ANIKA THERAPEUTICS INC
Form 10-K
March 16, 2011

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, 2010

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 o 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, 2010, the last day of the Registrant's most recently completed second fiscal quarter, was $79,383,470 based on the close price per share of Common Stock of $5.89 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 14, 2011, there were issued and outstanding 13,458,168 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, 2010. 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, 2010

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 new products;
- Our ability to achieve or maintain compliance with laws and regulations;
- The timing of and/or receipt of the 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 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 and research and development and collaboration opportunities;
- Our and Bausch & Lomb's performance under the non-exclusive, two-year extension of the supply agreement for AMVISC and AMVISC Plus ophthalmic viscoelastic products, and our expectations regarding revenue from ophthalmic products;
- Our ability, and the ability of our distribution partner, to market our aesthetic dermatology product;
- Our ability to commercialize AnikaVisc 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 and revenue growth;

- Our intention to increase 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 developments, 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 our ability to directly distribute HYDRELLE™ in the interim period and the impact such plan 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 ELEVESS product and the timing thereof;

- Our expectations regarding product gross margin;

- Our expectations regarding our U.S. MONOVISC trials and the results of the related premarket approval ("PMA") filing with the FDA, including the requested Advisory Panel review and the likelihood of our obtaining such approval and/or the anticipated timing thereof;

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

- Our expectations regarding our existing aesthetics product's line extensions;

- 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 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 expectations regarding our existing manufacturing facility and the Bedford, MA facility; our expectations related to costs, including financing costs, to build-out and occupy the new facility, the timing of construction, and our ability to obtain FDA licensure for the facility; and our expectation regarding the impact of our Bedford, MA facility on our business and the amount of the annual depreciation expense associated therewith;

- Our abilities to comply 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 integrate Fidia Advanced Biopolymers S.r.1. ("FAB"), our recently acquired subsidiary, into the Company and manage the operation from one with losses, into a company generating profits;

- Our abilities to integrate our research and development activity with those of FAB and effectively prioritize the many projects underway at both companies;

- Our ability to obtain U.S. approval for the orthopedic and other products of FAB, 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;

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Our ability to commercialize MONOVISC and the FAB products directly to customers, and the potential increase in expenses associated therewith; 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 Discussions 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 acquired 100% of the issued and outstanding stock of FAB on December 30, 2009 from Fidia Farmaceutici S.p.A., a privately held Italian corporation, for a purchase price consisting of $17.0 million in cash and 1,981,192 shares of the Company's common stock valued at $16.8 million based on the closing stock price of $8.49 per share. See Item 8: Financial Statements, Note 16, for additional information regarding this transaction. In December of 2010, FAB's name was changed to Anika Therapeutics S.r.l., but to avoid confusion, we will continue to refer to it as "FAB" in the rest of this document.

FAB has over 20 products currently commercialized, primarily in Europe. These products are also all made from hyaluronic acid, and 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. With the acquisition of FAB, the Company now offers therapeutic products in the following areas:

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

The Company plans to commercialize MONOVISC and certain FAB products in the U.S. once we receive FDA approval to market. In 2011, upon FDA approval, we will begin adding resources and materials to implement this commercialization strategy.

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

Orthobiologics

The Company's orthobiologics products are used in a wide range of treatments from providing relief from the pain of osteoarthritis, to regenerating damaged tissue such as cartilage defects. 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 U.S., Canada, Turkey 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 newest joint health products and 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-acetylglucosamine. 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, under the terms of a ten-year licensing, distribution, supply and marketing agreement which was entered into in December 2003 (the "JNJ Agreement").

We have a number of distribution relationships servicing international markets including Canada, Europe, Turkey, 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".

With the acquisition of FAB, we now offer several additional products used in connection with orthopedic regenerative medicine. The products currently available in Europe include Hyalograft C Autograft for cartilage regeneration; Hyalofast, a biodegradable support for human bone marrow mesenchymal stem cells; Hyalonect, a woven gauze used as a graft wrap; and Hyaloss, HYAFF fibers used to mix blood/bone grafts to form a paste for bone regeneration. FAB also offers Hyaloglide, an ACP gel used in tenolysis treatment, but with potential for flexor tendon adhesion prevention, and in the shoulder for adhesive capsulitis with additional clinical data. FAB's products are commercialized directly in Italy, and through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. One of Anika's areas of focus is to seek U.S. approval of a number of these products, as Anika believes it has the opportunity to expand its sales of these products in the U.S. In this regard, in October 2010, Anika filed 510(k) applications with the FDA to gain marketing clearance for three FAB products: Hyalofast®, Hyaloglide®, and Hyalonect®, but is currently unable to predict the timing of receipt of such clearance.

Dermal

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. and certain countries in South America. Internationally, this product is marketed under the ELEVESS name, and in the U.S. under the name HYDRELLE. Coapt Systems, Inc. ("Coapt") began selling HYDRELLE in the third quarter of 2009. In July 2010, Coapt made a general assignment for the benefit of creditors and an assignee began the liquidation of Coapt's assets. The Company's Distribution Agreement with Coapt has been terminated, and the Company has directly sold HYDRELLE in the interim while it reviews its franchise strategy and opportunities for new distribution partners.

With the acquisition of FAB, the Company entered the field of advanced wound care products. FAB offers over seven 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 skin substitutes. Leading products

include Hyalograft 3D, for the regeneration of skin; and Hyalomatrix, for treatment of burns and ulcers and the only product not contra-indicated for 3 rd degree burns. FAB's products are commercialized directly in Italy, and through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. Several of the products are also approved for sale in the United States, including Hyalomatrix and Hyalofill, and the Company is exploring domestic distribution opportunities.

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-II, Optivisc (formerly ShellGel), and recently FDA-approved AnikaVisc. 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 a supply agreement that expired on December 31, 2010 (the "2004 B&L Agreement") for viscoelastic products used in ophthalmic surgery. Effective January 1, 2011 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, recently acquired low-cost supplier to B&L. Under the 2004 B&L Agreement, the Company was restricted in its ability to commercialize viscoelastic products to only existing customers (STAAR Surgical Company and Hoya Surgical Optics, Inc.). That restriction has now expired, and the Company is free to market its own viscoelastic product AnikaVisc. B&L accounted for 21% of product revenue for the year ended 2010, and product revenue is expected to be significantly lower in 2011 under the new transition contract. Operating margins under the 2004 B&L Agreement were low, and the Company expects to see margin improvement through commercialization of its new AnikaVisc product. There can be no assurance that AnikaVisc will be successfully sold or that it will generate any profit for the Company. See also Item 1A. "Risk Factors."

Surgical

INCERT, approved for sale in Europe and Turkey, is designed as a family of HA based products, with chemically modified, cross-linked HA, for prevention of post-surgical adhesions. 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. INCERT is currently marketed in four countries. We see potential for expanded indications for the use of INCERT, but have made this a secondary goal to the successful launch and expanded distribution of our joint health and dermatology products. 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."

Hyalobarrier and Hyalobarrier Endo are a clinically proven post operative adhesion barrier approved for abdominal indications. The products are currently commercialized by FAB in Europe, the Middle East and certain Asian countries through a distribution network, but are not approved in the U.S.

FAB offers several products used in connection with the treatment of ENT disorders. The lead product is Merogel, a thick, viscous hydrogel composed of cross-linked hyaluronic acid—a biocompatible agent that creates a moist wound-healing environment. FAB is partnered with Medtronic for worldwide distribution.

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," 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 chemically modified formulations of HA designed for longer residence time in the body. For the years ended December 31, 2010, 2009 and 2008, these expenses were $6.9 million, $8.2 million, and $7.4 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

With the acquisition of FAB, we have enhanced both our research and development capabilities and our pipeline of candidate products. FAB has research and development programs for new products including Hyalobone, a bone tissue filler; Hyalospine, an adhesion prevention gel for use after spinal surgery; and Hyalofast, to repair cartilage defects.

In addition to the FAB products in the preceding paragraph, additional products in development include MONOVISC for U.S. marketing approval, and additional next generation joint health products. 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 crosslinked