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

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

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

For the transition period from to

Commission File Number 000-21326

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

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

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

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

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

Preferred Stock Purchase Rights

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting and non-voting equity held by non-affiliates of the Registrant as of June 30, 2014, the last day of the Registrant's most recently completed second fiscal quarter, was $682,060,021 based on the close price per share of common stock of $46.33 as of such date as reported on the NASDAQ Global Select Market. Shares of our common stock held by each executive officer, director and each person or entity known to the registrant to be an affiliate have been excluded in that such persons may be deemed to be affiliates; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. At March 9, 2015, there were issued and outstanding 14,546,275 shares of common stock, par value $.01 per share.

Documents Incorporated By Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2014. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

ANIKA THERAPEUTICS, INC.
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References in this Annual Report on Form 10-K to "we," "us," "our," "our company," and other similar references refer to Anika Therapeutics, Inc. and its subsidiaries unless the context otherwise indicates.

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

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

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

thereby;

- Our ability to license our aesthetics product to new distribution partners domestically and outside the United States;

- Our ability, and the ability of our distribution partners, to market our aesthetics dermatology product and our expectations regarding the distribution and sales of ELEVESS and the timing thereof;

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

- Our expectations regarding product gross margin;

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

- Our expectations for changes in operating expenses, including research and development and selling, general, and administrative expenses;

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

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

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

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

- The strength of the economies in which we operate or will operate, as well as the political stability of any of those geographic areas;

- Our ability to effectively prioritize the many research and development projects underway;

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

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

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

Forward-looking statements involve known and unknown risks, uncertainties, and other factors, some of which are beyond our control, including those factors described in the section titled "Risk Factors" in this Annual Report on Form 10-K or elsewhere in this report. These risks, uncertainties, and other factors may cause our actual results, performance or achievement to be materially different from the anticipated future results, performance, or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences,

including those factors discussed in the sections titled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” elsewhere in this Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors, new information, future events, or other changes.

PART I

ITEM 1. BUSINESS

Overview

We develop, manufacture, and commercialize therapeutic products for tissue protection, healing, and repair. These products are based on hyaluronic acid ("HA"), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells.

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

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

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

In December 2012, we announced a strategic shift which involved the closure of our tissue engineering facility in Abano Terme, Italy due to the inability to meet strict regulatory standards established by the European Medicines Agency ("EMA") for Advanced Therapy Medicinal Products ("ATMP") (cell based) products that became effective January 1, 2013. In 2013, we completed a restructuring plan which included a reduction-in-force of 12 people and provided for severance payments, disposals of related supplies, equipment, and other assets. This plan was intended to improve the efficiency and financial performance of our Italian operations by reducing costs and focusing on products and technology with strong commercial potential. In connection with the plan, we recorded a fourth quarter 2012 pre-tax charge of approximately $2.5 million, including $1.3 million for severance, various expenses, and write-offs of supplies and equipment, and a $1.2 million non-cash charge related to the abandonment of the HYALOGRAFT C autograft in-process research and development ("IPR&D") project.

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

Orthobiologics

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

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

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

In the United States, MONOVISC is also indicated for the treatment of pain caused by osteoarthritis of the knee in patients who have failed to respond adequately to conservative, non-pharmacologic therapy and to simple analgesics, such as acetaminophen. MONOVISC is a sterile, clear, viscous solution of partially cross-linked sodium hyaluronate in a phosphate buffered saline solution. A treatment of MONOVISC is comprised of one injection of the product delivered directly into the affected joint. MONOVISC became available for sale in the United States in April 2014, and it is also marketed by Mitek under the terms of a fifteen-year licensing, distribution, supply, and marketing agreement, which was entered into on December 21, 2011 (the “Mitek MONOVISC Agreement”). Outside of the United States, we have a number of distribution relationships servicing international markets including Canada, Europe, Latin America, Asia, and certain other international countries. We continue to seek to establish distribution relationships in other key markets. See the sections captioned “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Management Overview” and “Risk Factors.”

In addition to the three viscosupplementation products discussed above, we also offer several additional products used in connection with orthopedic regenerative medicine. These products are based on the HYAFF technology and are currently available in Europe, South America, and Asia. They include HYALOFAST, a biodegradable support for human bone marrow mesenchymal stem cells used for cartilage regeneration and as an adjunct for microfracture surgery; HYALONECT, a woven gauze used as a graft wrap; and HYALOSS MATRIX, HYAFF fibers used to mix blood/bone grafts to form a paste for bone regeneration. We also offer HYALOGLIDE, an ACP gel used in tenolysis treatment, with the potential for use in flexor tendon adhesion prevention and for use in the shoulder for prevention of adhesive capsulitis with additional clinical data. These products are commercialized through a network of distributors, primarily in Europe, the Middle East, and Korea.

Dermal

Our dermal products consist of advanced wound care products, based on the HYAFF technology, and aesthetic dermal fillers, based on our proprietary chemically modified cross-linked HA technology, BCDI. Products utilizing our HYAFF technology are used for the treatment of skin wounds, ranging from burns to diabetic ulcers. The products cover a variety of wound treatment solutions including debridement agents, advanced therapies to aid healing, and scaffolds used as skin substitutes. Leading products include HYALOMATRIX and HYALOFILL, for the treatment of complex wounds such as burns and ulcers. The dermal products are commercialized through a network of distributors, primarily in Europe, Latin America, and the Middle East. Several of the products are also cleared for sale in the United States including HYALOMATRIX, HYALOFILL, HYALOGRAN, and HYALOMATRIX 3D. In 2012, we entered into a distribution agreement for sales of advanced wound care products in nine South American countries, including Argentina, Brazil, Mexico, and Chile. In July 2014, we entered into an agreement with Medline Industries, Inc. to commercialize HYALOMATRIX in the United States on an exclusive basis through 2019.

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

Surgical

Our surgical business consists of products used to prevent surgical adhesions and to treat ENT disorders. HYALOBARRIER is a clinically proven post-operative adhesion barrier for use in the abdomino-pelvic area. The product is currently commercialized by Anika S.r.l. in Europe, the Middle East, and certain Asian countries through a distribution network, but it is not approved for sale in the United States. HYALOSPINE, a product designed to prevent post-surgical adhesions following spinal surgery, was CE Mark approved in January 2015 for sale in Europe. INCERT, approved for sale in Europe, Turkey, and Malaysia, is a chemically modified, cross-linked HA product, for the prevention of spinal post-surgical adhesions. There are currently no plans at this time to distribute INCERT in the United States. We co-own issued U.S. patents covering the use of INCERT for adhesion prevention. See the section captioned “Patent and Proprietary Rights.”

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

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

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. The ophthalmic products we manufacture include STAARVISC-II, OPTIVISC (formerly ShellGel), ANIKAVISC, and NUVISC. They are injectable, high molecular weight HA products used as viscoelastic agents in ophthalmic surgical procedures such as cataract extraction and intraocular lens implantation. These products coat, lubricate, and protect sensitive tissue such as the endothelium, and they function to maintain the shape of the eye, thereby facilitating ophthalmic surgical procedures.

We previously manufactured the AMVISC product line for Bausch & Lomb (“B&L”) under the terms of an exclusive supply agreement that expired on December 31, 2010 (the “2004 B&L Agreement”) for viscoelastic products used in ophthalmic surgery. Effective January 1, 2011, we entered into a non-exclusive, two year contract with B&L intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, low-cost supplier formerly affiliated with B&L, and continued to supply B&L with these products during 2011. Effective January 1, 2012, the parties agreed to a three year contract for us to continue to supply these products to B&L as a second supplier with committed annual volumes through year-end 2014, and the contract was not renewed upon expiration.

Veterinary

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

States and in selected countries in the Middle East.

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

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

See also the section captioned “Risk Factors —Risks Related to Our Business and Industry—A significant portion of our revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations” for a discussion regarding our dependence on large-volume customers and the effects that the loss of any such customer could have on our business and financial performance.

Research and Development of Potential Products

Our research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, the preparation and processing of applications for regulatory approvals or clearances at all relevant stages of product development, and process development and scale-up manufacturing activities for our existing and new products. Our development focus includes products for tissue protection, repair, and regeneration. For the years ended December 31, 2014, 2013 and 2012, these expenses were $8.1 million, $7.1 million, and $5.4 million, respectively. We anticipate that our research and development efforts, including pre-clinical studies and clinical trials, will increase significantly in the near future over historical levels.

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

The technologies obtained through our acquisition of Anika S.r.l. have enhanced our research and development capabilities and our pipeline of product candidates. Anika S.r.l. has research and development programs for new products including HYALOFAST, an innovative hyaluronic acid matrix for human bone marrow mesenchymal stem cells used to regenerate soft tissue. HYALOFAST received CE Mark approval in September 2009, and it is currently commercially available in Europe and certain international countries. During the second quarter of 2014, we submitted a proposed investigational device protocol to the FDA. Our current plan is to begin a phase III clinical trial in 2015. HYALOSPINE is an adhesion prevention gel for use after spinal surgery. We completed a pilot clinical study in 2012, submitted the CE Mark application in September 2013, and received the CE Mark approval in January 2015.

Our research and development efforts may not be successful in (1) developing our existing product candidates, (2) expanding the therapeutic applications of our existing products, or (3) resulting in new applications for our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We may not be able to obtain regulatory approval for any new applications we develop. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that we will achieve meaningful sales of such products or applications.

Patent and Proprietary Rights

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

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

In 2014, we were granted 5 new patents in the United States and Canada. The patents covered regenerative technologies and products and our HYALOSPINE product, among others. Other entities have filed patent applications for, or have been issued patents concerning, various aspects of HA-related products or processes. In addition, the products or processes we develop may infringe the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

We rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require certain customers and vendors, and all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. These agreements, however, may not provide adequate protection.

See also the section captioned “Risk Factors—Risks Related to Our Intellectual Property.”

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

Government Regulation

U.S. Regulation

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

Medical products regulated by the FDA are generally classified as drugs, biologics, and/or medical devices. Medical devices intended for human use are classified into three categor