Basic net income per share	\$ 0.53	\$ 0.42	\$ 0.63	\$ 1.04
Basic common shares outstanding	14,801	14,759	14,688	14,461
Diluted net income per share	\$ 0.51	\$ 0.40	\$ 0.60	\$ 0.97
Diluted common shares outstanding	15,278	15,435	15,493	15,499

**19. Subsequent Events**

On February 26, 2016, the Company entered into an accelerated stock repurchase agreement with Morgan Stanley & Co. LLC ("Morgan Stanley") pursuant to a Fixed Dollar Accelerated Share Repurchase Transaction ("ASR Agreement") to purchase \$25.0 million of shares of its common stock. Pursuant to the terms of the ASR Agreement, the Company paid Morgan Stanley \$25.0 million in cash and received an initial delivery of 377,155 shares of the Company's common stock on February 29, 2016. The total number of shares to be repurchased will be based generally on the daily volume-weighted average share prices of the Company's common stock during the term of the transaction. At settlement, Morgan Stanley may be required to deliver additional shares of common stock to the Company, or, under certain circumstances, the Company may be required to deliver shares of its common stock or may elect to make a cash payment to Morgan Stanley. Final settlement of the ASR Agreement is expected to be completed in the third

quarter of 2016, although the settlement may be accelerated at Morgan Stanley's option or extended, in either case subject to certain terms and conditions.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

(a) Evaluation of disclosure controls and procedures.

As required by Rule 13a-15 under the Securities Exchange Act of 1934 (“Exchange Act”), we carried out an evaluation under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based upon that evaluation, the chief executive officer and chief financial officer have concluded that our disclosure controls and procedures are effective as of December 31, 2015 to ensure that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by our company in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. On an on-going basis, we review and document our disclosure controls and procedures, and our internal control over financial reporting, and we may from time to time make changes aimed at enhancing their effectiveness and ensuring that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal year 2015 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

**Management’s Report on Internal Control over Financial Reporting**

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework* as issued in 2013.

Based on our assessment and those criteria, our management believes that our company maintained effective internal control over financial reporting as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included elsewhere in this Annual Report on Form 10-K.

#### **ITEM 9B. OTHER INFORMATION**

None.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015.

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

The information required under this item and Item 5 of this Annual Report on Form 10-K under the heading “Equity Compensation Plan Information” is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**



The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of our fiscal year ended December 31, 2015.

## **PART IV**

### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

#### **(1) Financial Statements**

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#### **(2) Schedules**

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

## (3) Exhibits

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

Exhibit Number	Description	Filed with this Form 10-K	Form	Incorporated by Reference Filing Date with SEC	Exhibit Number
	<i>Restated Articles of Organization, as amended, of Anika Therapeutics, Inc. (with date of filing with Secretary of State of the Commonwealth of Massachusetts):</i>				
3.1a	(a) Restated Articles of Organization (April 29, 1993)		10-K	March 13, 2015	3.1a
3.1b	(b) Certificate of Correction (November 10, 1993)		10-K	March 13, 2015	3.1b
3.1c	(c) Certificate of Vote of Directors Establishing a Series of a Class of Stock (May 18, 1995)		10-K	March 13, 2015	3.1c
3.1d	(d) Articles of Amendment (January 9, 1997)		10-QSB	January 14, 1997	3.1
3.1e	(e) Certificate of Vote of Directors Establishing a Series of a Class of Stock (April 7, 1998)		10-K	March 13, 2015	3.1e
3.1f	(f) Articles of Amendment (June 3, 1998)		10-QSB	August 13, 1998	3.1
3.1g	(g) Articles of Amendment (April 4, 2008)		10-K	March 9, 2009	3.7
3.2	Amended and Restated Bylaws of Anika Therapeutics, Inc.		10-Q	August 14, 2002	3.6
4.1	Shareholder Rights Agreement, dated as of April 7, 2008, between Anika Therapeutics, Inc. and American Stock Transfer & Trust Company		8-A12B	April 7, 2008	4.1
10.1	Lease, dated January 3, 2007, between Anika Therapeutics, Inc. and Farley White Wiggins, LLC, relating to 32 Wiggins Avenue, Bedford, Massachusetts		8-K	January 10, 2007	10.1
10.2	Lease Agreement, dated December 30, 2009, between Fidria Farmaceutici S.p.A. and Fidria Advanced Biopolymers S.r.l., relating to Via Ponte della Fabbrica 3/A and 3/B Abano Terme, Padua, Italy		8-K	January 6, 2010	10.2
10.3	Translation of Lease Agreement, dated October 9, 2015, between Anika Therapeutics S.r.l. and Consorzio Zona Industriale E Porto Fluviale di Padova relating to Land Registry of the Municipality of Padova, Page 148, cadastral map 516 and 517		8-K	October 14, 2015	10.1
	<i>Credit Agreement with Bank of America, N.A.:</i>				
10.4a	(a) Credit Agreement, dated as of January 31, 2008, among Anika Therapeutics, Inc., Anika Securities, Inc. and Bank of America,		8-K	February 6, 2008	10.1

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	N.A., as administrative agent			
10.4b	(b) Consent and First Amendment, dated as of December 30, 2009, by and among Anika Therapeutics, Inc., Anika Securities, Inc. and Bank of America, N.A., as administrative agent	8-K	January 6, 2010	10.4
10.4c	(c) Pledge Agreement on a Quota of Fidia Advanced Biopolymers S.r.l., dated March 12, 2010, by Anika Therapeutics, Inc. in favor of Bank of America, N.A., as agent bank	10-Q	May 10, 2010	10.1
10.5	Sale and Purchase Agreement, dated December 30, 2009, by and between Fidia Farmaceutici S.p.A. and Anika Therapeutics, Inc.	8-K	January 6, 2010	2.1
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Exhibit Number	Description	Filed with this Form 10-K	Form	Filing Date with SEC	Incorporated by Reference Exhibit Number
10.6	Tolling Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l		8-K	January 6, 2010	10.3
10.7	Registration Rights Agreement, dated December 30, 2009, between Anika Therapeutics, Inc. and Fidia Farmaceutici S.p.A.		8-K	January 6, 2010	10.1
*10.8	License Agreement, dated as of December 21, 2011, by and between Anika Therapeutics, Inc. and DePuy Mitek, Inc. <i>2003 Stock Option and Incentive Plan:</i>		8-K	December 22, 2011	10.1
†10.9a	(a) Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 5, 2011)		8-K	June 10, 2011	10.1
†10.9b	(b) Amendment to Second Amended and Restated 2003 Stock Option and Incentive Plan (adopted April 11, 2013)		8-K	June 21, 2013	10.1
†10.9c	(c) Form of Incentive Stock Option Agreement		8-K	October 5, 2004	10.3
†10.9d	(d) Form of Non-Qualified Stock Option Agreement for Non-Employee Directors		8-K	October 5, 2004	10.4
†10.9e	(e) Form of Performance Share Award Agreement		8-K	February 6, 2008	10.3
†10.9f	(f) Form of Restricted Deferred Stock Unit Award Agreement for Non-Employee Directors		10-K	March 9, 2009	10.25
†10.9g	(g) Form of Restricted Stock Award Agreement for Employees		10-K	March 12, 2008	10.27
†10.9h	(h) Form of Stock Appreciation Right Agreement for Employees		10-Q	May 9, 2006	10.1
†10.9i	(i) Form of Stock Appreciation Right Agreement for Non-Employee Directors		10-Q	May 9, 2006	10.2
†10.10	Anika Therapeutics, Inc. Senior Executive Incentive Compensation Plan		8-K	February 6, 2008	10.2
†10.11	Anika Therapeutics, Inc. Non-Employee Director Compensation Policy		10-K	March 12, 2008	10.28
†10.12a	Employment Agreement, dated March 22, 2010, between Anika Therapeutics, Inc. and Sylvia Cheung		10-K	May 5, 2014	10.42
†10.12b	Amendment No. 1 to the Employment Agreement, dated December 8, 2010, by and between Anika Therapeutics, Inc. and Sylvia Cheung		10-K	May 5, 2014	10.43
†10.13a	Employment Agreement, dated September 10, 2009, between Anika Therapeutics, Inc. and Frank J. Luppino		8-K	September 14, 2009	10.1
†10.13b	Amendment No. 1 to Employment Agreement, dated December 1, 2010, by and between Anika Therapeutics, Inc. and Frank J. Luppino		10-K	March 16, 2011	10.35
†10.14a	Employment Agreement, dated September 10, 2009, between Anika Therapeutics, Inc. and William J. Mrachek		8-K	September 14, 2009	10.2
†10.14b	Amendment No. 1 to Employment Agreement, dated December 1, 2010, by and between Anika Therapeutics, Inc. and William J. Mrachek		10-K	March 16, 2011	10.36

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†10.15	Employment Agreement, dated October 17, 2008, between Anika Therapeutics, Inc. and Kevin Quinlan	8-K	October 22, 2008	10.2
†10.16a	Employment Agreement, dated October 17, 2008, between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D.	8-K	October 22, 2008	10.1
†10.16b	Amendment No. 1 to Employment Agreement, dated December 8, 2010, by and between Anika Therapeutics, Inc. and Charles H. Sherwood, Ph.D.	10-K	March 16, 2011	10.33

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Exhibit Number	Description	Filed with this Form 10-K	Incorporated by Reference Filing Date with SEC	Exhibit Number
†10.17	Separation Agreement, effective November 26, 2014, by and between Anika Therapeutics, Inc. and Carol Barnett		10-K March 13, 2015	10.16
†10.18	Separation Agreement, effective November 7, 2014, by and between Anika Therapeutics, Inc. and John W. Sheets		10-K March 13, 2015	10.17
†10.19	Consulting Agreement, effective December 8, 2015, by and between Anika Therapeutics, Inc. and John C. Moran		8-K December 9, 2015	10.1
21.1	List of Subsidiaries of Anika Therapeutics, Inc.	X		
23.1	Consent of PricewaterhouseCoopers LLP	X		
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
**32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X		
***101	The following materials from the Annual Report on Form 10-K of Anika Therapeutics, Inc. for the fiscal year ended December 31, 2015, formatted in xBRL: (i) Consolidated Balance Sheets as of December 31, 2015 and December 31, 2014; (ii) Consolidated Statements of Operations for the Years Ended December 31, 2015, December 31, 2014, and December 31, 2013; (iii) Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2015, December 31, 2014, and December 31, 2013; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2015, December 31, 2014, and December 31, 2013; and (v) Notes to Consolidated Financial Statements	X		

† Management contract or compensatory plan or arrangement.

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

\*\* The certification attached as Exhibit 32.1 that accompanies this Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Anika Therapeutics, Inc. under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

\*\*\* Pursuant to Rule 406T of Regulation S-T, XBRL (Extensible Business Reporting Language) information is deemed not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934 and otherwise is not subject to liability under these sections.

## SIGNATURES

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

ANIKA THERAPEUTICS, INC.

/s/ CHARLES H. SHERWOOD, PH.D.

Date: March 10, 2016 By: Charles H. Sherwood, Ph.D.

*President and Chief Executive Officer*

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ CHARLES H. SHERWOOD, PH.D.</u>	President and Chief Executive Officer Director	
Charles H. Sherwood, Ph.D.	<i>(Principal Executive Officer)</i>	March 10, 2016
<u>/s/ SYLVIA CHEUNG</u>	Chief Financial Officer	
Sylvia Cheung	<i>(Principal Accounting Officer)</i>	March 10, 2016
<u>/s/ JOSEPH L. BOWER</u>		
Joseph L. Bower	Director	March 10, 2016
<u>/s/ RAYMOND J. LAND</u>	Director	March 10, 2016
Raymond J. Land		

/s/ GLENN R. LARSEN, PH.D.

Glenn R. Larsen

Director

March 10, 2016

/s/ JEFFERY S. THOMPSON

Jeffery S. Thompson

Director

March 10, 2016

/s/ STEVEN E. WHEELER

Steven E. Wheeler

Director

March 10, 2016