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.

ANIKA THERAPEUTICS, INC.
TABLE OF CONTENTS

FORM 10-K
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 HA-technology. We received Conformité Européene ("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 an investigational device exemption, or an IDE application, with the FDA, and completed the clinical segment of the U.S. MONOVISC pivotal trial in June 2009, and a follow-on retreatment study in September 2009. 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, which is the FDA's mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The Company has not yet received a date for an Advisory Panel meeting. We continue to believe that Monovisc should receive FDA approval. Our second single-injection osteoarthritis product under development is CINGAL™, which is based on the same technology platform used in MONOVISC, but with an added active therapeutic molecule to provide broad pain relief for a long period of time.

During the past year, we have integrated the research and development efforts of Anika and FAB and prioritized our new product development activities. There is a risk that our efforts will 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 expire between 2011 and 2023. 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. FAB's issued patents expire between 2011 and 2026. The FAB patent estate is extensive and intertwined with its former parent company, Fidia Farmaceutici S.p.A, through a cross-licensing agreement which provides both companies with access to each others 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."

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 products in accordance with the terms of the JNJ Agreement.

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"). Most Class I devices are exempt from the FDA review process and some are exempt from Good Manufacturing Practice. Class II devices are subject to general and special controls (for example, performance standards, postmarket 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 in intraocular use 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 intra-articular injection in horse joints to treat degenerative joint disease associated with synovitis. Most HA products for human use are regulated as medical devices. We believe that our INCERT product, should we decide to seek U.S. approval to market, will have to meet the regulatory requirements for Class III devices and will require clinical trials and a PMA submission. Our subsidiary, FAB, has three advanced wound care products approved in the U.S. as Class II devices through premarket notification (510(k))--Hyalomatrix, Hyalofill-R, and Hyalofill-F. All of FAB's ENT products are 510(k) cleared by Medtronic as Class II devices. The FDA's 510(k) clearance process is under review and changes to the process may have an impact on current or future product approvals. Three products were submitted for 510(k) clearance in 2010: Hyaloglide, Hyalofast and Hyalonect. There has been delay in the FDA's review process and the Company is unable to predict the timing of receipt of these clearances. There is no guarantee that the clearance process for these products will be successful or that additional data will not be required to support clearance.

Unless a new device is exempted from premarket notification, its manufacturer must obtain marketing clearance from the FDA through premarket notification (510(k)) or approval through PMA before the device can be introduced to the market. Product development and approval within the FDA regulatory framework takes a number of years and involves the expenditure of substantial resources. This regulatory framework may change or additional regulations may arise at any stage of our product development process and may affect approval of, or delay an application related to, a product, or require additional expenditures by us. There can be no assurance that the FDA review of marketing applications will result in product approval on a timely basis, if at all. The PMA approval process is lengthy, expensive, and typically requires, among other things, valid scientific evidence which generally includes extensive

data such as pre-clinical and clinical trial data to demonstrate a reasonable assurance of safety and effectiveness.

Human clinical trials in the U.S. for significant risk devices must be conducted under Good Clinical Practice ("GCP") regulations through Investigational Device Exemption ("IDE"), which must be submitted to the FDA and either be approved or be allowed to become effective before the trials may commence. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. In addition, the IDE approval process could result in significant delays. Even if the FDA approves an IDE or allows an IDE for a clinical investigation to become effective, clinical trials may be suspended at any time for a number of reasons. Among others, these reasons may include: a) failure to comply with applicable requirements; b) inadequacy of informed consent; and c) the data generated suggests that: the risks to clinical subjects are not outweighed by the anticipated benefits to clinical subjects and the importance of the knowledge to be gained, the investigation is scientifically unsound, or there is reason to believe that the device, as used, is ineffective. A trial may be terminated if serious unanticipated adverse events present an unreasonable risk to subjects. If clinical studies are suspended or terminated, we may be unable to continue the development of the investigational products affected.

Upon completion of required clinical trials, for Class III medical devices, results might be presented to the FDA in a PMA application. In addition to the results of clinical investigations, the New Drug Application ("NDA") applicant must submit other information relevant to the safety and efficacy of the device, including, among other things, the results of non-clinical tests and clinical trials; a full description of the device and its components; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms to the FDA's current Quality System Regulation ("QSR"), formerly known as GMP. FDA review of the PMA may not result in timely, or any, PMA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements. We have completed the clinical trail and PMA submissions for our MONOVISC product, which is currently under review by FDA. We have requested review of MONOVISC by the Orthopedic Advisory Panel, but we have not yet received a date for a panel meeting.

Upon completion of required clinical trials for pharmaceuticals, results might be presented to the FDA in a NDA or New Animal Drug Application ("NADA"). In addition to the results of clinical investigations, the NDA or NADA applicant must submit other information relevant to the safety and efficacy of the product, including, among other things, the results of non-clinical tests and clinical trials; a full description of the product formulation; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms with the FDA's current cGMP related to pharmaceuticals. FDA review of the NDA or NADA may not result in timely, or any, FDA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Post-approval product or manufacturing changes where such change affects the safety and efficacy of the medical products as well as the use of a different facility for manufacturing, could necessitate additional review and approval by the FDA. Post-approval changes in labeling, packaging or promotional materials may also necessitate further review and approval by the FDA.

Legally marketed products are subject to continuing requirements by the FDA relating to design control, manufacturing, quality control and quality assurance, maintenance of records and documentation, reporting of adverse events, and labeling and promotion. The FDC Act requires medical product manufacturers to comply with QSR for medical devices and cGMP regulations related to pharmaceuticals. The FDA enforces these requirements through periodic inspections of manufacturing facilities. To ensure full compliance with requirements set forth in the GMP/QSR regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Other federal, state, and local agencies may inspect manufacturing establishments as well.

A set of regulations known as the Medical Device Reporting and Drug Adverse Events Reporting System regulations obligates manufacturers to inform the FDA whenever information reasonably suggests that one of their medical products may have caused or contributed to a death or serious injury, or when one of their devices malfunctions and if the malfunction were to recur, the device or a similar device would be likely to cause or contribute to a death or serious injury.

The process of obtaining approvals from the FDA and foreign regulatory authorities can be costly, time consuming, and subject to unanticipated delays. Approvals of our products, processes or facilities may not be granted on a timely basis or at all, and we may not have available resources or be able to obtain the financing needed to develop certain of such products. Any failure or delay in obtaining such approvals could adversely affect our ability to market our products in the U.S. and in other countries.

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

FDA Warning Letter

In July 2008, we received a Warning Letter (the "Warning Letter") from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our manufacturing facility in Woburn, Massachusetts. The Company submitted corrective action plans, which have been accepted by the FDA and resulted in the clearance of the Warning Letter in September 2010.

Foreign Regulation

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

The CE mark, achieved in 1996, allows ORTHOVISC to be marketed without further approvals in most of the EU nations as well as other countries that recognize EU device regulations. ORTHOVISC ® mini, a treatment for osteoarthritis targeting small joints, is available in Europe under CE mark authorization received in 2008. In August 2004, we received an EC Design Examination Certificate which entitled us to affix a CE mark to INCERT-S as a barrier to adhesion formation following surgery. AMVISC ® and AMVISC ® Plus are CE marked, and in May 2005, we received an EC Design Examination Certificate which entitled us to affix a CE mark to ShellGel™/OptiVisc as an ophthalmic viscoelastic surgical device. Staarvisc, an ophthalmic viscoelastic surgical device, is licensed in Canada from May 2002. We received EU CE Mark approval for ELEVESS during the second quarter of 2007. MONOVISC, a medical device for treatment of pain associated with osteoarthritis, was approved in the EU in October 2007 and in Canada in August 2009. In addition, Anika received approval for several of its products in Latin America, Korea, Turkey, Middle East, UAE, Saudi Arabia, and other international markets.

Almost all of FAB's products are CE marked for European sale. In addition, FAB has received approval for several of its products in Argentina, Egypt, Hong Kong, Iran, Israel, Korea, Malaysia, Singapore, Mexico, Cyprus, Saudi Arabia, Taiwan, Turkey, and the United Arab Emirates. FAB's tissue engineered products Hyalograft C Autograft, Hyalograft 3D Autograft and Laserskin Autograft are currently marketed in Europe. However, the regulations for marketing of these products in Europe have been changed. Effective January 1, 2013, new regulations mandate these products to be approved by the European Medicines Agency ("EMA") as Advanced Therapeutics Medical Products ("ATMP") in order to remain on the EU market. FAB continues to be in discussion with the EMA and is implementing a plan to qualify for the new status while continuing to sell these products in the EU. There can be no assurance that required approvals will be obtained in a timely fashion. We may not be able to achieve and/or maintain the compliance required for CE marking or other foreign regulatory approvals for any or all of our products. The requirements relating to the conduct of clinical trials, product licensing, marketing, pricing, advertising, promotion and reimbursement also vary widely from country to country.

Competition

We compete with many companies, including, among others, large pharmaceutical firms and specialized medical products companies across all of our product lines. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations, which may be involved in research, development and commercialization of products. Many of our competitors also compete against us in securing relationships with collaborators for their

research and development and commercialization programs.

Competition in our industry is based primarily on product efficacy, safety, timing and the scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, product pricing and patent protection.

Some of the principal factors that may affect our ability to compete in our HA development and commercialization markets include:

- The quality and breadth of our technology and technological advances;
- Our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors;
- Our ability to recruit and retain skilled employees; and
- The availability of substantial capital resources to fund discovery, development and commercialization activities or the ability to defray such costs through securing relationships with collaborators for our research and development and commercialization programs.

We are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. All of the Company's products face substantial competition. There exist major worldwide competing products, made from HA and other materials, for use in ophthalmic surgery, orthopedics, surgical adhesion prevention, advanced wound care, ENT and cosmetic dermal fillers. There is a risk that we will be unable to compete effectively against our current or future competitors.

Employees

As of December 31, 2010, we had 114 employees, 42 of whom are located outside the U.S. and were added as a result of the FAB acquisition. We consider our relations with our employees to be good. None of our U.S. employees are represented by labor unions, and most of the employees based in Italy are represented by unions adding complexity and additional risks to the wage and employment decision process.

Environmental Laws

We believe that we are in compliance with all federal, state and local environmental regulations with respect to our manufacturing facilities and that the cost of ongoing compliance with such regulations does not have a material effect on our operations. Our leased Woburn manufacturing facility is located within the Wells G&H Superfund site in Woburn, Massachusetts. We have not been named and are not a party to any legal proceedings regarding the Wells G&H Superfund site.

Product Liability

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and we cannot assure you that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have coverage under our insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate, we cannot assure you that if material claims arise in the future, our insurance will be adequate to cover all situations. Moreover, we cannot assure you that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operation.

Available Information

Our Annual Reports on Form 10-K, including our consolidated financial statements, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information, including amendments and exhibits to such reports, filed or furnished pursuant to the Securities Exchange Act of 1934, as amended, are available free of charge in the "SEC Filings" section of our website located at http://www.anikatherapeutics.com, as soon as reasonably practicable after the reports are filed with or furnished to the Securities and Exchange Commission ("SEC"). The information on our website is not part of this Annual Report on Form 10-K. Reports filed with the SEC may be viewed at www.sec.gov or obtained at the SEC Public Reference Room at 100F Street NE, Washington, D.C. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and could in the future vary significantly depending on a number of factors. From time to time, information provided by us, or statements made by our employees, contain “forward-looking” information that involves risks and uncertainties. In particular, statements contained in this Annual Report on Form 10-K, and in the documents incorporated by reference into this Annual Report on Form 10-K, that are not historical facts, including, but not limited to statements concerning new products, product development, regulatory approval, and offerings, product and price competition, competition and strategy, customer diversification, product price and inventory, contingent consideration payments, deferred revenues, economic and market conditions, potential government regulation, seasonal factors, international expansion, revenue recognition, profits, growth of revenues, composition of revenues, cost of revenues, operating expenses, sales, marketing and support expenses, general and administrative expenses, product gross profit, interest income, interest expense, anticipated operating and capital expenditure requirements, cash inflows, contractual obligations, tax rates, stock-based compensation, leasing and subleasing activities, acquisitions, liquidity, litigation matters, intellectual property matters, distribution channels, stock price, third party licenses and potential debt or equity financings constitute forward-looking statements and are made under the safe harbor provisions of Section 27 of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are neither promises nor guarantees. Our actual results of operations and financial condition have varied and could in the future vary significantly from those stated in any forward-looking statements. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Form 10-K, in the documents incorporated by reference into this Form 10-K or presented elsewhere by our management from time to time. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition.

Our business is subject to comprehensive and varied government regulation and, as a result, failure to obtain FDA or other U.S. and foreign governmental approvals for our products may materially adversely affect our business, results of operations and financial condition.

Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA will grant approval for our new products on a timely basis if at all, or that FDA review will not involve delays that will adversely affect our ability to commercialize additional products or expand permitted uses of existing products, or that the regulatory framework will not change, or that additional regulation will not arise at any stage of our product development process which may adversely affect approval of or delay an application or require additional expenditures by us. In the event our future products are regulated as human drugs or biologics, the FDA’s review process of such products typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

Products in development include a next generation HYDRELLE/ELEVESS™ line extension, and joint health related 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 HA- technology. We received CE Mark approval for MONOVISC in October 2007. We have completed a pivotal trial in the U.S., and submitted the results for a PMA application in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter, which is the FDA's mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The Company has not yet received a date for an Advisory Panel meeting. There can be no assurance that the FDA will grant the Company's request for a orthopedic advisory panel meeting. Even if such request is granted, the panel may not find favorably for Anika, or the FDA may not accept the panel's findings even if such findings are favorable to Anika.

Our second single-injection osteoarthritis product is Cingal, which is based on the technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time. In addition, in October 2010, Anika filed 510(k) applications with the FDA to gain marketing clearance for three FAB products: Hyalofast®, Hyaloglide®, and Hyalonect®. There has been delay in the FDA's review process and the Company is unable to predict the timing of receipt of these clearances. There can be no guarantee that the clearance process for these product will be successful or that additional data will not be required to support clearance.

FAB's tissue engineered products Hyalograft C Autograft, Hyalograft 3D Autograft and Laserskin Autograft are currently marketed in Europe. However, the regulations for marketing of these products in Europe have changed. Effective January 1, 2013, new regulations mandate these products to be approved by the European Medicines Agency ("EMA") in order to remain on the EU market. FAB continues to be in discussion with the EMA and is implementing a plan to qualify for the new status. There can be no assurance that approval will be timely obtained.

In addition, we cannot assure you that:

- We will begin or successfully complete U.S. clinical trials for next generation products;
- The clinical data will support the efficacy of these products;
- We will be able to successfully complete the FDA or foreign regulatory approval or clearance process, where required;
- Additional clinical trials will support a PMA application and/or FDA approval or other foreign regulatory approvals, where required, in a timely manner or at all; or
- European and other regulations may not change for the marketing of cell based products and thus impact our ability to continue commercialization of these products.

We also cannot assure you that any delay in receiving FDA approvals will not adversely affect our competitive position. Furthermore, even if we do receive FDA approval or clearance:

- The approval may include significant limitations on the indications and other claims sought for use for which the products may be marketed;
- The approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements; and
- Meaningful sales may never be achieved.

Once obtained, marketing approval can be withdrawn by the FDA for a number of reasons, including, among others, the failure to comply with regulatory requirements, or the occurrence of unforeseen problems following initial approval. We may be required to make further filings with the FDA under certain circumstances. The FDA's regulations require a PMA supplement for certain changes if they affect the safety and effectiveness of an approved device, including, but not limited to, new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Our failure to receive approval of a PMA supplement regarding the use of a different manufacturing facility or any other change affecting the safety or effectiveness of an approved device on a timely basis, or at all, may have a material adverse effect on our business, financial condition, and results of operations. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of such products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per FDA regulations of one or several of our products. Significant delay or cost in obtaining, or failure to obtain FDA approval to market products, any FDA limitations on the use of our products, or any withdrawal or suspension of approval or rescission of approval by the FDA could have a material adverse effect on our business, financial condition, and results of operations.

In addition, all FDA approved or cleared products manufactured by us must be manufactured in compliance with the FDA's Good Manufacturing Practices ("GMP") regulations and, for medical devices, the FDA's Quality System Regulations ("QSR"). Ongoing compliance with QSR and other applicable regulatory requirements is enforced through periodic inspection by state and federal agencies, including the FDA. The FDA may inspect our facilities, from time to time, to determine whether we are in compliance with regulations relating to medical device and pharmaceutical companies, including regulations concerning manufacturing, testing, quality control and product labeling practices. We cannot assure you that we will be able to comply with current or future FDA requirements applicable to the manufacture of our products.

FDA regulations depend heavily on administrative interpretation and we cannot assure you that the future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. In addition, changes in the existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products.

Failure to comply with applicable regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the FDA to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals and criminal prosecution.

In July 2008, we received a Warning Letter (the "Warning Letter") from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our manufacturing facility in Woburn, Massachusetts. The Company submitted corrective action plans, which have been accepted by the FDA and resulted in the clearance of the Warning Letter in September 2010.

In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local and foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, quality system and manufacturing requirements, import restrictions, tariff regulations, duties and tax requirements. We cannot assure you that we will be able to achieve and/or maintain compliance required for CE marking or other foreign regulatory approvals for any or all of our products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements. Federal, state, local and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

The process of obtaining approvals from the FDA and other regulatory authorities can be costly, time consuming, and subject to unanticipated delays. We cannot assure you that approvals or clearances of our products will be granted or that we will have the necessary funds to develop certain of our products. Any failure to obtain, or delay in obtaining such approvals or clearances, could adversely affect our ability to market our products.

Uncertain economic conditions, including the credit crisis affecting the financial markets and global recession, could adversely affect our business, results of operations and financial condition.

The worldwide financial markets have experienced turmoil, characterized by volatility in security prices, rating downgrades of investments and reductions in available credit. These events materially and adversely impacted the availability of financing to a wide variety of businesses, and the resulting uncertainty led to reductions in capital investments, overall spending levels, future product plans, and sales projections across industries and markets.

The financial markets remain uncertain and renewed turmoil could have a material adverse impact on our business, our ability to achieve planned results of operations and our financial condition by:

- Reducing demand for our products;
- Increasing risk of order cancellations or delays;
- Increasing pressure on the prices for our products;
- Creating greater difficulty in collecting accounts receivable; and
- Increasing the risks to our liquidity, including the possibility that we might not have sufficient access to cash when needed.

We are unable to predict the likelihood of renewed disruption in financial markets and adverse economic conditions in the U.S. and other countries.

Substantial competition could materially affect our financial performance.

We compete with many companies, including, among others, large pharmaceutical companies, specialized medical products companies and healthcare companies. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations and

more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations that may be involved in research, development and commercialization of products. Because a number of companies are developing or have developed HA products for similar applications and have received FDA approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. For example, we are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. There exist major competing products for the use of HA in ophthalmic surgery. In addition, certain HA products made by our competitors for the treatment of osteoarthritis in the knee have received FDA approval before ours and have been marketed in the U.S. since 1997, as well as select markets in Canada, Europe and other countries. To date, the FDA approved nine HA products for the treatment of facial wrinkles which have been marketed internationally for a number of years. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

We are uncertain regarding the success of our clinical trials.

Several of our products do require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. There can be no assurance that we will be able to successfully complete the U.S. or international regulatory approval process for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials will be deemed sufficient in size and scope to satisfy regulatory approval requirements, or, if completed, will ultimately demonstrate these products to be safe and efficacious. We completed a pivotal clinical trial on MONOVISC and submitted the data as part of our PMA filing in December 2009. We were informed that there were deficiencies in our submissions through a deficiency/non-approvable letter, which is the FDA's mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The Company has not yet received a date for an Advisory Panel meeting.

We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition and results of operations.

Our success will be dependent, in part, upon the efforts of our marketing and distribution partners and the terms and conditions of our relationships with such partners. We cannot assure you that such partners will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. We are continuing to seek to establish long-term distribution relationships in regions not covered by existing agreements, but can make no assurances that we will be successful in doing so. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such partners. There can be no assurance that we will obtain European or other reimbursement approvals or, if such approvals are obtained, they will be obtained on a timely basis or at a satisfactory level of reimbursement.

We may need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.

Anika has never directly commercialized products on our own before.

We have announced our desire to pursue the option of directly commercializing MONOVISC and certain FAB orthopedic products in the United States. Historically Anika has sold its products through a network of distributors, and there can be no assurance that we will successfully find and hire the appropriate people to succeed in a direct commercialization effort. We will be competing against larger companies with greater resources and portfolios of products for access to the customer. In addition, we will have limited resources for advertising and promotion of the products.

Our future success depends upon market acceptance of our existing and future products.

Our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some

or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to adequately protect our intellectual property rights.

Our efforts to enforce our intellectual property rights may not be successful. We rely on a combination of copyright, trademark, patent and trade secret laws, confidentiality procedures and contractual provisions to protect our proprietary rights. Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties when necessary, and conduct our business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical products and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that any patent applications will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or commercial advantage, or will not be circumvented by others. In the event a third party has also filed one or more patent applications for any of its inventions, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("PTO") to determine priority of invention, which could result in failure to obtain, or the loss of, patent protection for the inventions and the loss of any right to use the inventions. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us, and diversion of management's attention away from our operations. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others and the defense of patent infringement claims by others can be expensive and time consuming. There can be no assurance that in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, could be subject to significant liabilities to such third party, and could be required to license technologies from such third party. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate. However, no assurance can be given that any patent application will be filed, that any filed applications will result in issued patents or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents.

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. There can be no assurance that the products or processes developed by us will not infringe on the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and our technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

Pursuant to the 2004 B&L Agreement, we have agreed to transfer to Bausch & Lomb, upon expiration of the term of the 2004 B&L Agreement on December 31, 2010, our manufacturing process, know-how and technical information,

which relate only to AMVISC products.

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 we are free to market our 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.

Our manufacturing processes involve inherent risks and disruption could materially adversely affect our business, financial condition and results of operations.

The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure or substandard performance of equipment, the occurrence of natural and other disasters, and the need to comply with the requirements of directives of government agencies, including the FDA. In addition, we rely on a single supplier for certain key raw materials and a small number of suppliers for a number of other materials required for the manufacturing and delivery of our HA products. Although we believe that alternative sources for many of these and other components and raw materials that we use in our manufacturing processes are available, any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

Furthermore, our manufacturing processes and research and development efforts involve animals and products derived from animals. We procure our animal-derived raw materials from qualified vendors, control for contamination and have processes that effectively inactivate infectious agents; however, we cannot assure you that we can completely eliminate the risk of transmission of infectious agents. Furthermore, regulatory authorities could in the future impose restrictions on the use of animal-derived raw materials that could impact our business.

The utilization of animals in research and development and product commercialization is subject to increasing focus by animal rights activists. The activities of animal rights groups and other organizations that have protested animal based research and development programs or boycotted the products resulting from such programs could cause an interruption in our manufacturing processes and research and development efforts. The occurrence of material operational problems, including but not limited to the events described above, could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties.

Our new facility construction and validation processes could materially adversely affect our operations.

We entered into a new lease on January 4, 2007, for a new headquarters facility consisting of approximately 134,000 square feet of general office, research and development and manufacturing space located in Bedford, Massachusetts. The lease has an initial term of ten and a half years, and commenced on approximately May 1, 2007 when certain agreed upon landlord improvements were completed. We commenced the build-out of the new facility during the second quarter of 2007. Our administrative, marketing, regulatory, and research and development personnel moved into the Bedford facility in November 2007. The remaining build-out was completed in mid-2008 and validation and approval for operation in the new manufacturing space is ongoing.

We received FDA approval to manufacture our terminally sterilized product, ELEVESS™, in our Bedford facility in November 2010. We believed that we had an agreement with the FDA to temporarily move certain critical equipment used to manufacture our ophthalmic and orthopedic products to Bedford, validate its use at that facility and then briefly return it to service in Woburn. We understood such validation data and reports would be utilized as part of a final inspection of the Bedford facility scheduled for December 2010. That final inspection did not occur and will not occur now until the equipment is permanently installed in Bedford. In order to fill product orders and build sufficient safety stock to accommodate any further approval delays, we currently expect manufacturing of the ophthalmic and

orthopedic products to continue in Woburn into June 2011.

We provide no assurance that the installation of such equipment or the validation and approval processes for our Bedford facility will be completed in a timely fashion, if at all. Furthermore, we cannot assure you that the transition from the existing facilities to the new facility will be efficient and successful. In the event the validation or approval is delayed or the move transition is unsuccessful, it may result in business interruptions. We have incurred additional expense as a result of maintaining two facilities, and will continue to incur additional expenses if we have to maintain both facilities, for a prolonged period.

Our financial performance depends on the continued growth and demand for our products and we may not be able to successfully manage the expansion of our operations.

Our future success depends on substantial growth in product sales. There can be no assurance that such growth can be achieved or, if achieved, can be sustained. There can be no assurance that even if substantial growth in product sales and the demand for our products is achieved, we will be able to:

- Develop the necessary manufacturing capabilities;
- Obtain the assistance of additional marketing partners;
- Attract, retain and integrate the required key personnel; and
- Implement the financial, accounting and management systems needed to manage growing demand for our products.

Our failure to successfully manage future growth could have a material adverse effect on our business, financial condition, and results of operations.

We engage in acquisitions as a part of our growth strategy in which we will incur a variety of costs and may never realize the anticipated benefits of such acquisitions.

Our business strategy includes the acquisition of businesses, technologies, services or products that we believe are a strategic fit with our business. Such acquisitions could reduce stockholders' ownership, cause us to incur debt, expose us to liabilities and result in amortization expenses related to intangible assets with definite lives. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering new markets with which we have limited experience or where distribution alliances with experienced distributors are not available. Our future profitability may depend in part upon our ability to develop further our resources to adapt to these new products or business areas and to identify and enter into satisfactory distribution networks. Moreover, we may fail to realize the anticipated benefits of any acquisition as rapidly as expected or at all, or the acquired business may not perform in accordance with our expectations. We may also incur significant expenditures in anticipation of an acquisition that is never realized.

We may not realize the expected benefits from acquisitions due to difficulties integrating the businesses, operations and product lines.

Our ability to achieve the benefits of acquisitions depends in part on the integration and leveraging of technology, products, operations, sales and marketing channels and personnel. If we undertake any acquisition, the process of integrating an acquired business may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business even if completed in a timely and efficient manner.

We may have difficulty successfully integrating acquired businesses, the domestic and foreign operations or the product lines, and as a result, we may not realize any of the anticipated benefits of the acquisitions. Moreover, we may lose key clients or employees of acquired businesses as a result of the change in ownership to us. Additionally, we cannot assure that our growth rate will equal the growth rates that have been experienced by us and the acquired companies, respectively, operating as separate companies in the past.

Customer, vendor and employee uncertainty about the effects of any acquisitions could harm us.

We and the customers of any companies we acquire may, in response to the consummation of any acquisitions, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by customers could adversely affect our business. Similarly, employees of acquired companies may experience uncertainty about their future role until or after we execute our strategies with regard to employees of acquired companies. This may adversely affect our ability to attract and retain key management, sales, marketing and technical personnel following an acquisition.

The acquisitions we have made or may make in the future may make us the subject of lawsuits from either an acquired company's stockholders, an acquired company's previous stockholders or our current stockholders.

We may be the subject of lawsuits from either an acquired company's stockholders, an acquired company's previous stockholders or our current stockholders. These lawsuits could result from the actions of the acquisition target prior to the date of the acquisition, from the acquisition transaction itself or from actions after the acquisition. Defending potential lawsuits could cost us significant expense and detract management's attention from the operation of the business. Additionally, these lawsuits could result in the cancellation of or the inability to renew, certain insurance coverage that would be necessary to protect our assets.

Attractive acquisition opportunities may not be available to us in the future.

We will consider the acquisition of other businesses. However, we may not have the opportunity to make suitable acquisitions on favorable terms in the future, which could negatively impact the growth of our business. In order to pursue such opportunities, we may require significant additional financing, which may not be available to us on favorable terms, if at all. The availability of such financing is limited by the recent tightening of the global credit markets. We expect that our competitors, many of which have significantly greater resources than we do, will compete with us to acquire compatible businesses. This competition could increase prices for acquisitions that we would likely pursue.

Sales of our products are largely dependent upon third party reimbursement and our performance may be harmed by health care cost containment initiatives.

In the U.S. and other markets, health care providers, such as hospitals and physicians, that purchase health care products, such as our products, generally rely on third party payers, including Medicare, Medicaid and other health insurance and managed care plans, to reimburse all or part of the cost of the health care product. We depend upon the distributors for our products to secure reimbursement and reimbursement approvals. Reimbursement by third party payers may depend on a number of factors, including the payer's determination that the use of our products is clinically useful and cost-effective, medically necessary and not experimental or investigational. Since reimbursement approval is required from each payer individually, seeking such approvals can be a time consuming and costly process which, in the future, could require us or our marketing partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payer separately. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and any failure or delay in obtaining reimbursement approvals can negatively impact sales of our new products. In addition, third party payers are increasingly attempting to contain the costs of health care products and services by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. Also, Congress and certain state legislatures have considered reforms that may affect current reimbursement practices, including controls on health care spending through limitations on the growth of Medicare and Medicaid spending. There can be no assurance that third party reimbursement coverage will be available or adequate for any products or services developed by us. Outside the U.S., the success of our products is also dependent in part upon the availability of reimbursement and health care payment systems. Domestic and international reimbursement laws and regulations may change from time to time. Lack of adequate coverage and reimbursement provided by governments and other third party payers for our products and services, including change of classification by CMS for ORTHOVISC under a unique Q-code for Medicare/Medicaid reimbursement, could have a material adverse effect on our business, financial condition, and results of operations.

We may seek financing in the future, which could be difficult to obtain and which could dilute your ownership interest or the value of your shares.

We had cash and cash equivalents of approximately $28.2 million at December 31, 2010. Our future capital requirements and the adequacy of available funds will depend, however, on numerous factors, including:

- Market acceptance of our existing and future products;
- The success and sales of our products under various distributor agreements;
- The successful commercialization of products in development;
- Progress in our product development efforts;

- The magnitude and scope of such product development efforts;
- Any potential acquisitions of products, technologies or businesses;
- Progress with preclinical studies, clinical trials and product clearances by the FDA and other agencies;
- The cost and timing of our efforts to manage our manufacturing capabilities and related costs;
- The cost and timing of validation and approval processes for our new manufacturing space;
- The cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights and the cost of defending any other legal proceeding;
- Competing technological and market developments;
- The development of strategic alliances for the marketing of certain of our products;
- The terms of such strategic alliances, including provisions (and our ability to satisfy such provisions) that provide upfront and/or milestone payments to us;
- Our abilities to meet debt covenant and repayment requirements; and
- The cost of maintaining adequate inventory levels to meet current and future product demands.

To the extent funds generated from our operations, together with our existing capital resources are insufficient to meet future requirements, we will be required to obtain additional funds through equity or debt financings, strategic alliances with corporate partners and others, or through other sources. The terms of any future equity financings may be dilutive to you and the terms of any debt financings may contain restrictive covenants, which limit our ability to pursue certain courses of action. Our ability to obtain financing is dependent on the status of our future business prospects as well as conditions prevailing in the relevant capital markets. No assurance can be given that any additional financing will be made available to us or will be available on acceptable terms should such a need arise.

We are subject to debt covenants and any failure to comply with these could materially adversely affect our business, financial condition and results of operations.

On January 31, 2008, we entered into a Credit Agreement (the “Credit Agreement”). Under the Credit Agreement, our lender made periodic loans to us through December 31, 2008. We borrowed $16,000,000 in 2008, the maximum allowed amount under the Credit Agreement. At December 31, 2008, the borrowings were converted into a 7-year term loan. On December 30, 2009, the Credit Agreement was amended as part of the FAB acquisition. The Credit Agreement was entered into in order to finance the construction and validation of our Bedford facility. Construction of the new facility commenced in the spring of 2007 and was substantially completed in mid-2008. Validation of our new manufacturing facility will continue into 2011. See Note 15 to our Consolidated Financial Statements for additional information relative to this debt facility.

There can be no assurance that we will be successful in qualifying the new facility under the FDA and European Union regulations. The Credit Agreement contains certain debt covenants, representations and warranties that we must comply with. If we do not comply with the specified covenants and restrictions, we could be in default under our Credit Agreement. Our ability to comply with the provisions of our Credit Agreement governing our other indebtedness may be affected by changes in the economic or business conditions or other events beyond our control.

We could become subject to product liability claims, which, if successful, could materially adversely affect our business, financial condition and results of operations.

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and there can be no assurance that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have an insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate to cover such claims should they arise, there can be no assurance that material claims will not arise in the future or that our insurance will be adequate to cover all situations. Moreover, there can be no assurance that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition and results of operations.

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

We are highly dependent on the members of our management and technical staff, the loss of one or more of whom could have a material adverse effect on us. We have experienced a number of management changes in recent years. There can be no assurances that such management changes will not adversely affect our business. We believe that our future success will depend in large part upon our ability to attract and retain highly skilled, technical, managerial and manufacturing personnel. We face significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. There can be no assurance that we will be successful in hiring or retaining the personnel we require. The failure to hire and retain such personnel could have a material adverse effect on our business, financial condition and results of operations.

We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

We are subject to a variety of local, state and federal government regulations relating to the storage, discharge, handling, emission, generation, manufacture and disposal of toxic, or other hazardous substances used in the manufacture of our products. Any failure by us to control the use, disposal, removal or storage of hazardous chemicals or toxic substances could subject us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

As our international sales and operations grow, including through our recent acquisition of FAB, we could become increasingly subject to additional economic, political and other risks that could harm our business.

Since we manufacture and sell our products worldwide, our business is subject to risks associated with doing business internationally. During the years ended December 31, 2010 and 2009, approximately, 31% and 25%, respectively, of our product sales were to international distributors. However, as a result of our acquisition of FAB, we anticipate the percentage of our product sales resulting from international operations to increase in fiscal year 2011 offset by lower B&L revenue. As a result of this international growth, we have become increasingly subject to a variety of risks, which could cause fluctuations in the results of our international and domestic operations. These risks include:

- The impact of recessions and other economic conditions in economies, including Europe in particular, outside the United States;
- Instability of foreign economic, political and labor conditions;
- Unfavorable labor regulations applicable to European operations, such as severance and the unenforceability of non-competition agreements in the European Union;
- The impact of strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices or other collective bargaining disputes;
- Difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs or other trade barriers or by U.S. export laws;
- Imposition of governmental controls limiting the volume of international sales;
- Longer accounts receivable payment cycles;
- Potentially adverse tax consequences, including, if required, difficulties transferring funds generated in non-U.S. jurisdictions to the U.S. in a tax efficient manner;

· Difficulties in protecting intellectual property;

- Difficulties in managing international operations; and
- Burdens of complying with a wide variety of foreign laws.

Our success depends, in part, on our ability to anticipate and address these risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results.

Currency exchange rate fluctuations may have a negative impact on our reported earnings.

Approximately 15% of our business from continuing operations during fiscal year 2010 was conducted in functional currencies other than the U.S. dollar, which is our reporting currency. As a result of our acquisition of FAB, we anticipate this percentage to increase to approximately 20% during fiscal year 2011. Thus, currency fluctuations among the U.S. dollar and the other currencies in which we do business have caused and will continue to cause foreign currency transaction gains and losses. Currently, we attempt to manage foreign currency risk through the matching of assets and liabilities. In the future, we may undertake to manage foreign currency risk through additional hedging methods. We recognize foreign currency gains or losses arising from our operations in the period incurred. We cannot guarantee that we will be successful in managing foreign currency risk or in predicting the effects of exchange rate fluctuations upon our future operating results because of the variability of currency exposure and the potential volatility of currency exchange rates.

Our stock price has been and may remain highly volatile, and we cannot assure you that market making in our common stock will continue.

The market price of shares of our common stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by us or our competitors, disclosure of results of clinical testing or regulatory proceedings, governmental regulation and approvals, developments in patent or other proprietary rights, public concern as to the safety of products developed by us and general market conditions may have a significant effect on the market price of our common stock. The trading price of our common stock could be subject to wide fluctuations in response to quarter-to-quarter variations in our operating results, material announcements by us or our competitors, governmental regulatory action, conditions in the health care industry generally or in the medical products industry specifically, or other events or factors, many of which are beyond our control. In addition, the stock market has experienced extreme price and volume fluctuations which have particularly affected the market prices of many medical products companies and which often have been unrelated to the operating performance of such companies. Our operating results in future quarters may be below the expectations of equity research analysts and investors. In such event, the price of our common stock would likely decline, perhaps substantially.

No person is under any obligation to make a market in the common stock or to publish research reports on us, and any person making a market in the common stock or publishing research reports on us may discontinue market making or publishing such reports at any time without notice. There can be no assurance that an active public market in our common stock will be sustained.

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

Certain provisions of our Restated Articles of Organization and Amended and Restated By-laws could have the effect of discouraging a third party from pursuing a non-negotiated takeover of us and preventing certain changes in control. These provisions include a classified Board of Directors, advance notice to the Board of Directors of stockholder proposals, limitations on the ability of stockholders to remove directors and to call stockholder meetings, the provision that vacancies on the Board of Directors be filled by vote of a majority of the remaining directors. In addition, the Board of Directors renewed a Shareholders Rights Plan in April 2008. We are also subject to Chapter 110F of the

Massachusetts General Laws which, subject to certain exceptions, prohibits a Massachusetts corporation from engaging in any of a broad range of business combinations with any "interested stockholder" for a period of three years following the date that such stockholder became an interested stockholder. These provisions could discourage a third party from pursuing a takeover of us at a price considered attractive by many stockholders, since such provisions could have the effect of preventing or delaying a potential acquirer from acquiring control of us and our Board of Directors.

Our revenues are derived from a small number of customers, the loss of which could materially adversely affect our business, financial condition and results of operations.

We have historically derived the majority of our revenues from a small number of customers, most of whom resell our products to end-users and most of whom are significantly larger companies than us. For the year ended December 31, 2010, five customers accounted for 82% of product revenue. We expect to continue to be dependent on a small number of large customers for the majority of our revenues. Our failure to generate as much revenue as expected from these customers or the failure of these customers to purchase our products would seriously harm our business. In addition, if present and future customers terminate their purchasing arrangements with us, significantly reduce or delay their orders, or seek to renegotiate their agreements on terms less favorable to us, our business, financial condition, and results of operations will be adversely affected. If we accept terms less favorable than the terms of the current agreement, such renegotiations may have a material adverse effect on our business, financial condition, and/or results of operations. Furthermore, in any future negotiations we may be subject to the perceived or actual leverage that these customers may have given their relative size and importance to us. Any termination, change, reduction or delay in orders could seriously harm our business, financial condition, and results of operations. Accordingly, unless and until we diversify and expand our customer base, our future success will significantly depend upon the timing and size of future purchases by our largest customers and the financial and operational success of these customers. The loss of any one of our major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations.

We may not fully realize the benefits of our acquisitions or strategic alliances.

In December 2009, we acquired FAB which we accounted for as a business combination. We may not be able to realize the expected synergies and cost savings from the integration with our existing operations or technologies that we may acquire. In addition, the integration process for our acquisitions may be complex, costly, and time consuming and include unanticipated issues, expenses and liabilities. We may have difficulty in developing, manufacturing and marketing the products of a newly acquired company in a manner that enhances the performance of our combined businesses or product lines and allows us to realize value from expected synergies. Following an acquisition, we may not achieve the revenue or net income levels that justify the acquisition. Acquisitions may also result in one-time charges, such as write-offs or restructuring charges, or in the future, impairment of goodwill or acquired IPR&D, which adversely affect our operating results. Additionally, we may fund acquisitions of new businesses, strategic alliances or joint ventures by utilizing our cash, incurring debt, issuing shares of our common stock, or by other means.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

personnel moved into the Bedford facility in November of 2007. The remaining build-out at the Bedford facility was completed in mid-2008. We received FDA approval to manufacture our terminally sterilized product, ELEVESS™, in our Bedford facility in November 2010 and are waiting to schedule the final FDA inspection for the manufacture of the Company's ophthalmic and orthopedic products. As a result, the validation for this manufacturing space will continue into 2011.

Our prior corporate headquarters was located in Woburn, Massachusetts and the lease for that facility ended on December 31, 2007. We also lease approximately 37,000 square feet of space at a separate location in Woburn, Massachusetts, which currently houses our manufacturing facility and warehouse for several major products. This facility has received all FDA, state and European regulatory approvals to operate as a sterile device and drug manufacturer. We extended our lease for this facility to June 30, 2011. As part of the acquisition of FAB, we now lease approximately 26,000 square feet of laboratory, warehouse and office space in Abano Terme, Italy. The lease commenced on December 30, 2009 for an initial term of six (6) years. For the year ended December 31, 2010, we had aggregate facility lease expenses of approximately $2,888,277.

Our aggregate expenditures to build out the Bedford facility, which will serve as our corporate headquarters and manufacturing facility for the foreseeable future, were approximately $34.6 million through December 31, 2010. We have borrowed $16 million under our Credit Agreement which we entered into on January 31, 2008. There can be no assurance that we will be successful in re-qualifying the new facility under the FDA and European Union regulations, in which case we may need to further extend our Woburn lease.

ITEM 3. LEGAL PROCEEDINGS

On July 7, 2010, Genzyme Corporation filed a complaint against the Company in the United States District Court for the District of Massachusetts seeking unspecified damages and equitable relief. The Complaint alleges that the Company has infringed U.S. Patent No. 5,143,724 by manufacturing MONOVISC in the United States for sale outside the United States and will infringe U.S. Patent Nos. 5,143,724 and 5,399,351 if the Company begins manufacture and sale of MONOVISC in the United States. On August 30, 2010, the Company filed an answer denying liability. The Company believes that neither MONOVISC, nor its manufacture, does or will infringe any valid and enforceable claim of the asserted patents. Management has assessed and determined that contingent losses related to this matter are remote and inestimable. Therefore, pursuant to Accounting Standards Codification (“ASC”) 450, Contingencies, an accrual has not been recorded for this loss contingency.

Artes Medical, Inc. (“Artes”), the former U.S. distributor of HYDRELLE, filed a liquidating bankruptcy case under Chapter 7 of the United States Bankruptcy Code. Artes’ Trustee in Bankruptcy demanded the Company pay $359,768 to the Trustee, representing the total amount of three payments received by the Company from Artes within the 90 days prior to the filing of Artes' liquidating bankruptcy. The Trustee asserts that the payments are recoverable as preferences under the Bankruptcy Code.

The Company believes that the payments it received either do not meet the legal requirements of avoidable preferences or are subject to one or more exceptions to the Trustee's powers to recover preferences and has recently so advised the Trustee. Management has assessed and determined that contingent losses related to this matter are remote. Therefore, pursuant to ASC 450, an accrual has not been recorded for this loss contingency.

We are also involved in various other legal proceedings arising in the normal course of business. Although the outcomes of these other legal proceedings are inherently difficult to predict, we do not expect the resolution of these other legal proceedings to have a material adverse effect on our financial position, results of operations or cash flow.

ITEM 4. (Removed and Reserved).

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

COMMON STOCK INFORMATION

Our common stock has traded on the NASDAQ Global Select Market since November 25, 1997, under the symbol "ANIK." The following table sets forth, for the periods indicated, the high and low sales prices of our common stock on the NASDAQ Global Select Market. These prices represent prices between dealers and do not include retail mark-ups, markdowns, or commissions and may not necessarily represent actual transactions.

Year Ended December 31, 2010	High	Low
First Quarter	$ 7.97	$ 6.04
Second Quarter	7.40	5.83
Third Quarter	6.48	4.83
Fourth Quarter	6.98	5.30

Year Ended December 31, 2009	High	Low
First Quarter	$ 5.01	$ 3.05
Second Quarter	5.80	4.51
Third Quarter	7.15	4.81
Fourth Quarter	9.05	6.11

At December 31, 2010, the closing price per share of our common stock was $6.67 as reported on the NASDAQ Global Select Market and there were approximately 232 holders of record. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings, if any, for use in our business and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs, and plans for expansion.

Performance Graph (Unaudited)

Set forth below is a graph comparing the total returns of the Company, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes $100 is invested on December 31, 2005 in the Company's Common Stock and each of the indices.

	Dec-05	Dec-06	Dec-07	Dec-08	Dec-09	Dec-10
Anika Therapeutics Inc	$100.00	$113.52	$124.47	$26.01	$65.27	$57.06
NASDAQ Composite Index	100.00	109.52	120.27	71.51	102.89	120.29
NASDAQ Biotechnology Index	100.00	101.02	105.65	92.31	106.74	122.76

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with the Consolidated Financial Statements and the Notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2010 and 2009 and the Statement of Operations Data for each of the three years ended December 31, 2010, 2009 and 2008 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2008, 2007 and 2006, and the Statement of Operations Data for each of the two years in the period ended December 31, 2007 have been derived from the audited Consolidated Financial Statements for such years not included in this Annual Report on Form 10-K.

Statement of Operations Data
(In thousands, except per share data)

	Years ended December 31,									
	2010		2009		2008		2007		2006	
Product Revenue	$ 52,736		$ 37,321		$ 33,055		$ 26,905		$ 23,953	
Licensing, milestone and contract revenue	2,821		2,815		2,725		3,925		2,887	
Total revenue	55,557		40,136		35,780		30,830		26,840	
Cost of product revenue	23,827		13,670		13,189		11,881		11,118	
Product gross profit	28,909		23,651		19,866		15,024		12,835	
Product gross margin	55	%	63	%	60	%	56	%	54	%
Total operating expenses	48,019		34,549		31,533		24,242		21,413	
Net Income	4,316		3,688		3,629		6,035		4,604	
Diluted net income per common share	0.32		0.32		0.32		0.53		0.41	
Diluted common shares outstanding	13,647		11,562		11,461		11,454		11,155	

Balance Sheet Data
(In thousands)

	Years ended December 31,				
	2010	2009	2008	2007	2006
Cash, cash equivalents and short-term investments	$ 28,202	$ 24,427	$ 43,194	$ 39,406	$ 47,167
Working capital	36,952	33,307	46,798	41,805	52,145
Total assets	128,937	129,431	95,821	79,497	68,114
Retained earnings	25,786	21,470	17,782	14,153	8,118
Stockholder's equity	85,190	82,144	60,757	54,961	45,488

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 Note 16 to our Consolidated Financial Statements for additional information regarding the acquisition.

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

The following section of this Annual Report on Form 10-K titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains statements that are not statements of historical fact and are forward-looking statements within the meaning of the federal securities laws. These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievement to differ materially from anticipated results, performance, or achievement, expressed or implied in such forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We discuss many of these risks and uncertainties at the beginning of this Annual Report on Form 10-K and under Item 1 "Business" and Item 1A "Risk Factors." The following discussion should also be read in conjunction with the Consolidated Financial Statements of Anika Therapeutics, Inc. and the Notes thereto appearing elsewhere in this report.

Management Overview

Anika Therapeutics, Inc. ("Anika," and together, with its subsidiaries, the "Company") 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. ("Fidia"), 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 Note 16 to our Consolidated Financial Statements for additional information regarding the acquisition.

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	

Orthobiologics

Anika's orthobiologics business contributed 58% to our product revenue in the year ended December 31, 2010. This includes FAB's products which added $1,923,256 to orthobiologics revenue in 2010. Our orthobiologics products consist of joint health and orthopedic products. Joint health products include ORTHOVISC, ORTHOVISC mini, and

MONOVISC. ORTHOVISC is available in the U.S., Canada, and some 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.

Anika has marketed ORTHOVISC, our product for the treatment of osteoarthritis of the knee, internationally since 1996 through various distribution agreements. International sales of ORTHOVISC contributed 9% of product revenue for the year ended December 31, 2010. Our strategy is to continue to add new products, to expand the indications for usage of these products, and to add additional countries to our distribution network. The joint health area has been the fastest growing area for the Company, growing from 27% of our product revenue in 2006 to 58% of our product revenue in 2010. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2011 compared to 2010.

With the acquisition of FAB, we now offer several orthopedic products used in connection with 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. We also offer 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. These products are commercialized directly in Italy, and through a network of distributors, primarily in Europe, the Middle East, Argentina, and Korea. Anika believes that the U.S. market offers excellent expansion potential to increase revenue, and this will continue to be a major focus area for the Company.

Dermal

Our dermal products consist of advanced wound care products, a field new to the Company with the acquisition of FAB, and aesthetic dermal fillers. Altogether, our dermal products contributed 7% of our product revenue for the year ended December 31, 2010. We offer over seven products for 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. These 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, and the Company is exploring distribution opportunities.

Our aesthetic dermatology business is designed as a family of products for facial wrinkles and scar remediation, and is intended to supplant collagen-based products and to compete with 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. This product has been marketed in the U.S. under the name of HYDRELLETM.

Coapt Systems, Inc. (“Coapt”) began selling HYDRELLETM in the third quarter of 2009 under a distribution agreement granting Coapt an exclusive and non-transferable right to market HYDRELLE™ in the United States. On July 2, 2010 we were notified by Coapt that it had filed for an Assignment for the Benefit of Creditors under the laws of the State of California. The Company’s Distribution Agreement with Coapt was subsequently terminated. The Company plans to directly distribute HYDRELLETM in the interim while it reviews its franchise strategy. We recorded $500,064 and $1,471,165 of aesthetic dermatology revenue in 2010 and 2009, respectively, with revenue in 2009 primarily derived from sales to Coapt.

Ophthalmic

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2010, sales of ophthalmic products contributed 23% of our product revenue, 94% of which represents sales to Bausch & Lomb. Anika manufactures the AMVISC product line for Bausch & Lomb under the terms of a supply agreement that expired on December 31, 2010 (the “2004 B&L Agreement”) for viscoelastic products used in ophthalmic surgery. Effective January 1, 2011, the parties entered into a non-exclusive, two year contract intended to transition the manufacture of AMVISC and AMVISC Plus to an alternative, 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 called AnikaVisc. B&L accounted for 21% of product revenue for the year ended 2010, but 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 Item 1A. “Risk Factors.”

Surgical

Our surgical group consists of products used to prevent surgical adhesions, and to treat ENT disorders. For the year ended December 31, 2010, sales of surgical products contributed 7% of our product revenue, INCERT, approved for sale in Europe and Turkey is a chemically modified, cross-linked HA barrier gel, for prevention of post-surgical adhesions in connection with spinal surgeries such as discectomies with a laminectomy or laminotomy. 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 advanced wound care products. There are currently no plans to distribute INCERT in the U.S.

Hyalobarrier and Hyalobarrier Endo are also clinically proven post operative adhesion barrier products, 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 also 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 or Merogel.

Veterinary

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 5% to product revenue for the year ended December 31, 2010. We continue to look at other veterinary applications and opportunities to expand geographic territories.

Research and Development

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. Our investment in R&D has been important over the years, and varies considerably depending on the number and size of clinical trials and studies underway. For the years 2010 and 2009, these expenses were $6.9 million and $8.2 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. Other key projects include obtaining FDA approval to market FAB's suite of orthopedic products in the U.S. These products consist of Hyalofast, Hyaloglide, and Hyalonect.

In addition to the FAB products in the preceding paragraph, additional products in development include MONOVISC for U.S. marketing approval, and our first next generation osteoarthritis product. MONOVISC is a single-injection treatment product that uses a non-animal source HA. MONOVISC is also our first osteoarthritis product based on our proprietary crosslinked HA-technology. We received 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 an investigational device exemption, or an IDE application, with the FDA, and completed the clinical segment of the U.S. MONOVISC pivotal trial in June 2009, and a follow-on retreatment study in September

2009. 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, which is the FDA's mechanism for informing companies of deficiencies. We submitted additional data and analyses throughout 2010, and have been informed by FDA that deficiencies remain. Acting on an option presented by the FDA to resolve the remaining open issues, Anika requested a review by the Orthopedic Advisory Panel. The Company has not yet received a date for an Advisory Panel meeting. We continue to believe that Monovisc should receive FDA approval. Our second single-injection osteoarthritis product under development is CINGAL™, which is based on the same technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time. During the past year, we have integrated the research and development efforts of Anika and FAB, and prioritized our new product development activities.

Summary of Critical Accounting Policies; Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We monitor our estimates on an on-going basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations is discussed throughout “Management’s Discussion and Analysis of Financial Condition and Results of Operations” where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 2 in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K for the year ended December 31, 2010.

Foreign Currency Translation

The functional currency of our foreign subsidiary is the Euro. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using the monthly average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as a component of accumulated other comprehensive income (loss).

Fair Value Measurements

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

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

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

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

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

Allowance for Doubtful Accounts

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

Inventories

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

The Company’s policy is to write-down inventory when conditions exist that suggest inventory may be in excess of anticipated demand or is obsolete based upon assumptions about future demand for the Company’s products and market conditions. The Company regularly evaluates the ability to realize the value of inventory based on a combination of factors including, but not limited to: historical usage rates, forecasted sales or usage, product end of life dates, and estimated current or future market values. Purchasing requirements and alternative usage avenues are explored within these processes to mitigate inventory exposure.

Revenue Recognition - General

We recognize revenue from product sales when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller's price to the buyer is fixed or determinable; and collection from the customer is reasonably assured.

Product Revenue

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

Product revenue also includes royalties. Royalty revenue is based on our distributors’ sales and recognized in the same period our distributors record their sale of products manufactured by us. On a quarterly basis we record royalty revenue based upon sales projections provided to us by our distributor customers. If necessary we adjust our estimates based upon final sales data received prior to issuing our annual audited financial statements.

Licensing, Milestone and Contract Revenue

Licensing, milestone, and contract revenue consists of revenue recognized on initial and milestone payments, as well as contractual amounts received from partners. The Company’s business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company’s products.

The terms of the agreements typically include non-refundable license fees, funding of research and development, payments based upon achievement of certain milestones, and royalties on product sales. The Company evaluates each agreement, and elements within each agreement, in accordance with ASC Subtopic 605-25, Multiple Element Arrangements (“ASC 605-25”). Under ASC 605-25, in order to account for an element as a separate unit of accounting, the element must have had stand-alone value and there must have been objective and reliable evidence of fair value of the undelivered elements. In general, non-refundable upfront fees and milestone payments were recognized as revenue over the term of the arrangement as the Company completes its performance obligations.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Computer hardware and software are typically amortized over three to five years, and furniture and fixtures over three to eight years. Leasehold improvements are amortized over the shorter of their useful lives or the remaining terms of the related leases. Property and equipment under capital leases are amortized over the lesser of the lease terms or their estimated useful lives. Maintenance and repairs are charged to expense when incurred; additions and improvements are capitalized. When an item is sold or retired, the cost and related accumulated depreciation is relieved, and the resulting gain or loss, if any, is recognized in income.

Goodwill and Acquired Intangible Assets

Goodwill is the amount by which the purchase price of acquired net assets in a business combination exceeded the fair values of net identifiable assets on the date of acquisition. Acquired In-Process Research and Development ("IPR&D") represents the fair value assigned to research and development assets that we acquire that have not been completed at the date of acquisition or are pending regulatory approval in certain jurisdictions. The value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenue from the projects, and discounting the net cash flows to present value.

Goodwill and IPR&D, are evaluated for impairment annually or more frequently if events or changes in circumstances indicate that the asset might be impaired. Factors we consider important, on an overall company basis, that could trigger an impairment review include significant underperformance relative to historical or projected future operating results, significant changes in our use of the acquired assets or the strategy for our overall business, significant negative industry or economic trends, a significant decline in our stock price for a sustained period, or a reduction of our market capitalization relative to net book value.

To conduct impairment tests of goodwill, the fair value of the reporting unit is compared to its carrying value. If the reporting unit's carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of goodwill exceeds its implied fair value. We estimate the fair value for reporting units using discounted cash flow valuation models which require the use of significant estimates and assumptions including but not limited to: risk free rate of return on an investment, weighted average cost of capital, future revenue, operating margin, working capital and capital expenditure needs. Our annual assessment for impairment of goodwill as of November 30, 2010 indicated that the fair value of our reporting units exceeded the carrying value of the reporting units. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

To conduct impairment tests of IPR&D, the fair value of the IPR&D project is compared to its carrying value. If the carrying value exceeds its fair value, we record an impairment loss to the extent that the carrying value of the IPR&D project exceeds its fair value. We estimate the fair values for IPR&D projects using discounted cash flow valuation models which require the use of significant estimates and assumptions including but not limited to: estimating the timing of and expected costs to complete the in process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from completed projects and in process projects, and developing appropriate discount rates. Our annual assessment for impairment of IPR&D indicated that the fair value of our IPR&D as of November 30, 2010 exceeded their respective carrying values. There can be no assurance that, at the time future impairment tests are completed, a material impairment charge will not be recorded.

Long-Lived Assets

Long-lived assets primarily include property and equipment and intangible assets with finite lives (including purchased software and trade names). Purchased software is amortized over 2 to 10 years and trade names are amortized over 10 years. We review long-lived assets for impairment when events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of those assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flows to the recorded value of the asset. If impairment is indicated, the asset is written down to its estimated fair value based on a discounted cash flow analysis.

Stock-Based Compensation

We measure the compensation cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the underlying award. That cost is recognized over the period during which an

employee is required to provide service in exchange for the award. See Note 10 for a description of the types of stock-based awards granted, the compensation expense related to such awards, and detail of equity-based awards outstanding. See Note 14 of the accompanying Consolidated Financial Statements for details relative to the tax benefit recognized in the consolidated statement of operations for stock-based compensation.

Income Taxes

Our income tax expense includes U.S. and international income taxes. Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of these differences are reported as deferred tax assets and liabilities. Deferred tax assets are recognized for the estimated future tax effects of deductible temporary differences and tax operating loss and credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that it is more likely than not that all or a portion of deferred tax assets will not be realized, we establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we include an expense within the tax provision in the consolidated statement of operations.

Comprehensive Income

Comprehensive income consists of net income and other comprehensive income (loss), which includes foreign currency translation adjustments. For the purposes of comprehensive income disclosures, we do not record tax provisions or benefits for the net changes in the foreign currency translation adjustment, as we intend to reinvest permanently undistributed earnings of our foreign subsidiary. Accumulated other comprehensive income (loss) is reported as a component of stockholders' equity and, as of December 31, 2010 and 2009, was comprised solely of cumulative translation adjustment gains.

Segment Information

Operating segments, as defined under U.S. GAAP, are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company’s chief operating decision maker is its Chief Executive Officer. Based on the criteria established by ASC 280, Segment Reporting, the Company has one reportable operating segment the results of which are disclosed in the accompanying Consolidated Financial Statements.

Results of Operations

Year ended December 31, 2010 compared to year ended December 31, 2009

The historical results of operations discussion below for 2009 pertains only to Anika Therapeutics, Inc. and does not include a discussion of FAB’s operation or its impact on Anika’s historical results.

Statement of Operations Detail

	Year Ended December 31,				
	2010	2009	Inc/(Dec)	Inc/(Dec)	
Product revenue	$52,735,730	$37,320,906	15,414,824	41	%
Licensing, milestone and contract revenue	2,820,864	2,814,798	6,066	0	%
Total revenue	55,556,594	40,135,704	15,420,890	38	%
Operating expenses:					
Cost of product revenue	23,826,604	13,670,228	10,156,376	74	%
Research & development	6,874,633	8,181,532	(1,306,899)	-16	%
Selling, general & administrative	17,317,671	10,545,351	6,772,320	64	%