ANIKA THERAPEUTICS INC
Form 10-K
March 14, 2013

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2012

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

For the transition period from to

Commission File Number 000-21326

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

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

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

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

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

Preferred Stock Purchase Rights

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

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

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

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

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

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

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

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

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

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

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

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

Documents Incorporated By Reference

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

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ANIKA THERAPEUTICS, INC.
For Fiscal Year Ended December 31, 2012

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

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

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

- Our expectations regarding HYVISC sales;

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

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

- Our expectations regarding aesthetics product line extensions;

- Our expectations regarding product gross margin;

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

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

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

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

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

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

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

- Our ability to remain in compliance with debt covenants;

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

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

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

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

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

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

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

PART I

ITEM 1. BUSINESS

Overview

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

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

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

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

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

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

Orthobiologics

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

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

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

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

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

Dermal

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

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

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

Surgical

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

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

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

Ophthalmic

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

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

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

Veterinary

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

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

Research and Development of Potential Products

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

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

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

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

Patent and Proprietary Rights

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

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

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

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

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

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

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

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

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

Government Regulation

United States Regulation

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

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

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

AMVISC, AMVISC Plus, ShellGel/Optivisc, STAARVISC, and AnikaVisc are approved as Class III medical devices in the U.S. for intraocular ophthalmic surgical procedures used in humans. ORTHOVISC is approved as a Class III medical device in the U.S. for treatment of pain resulting from osteoarthritis of the knee in humans. HYDRELLE is approved as a Class III medical device in the U.S. for treatment of facial wrinkles and folds, such as nasolabial folds. HYVISC is approved as an animal drug for