

ANIKA THERAPEUTICS INC  
Form 10-K  
March 16, 2010

---

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒

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

For the fiscal year ended December 31, 2009

☐

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  
(State or Other Jurisdiction of Incorporation or  
Organization)

04-3145961  
(IRS Employer Identification No.)

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

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

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

Preferred Stock Purchase Rights

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

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

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

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

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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

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

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

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

---

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐  
(Do not check if a smaller  
reporting company)

Smaller reporting company ☐

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

The aggregate market value of voting and non-voting stock held by non-affiliates of the Registrant as of June 30, 2009, the last day of the Registrant’s most recently completed second fiscal quarter, was \$54,330,410 based on the close price per share of Common Stock of \$4.75 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 1, 2010, there were issued and outstanding 13,449,210 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, 2009. 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

	Page
<u>Part I</u>	
<u>Item 1.</u>	<u>Business</u> 6
<u>Item 1A.</u>	<u>Risk Factors</u> 14
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u> 24
<u>Item 2.</u>	<u>Properties</u> 24
<u>Item 3.</u>	<u>Legal Proceedings</u> 25
<u>Item 4.</u>	<u>(Removed and Reserved)</u> 25
<u>Part II</u>	
<u>Item 5.</u>	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 26
<u>Item 6.</u>	<u>Selected Financial Data</u> 27
<u>Item 7.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 28
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> 42
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u> 44
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> 69
<u>Item 9A.</u>	<u>Controls and Procedures</u> 69
<u>Item 9B.</u>	<u>Other Information</u> 69
<u>Part III</u>	
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u> 70
<u>Item 11.</u>	<u>Executive Compensation</u> 70
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 70
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u> 70
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u> 70
<u>Part IV</u>	
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u> 70
<u>Signatures</u>	75

FORM 10-K  
ANIKA THERAPEUTICS, INC.  
For Fiscal Year Ended December 31, 2009

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 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 existing supply agreement for certain of our ophthalmic viscoelastic products, our ability to remain the exclusive global supplier for AMVISC and AMVISC Plus to Bausch & Lomb beyond the December 31, 2010 expiration date, and our expectations regarding revenue from ophthalmic products;

- our ability, and the ability of our distribution partner, to market our aesthetic dermatology product;

• 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 expectations regarding the development and commercialization of INCERT, and the market potential for INCERT;

- our expectations regarding HYDRELLE™ product sales in the United States;

- our ability to license our aesthetics product to new distribution partners outside of the United States;

- 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 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 decline in interest income;

- 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;

- 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 plans to address the FDA’s Warning Letter and Form 483 Notice of Observations and the impact any associated regulatory action would have on our business and operations;

- our expectations regarding the timing of receipt of clearance of the FDA Warning Letter;

• Our abilities to successfully integrate Fidia Advanced Biopolymers, our recently acquired subsidiary (“FAB”) into the Company and turnaround the operation from one with losses, into a company generating profits.

• Our ability to obtain U.S. approval for the products of Fidia Advanced Biopolymers and to expand sales of these products in the U.S., including our ability to obtain FDA approval for FAB’s suite of orthopedic products; and

- Our ability to directly commercialize MONOVISC and the FAB products directly to customers

Furthermore, additional statements identified by words such as “will,” “likely,” “may,” “believe,” “expect,” “anticipate,” “intend,” “seek,” “designed,” “develop,” “would,” “future,” “can,” “could” and other expressions that are predictions of or indicate future 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. 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, of 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 in 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.

On December 30, 2009, Anika Therapeutics, Inc. entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A., a privately held Italian corporation, pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l. (“FAB”), a privately held Italian corporation for a purchase price consisting of \$17.1 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 19, “Acquisition of Fidia Advanced Biopolymers, S.r.l.” 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, beginning in 2010, the Company now offers therapeutic products in the following areas:

	Anika	FAB
Orthopedic/joint health	X	X
Advanced wound care		X
Ophthalmic surgery	X	
Surgical/Anti-adhesion	X	X
Ear, nose & throat care (Otolaryngology)		X
Aesthetic dermatology	X	
Veterinary	X	

The Company plans to directly commercialize MONOVISC and certain FAB products in the U.S. once we receive FDA approval to market. In 2010 we will begin adding resources and materials to implement this plan.

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

## Orthopedic/Joint Health Business

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 during the second quarter of 2008. Our revenue from joint health products has increased 22% in 2009 from 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. ORTHOVISC has been approved for use in all joints in Europe and certain other international markets. 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 (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. 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 area 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.

#### Advanced Wound Care Business

With the FAB acquisition, the Company has now entered the field of advanced wound care products. FAB offers 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 3rd 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, and the Company is exploring distribution opportunities.

#### Ophthalmic Business

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, and ShellGel. 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 manufactures the AMVISC product line for Bausch & Lomb under the terms of a supply agreement through December 31, 2010 (the “2004 B&L Agreement”) for viscoelastic products used in ophthalmic surgery. B&L accounts for 27% of product revenue for the year ended 2009. Under the 2004 B&L Agreement, we will continue to be the exclusive global supplier (other than with respect to Japan) for AMVISC and AMVISC Plus to Bausch & Lomb through December 31, 2010. The 2004 B&L Agreement also provides us with a right to negotiate to manufacture future surgical ophthalmic viscoelastic products developed by Bausch & Lomb, while Bausch & Lomb has been granted rights to commercialize certain future surgical ophthalmic viscoelastic products developed by us. Under the 2004 B&L Agreement, we are entitled to continue providing surgical viscoelastic products to our existing customers (STAAR Surgical Company and Hoya Surgical Optics, Inc.) who currently receive such products from us. See also Item 1A. “Risk Factors.”

#### Surgical/Anti-adhesion Business

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 three 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 aesthetic 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 Propriety 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.

#### Ear, Nose and Throat ("ENT") Business

FAB offers eight 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.

#### Aesthetic Dermatology Business

Our aesthetic dermatology business is designed to have 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. This product is marketed in the U.S. by Coapt under the name of HYDRELLE™. Our distribution agreement with Coapt was signed in May 2009. Coapt began selling the product in the third quarter of 2009. Internationally the product is marketed under the ELEVESS™ name, and in 2010 expected to also be marketed under the HYDRELLE™ brand. We continue to focus on the development and expansion of the product in additional countries.

In late 2009, Anika received a CE mark for a less concentrated formulation product branded ELEVESS Light. We plan to begin marketing this product in Europe in 2010 through our existing distribution network.

#### Veterinary Business

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 15 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 at all relevant stages of development, and process development and scale-up manufacturing activities relative to our Bedford manufacturing facility. Our development focus includes chemically modified formulations of HA designed for longer residence time in the body. For the years ended December 31, 2009, 2008 and 2007, these expenses were \$8.2 million, \$7.4 million, and \$4.4 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 significant 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 small 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, and we expect to receive FDA approval in the second half of 2010. 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. One of our primary goals for the upcoming year is to integrate the research and development efforts of both companies, and rationalize and optimize 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 2010 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 own patents covering composition of matter and certain manufacturing processes. FAB’s issued patents expire between 2010 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”) governs 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. All of our existing products, with the exception of HYVISC, are subject to the applicable rules related to Class III devices.

AMVISC, AMVISC Plus, ShellGel and STAARVISC 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 new subsidiary, FAB, has three advanced wound care products approved in the U.S. as Class II devices through premarket notification (510(k))--Hyalomatrix PA, Hyalofill-R, and Hyalfill-F. All of FAB’s ENT products are 510(k) cleared through Medtronic as Class II devices.

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 a 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 are 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 with 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.

Upon completion of required clinical trials for pharmaceuticals, results are presented to the FDA in a NDA or New Animal Drug Application (“NADA”). In addition to the results of clinical investigations, the PMA 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 QSR 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.

Product or manufacturing changes after approval where such change affects 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 other quality system 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 regulations obligates manufacturers to inform the FDA whenever information reasonably suggests that one of their devices 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 current manufacturing facility in Woburn, Massachusetts. We have fully cooperated with the FDA to address the issues in the Form 483 filing and have issued a response to the FDA’s Warning Letter. We have developed a corrective action plan and we have provided the FDA with progress reports. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. The FDA did conduct follow up inspections of the Company’s Woburn facility in March and December 2009. Follow on deficiencies were noted in each of those inspections as documented on Form 483. The Company has submitted additional corrective action plans which have been accepted by the FDA. Discussions are ongoing to address all issues and clear the Warning Letter as rapidly as possible. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter in the near future. Failure to comply with applicable regulatory requirements and to address the issues raised by the FDA in the Warning Letter could result in regulatory action. Any such regulatory action would be expected to have a material adverse effect on our business and operations.

## 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 Conformité Européene (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™ 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. 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, Lorea, 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) in order to remain on EU market. FAB continues to be in discussion with EMA and is implementing plan to qualify for the new status. There can be no assurance that approval will be timely obtained. We may not be able to achieve and/or maintain 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. In the third quarter of 2006, the government of Turkey eliminated reimbursement for over 100 drugs including ORTHOVISC, designated as a drug in Turkey, and its competing products. International sales declined in 2007 compared to 2006 due to the reimbursement change in Turkey. We did not ship product to our Turkish distributor during the 10 months ended May 2007. Starting in June 2007, sales to Turkey have been at a lower level reflective of a private pay business.

## 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 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, 2009, we had 133 employees, 50 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 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, 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. The information on our website is not part of this Annual Report on Form 10-K. Reports filed with the SEC may be viewed at [www.sec.gov](http://www.sec.gov) or obtained at the SEC Public Reference Room at 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 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, SFAS 123R, 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 the MONOVISC product in October 2007. We have completed a pivotal trial in the U.S., and submitted the results for a PMA application during December 2009. 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. 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 European Medicines Agency (EMA) to stay on EU market. FAB continues to be in discussion with EMA and is implementing plan to qualify for the new status. There can be no assurance that approval will be timely obtained.



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 process, where required; or
- 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.

European and other regulations may not change for the marketing of cell base products and thus impact our ability to continue commercialization of these products; or

Lack of timely clearance of the Warning Letter will not impact revenues due to the limits placed on expansion of products into new territories, delays in U.S. and foreign regulatory approvals of new products, and potential impact on sale of current 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:

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 Woburn facility. We have fully cooperated with the FDA to address the issues in the Form 483 filing and have issued a response to the FDA’s Warning Letter. We have developed a corrective action plan and we have provided the FDA with progress reports. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. The FDA did conduct follow up inspections of the Company’s Woburn facility in March and December 2009. Follow on deficiencies were noted in each of those inspections as documented on Form 483. The Company has submitted additional corrective action plans which have been accepted by the FDA. Discussions are ongoing to address all issues and clear the Warning Letter as rapidly as possible. Failure to comply with applicable regulatory requirements and to address the issues raised by the FDA in the Warning Letter could result in regulatory action. Any such regulatory action would be expected to have a material adverse effect on our business and operations.

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.

Current 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 are currently experiencing turmoil, characterized by volatility in security prices, rating downgrades of investments and reductions in available credit. These events have materially and adversely impacted the availability of financing to a wide variety of businesses, and the resulting uncertainty has led to reductions in capital investments, overall spending levels, future product plans, and sales projections across industries and markets. These trends could have a material adverse impact on our business, our ability to achieve planned results of operations and our financial condition as a result of:

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

We are unable to predict the likely duration and severity of the current disruption in financial markets and adverse economic conditions in the U.S. and other countries, but the longer the duration the greater the risks we face in operating our business.

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. Our current product in a pivotal clinical trial is MONOVISC.

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 intention to directly commercialize 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, or in connection with earlier termination in certain circumstances,

our manufacturing process, know-how and technical information, which relate to only AMVISC products. Upon expiration of the 2004 B&L Agreement, there can be no assurance that Bausch & Lomb will continue to use us to manufacture AMVISC and AMVISC Plus. If Bausch & Lomb discontinues the use of us as a manufacturer after such time, our business, financial condition, and results of operations would likely be materially and adversely affected.

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 buildout 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 buildout was completed in mid-2008 and validation and approval for operation in the new manufacturing space is expected to be completed in the second half of 2010. We provide no assurance that the validation and approval processes will be completed on time, if at all. Furthermore, we cannot assure you that the transition from the existing facilities to the new facility will be seamless and successful. In the event the construction is delayed or the move transition is unsuccessful, it may result in business interruptions. We may also incur additional expenditures in the event that we have to maintain two 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 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 \$24.4 million at December 31, 2009. 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;
  - 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 that 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 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 late 2010. 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 these 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 Fidia Advanced Biopolymers S.r.l. ("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, 2009 and 2008, approximately, 26% and 27%, respectively, of our product sales were to international distributors. However, as a result of our acquisition of Fidia Advanced Biopolymers S.r.l., we anticipate the percentage of our product sales resulting from international operations to increase in fiscal year 2010. 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;

• 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.

A very small percentage of our business from continuing operations during fiscal year 2009 was conducted in functional currencies other than the U.S. dollar, which is our reporting currency. As a result of our acquisition of Fidia Advanced Biopolymers S.r.l., we anticipate this percentage to increase to approximately 20% during fiscal year 2010. 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, 2009, four customers accounted for 83% 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.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

We have received no written comments regarding our periodic or current reports from the staff of the Securities and Exchange Commission that were issued 180 days or more preceding the end of our 2009 fiscal year and that remain unresolved.

#### 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 buildout at the Bedford facility was completed in mid-2008 and validation for the manufacturing space will continue into 2010. 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. 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 May 31, 2010. 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, 2009, we had aggregate facility lease expenses of approximately \$1,651,713.

Our aggregate expenditures to build out the Bedford facility that will serve as our corporate headquarters and manufacturing facility for the foreseeable future are expected to be approximately \$34 million. Through December 31, 2009, approximately \$33 million has already been spent in connection with the buildout. 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 December 12, 2007, Colbar Lifescience Ltd., a subsidiary of Johnson and Johnson, filed an opposition proceeding before the U.S. Patent & Trademark Office's Trademark Trial & Appeal Board ("Trademark Board"), objecting to one of the Company's applications to register the trademark ELEVESS, alleging that the mark is confusingly similar to Colbar's previous mark EVOLENCE. In October 2008, Colbar filed a petition with the Trademark Board requesting cancellation of the Company's second ELEVESS trademark that had been registered in September 2008. Throughout the discussions, the Company has maintained that Colbar's claim and petition are without merit, and has denied all substantive allegations in the notice of opposition. In November 2009, Colbar and Anika settled the matter and the parties signed a stipulation filed with the court, whereby Anika abandoned the US applications and registrations, and Colbar dismissed the opposition/cancellation proceedings. The Trademark Board has approved the stipulation and dismissed the case.

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, 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

Year Ended December 31, 2008	High	Low
First Quarter	\$15.18	\$8.10
Second Quarter	10.46	8.42
Third Quarter	9.37	7.10
Fourth Quarter	7.67	3.00

At December 31, 2009, the closing price per share of our common stock was \$7.63 as reported on the NASDAQ Global Select Market and there were approximately 272 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, 2004 in the Company's Common Stock and each of the indices.

	Dec-04	Dec-05	Dec-06	Dec-07	Dec-08	Dec-09
Anika Therapeutics	\$ 100.00	\$ 127.76	\$ 145.03	\$ 159.02	\$ 33.22	\$ 83.39
NASDAQ Composite Index	\$ 100.00	\$ 101.37	\$ 111.03	\$ 121.92	\$ 72.49	\$ 104.31
NASDAQ Biotechnology Index	\$ 100.00	\$ 102.84	\$ 103.89	\$ 108.65	\$ 94.93	\$ 109.77

## EQUITY COMPENSATION PLAN INFORMATION

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

The following table sets forth information concerning the Company's equity compensation plan as of December 31, 2009.

Plan category	Equity Compensation Plan Information		
	Number of securities to be issued upon exercise of outstanding options, stock appreciation rights, and restricted stock (a)	Weighted Average exercise price of outstanding options, stock appreciation rights, and restricted stock (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,467,910	\$ 7.43	887,840
Equity compensation plans not approved by security holders	—	—	—
Total	1,467,910	\$ 7.43	887,840

## 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, 2009 and 2008 and the Statement of Operations Data for each of the three years ended December 31, 2009 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, 2007, 2006 and 2005, and the Statement of Operations Data for each of the two years in the period ended December 31, 2006 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,									
	2009		2008		2007		2006		2005	
Product revenue	\$37,321		\$33,055		\$26,905		\$23,953		\$20,534	
Licensing, milestone and contract revenue	2,815		2,725		3,925		2,887		9,301	
Total revenue	40,136		35,780		30,830		26,840		29,835	
Cost of product revenue	13,670		13,189		11,881		11,118		11,144	
Product gross profit	23,651		19,866		15,024		12,835		9,390	
Product gross margin	63	%	60	%	56	%	54	%	46	%
Total operating expenses	34,549		31,553		24,242		21,413		21,284	
Net income	\$3,688		\$3,629		\$6,035		\$4,604		\$5,893	
Diluted net income per common share	\$0.32		\$0.32		\$0.53		\$0.41		\$0.52	
Diluted common shares outstanding	11,562		11,461		11,454		11,155		11,428	

Balance Sheet Data  
(In thousands)

	December 31,				
	2009	2008	2007	2006	2005
Cash, cash equivalents and short-term investments	\$24,427	\$43,194	\$39,406	\$47,167	\$44,747
Working capital	33,270	46,798	41,805	52,145	46,584
Total assets	130,702	95,821	79,497	68,114	62,618
Retained earnings	21,470	17,782	14,153	8,118	3,514
Stockholders' equity	82,144	60,757	54,961	45,488	37,892

On June 30, 2006, the Company entered into a License and Development Agreement and a Supply Agreement with Galderma for the exclusive worldwide development and commercialization of hyaluronic acid based aesthetic dermatology products. Due to disagreements concerning certain aspects of the formulation of the current and future products as well as some elements of the strategy and timing for commercialization, in November 2007 the Galderma agreements were terminated. As a result, we reacquired the worldwide rights and control of the future development and marketing of ELEVESS. As a result of the contract terminations, during the fourth quarter of 2007, we recorded net revenue of approximately \$1.2 million for the upfront and milestone payments received and termination payment made to Galderma.

On September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement. Under the terms of the termination agreement, we received a final payment of \$3.1 million from OrthoNeutrogena including \$0.8 million for all outstanding clinical study costs incurred and committed to by the Company at the termination date, plus a mutually agreed upon termination fee of \$2.1 million. Given that there were no continuing performance obligations with respect to the development and commercialization agreement or the related termination agreement, all amounts were recognized as contract revenue during the third quarter of 2005, including \$0.3 million of previously deferred revenue under the performance-based model.



## 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. See Item 1: “Business” in this Form 10-K for details regarding the Company’s currently manufactured and marketed products.

On December 30, 2009, Anika entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A., a privately held Italian corporation (the “Seller”) pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l., a privately held Italian corporation (“FAB”) for a purchase price consisting of \$17.1 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. FAB’s operating results and cash flow changes were immaterial for the one day of post-acquisition activity. (See Item 8: Financial Statements, Note 19, “Acquisition of Fidia Advanced Biopolymers, S.r.l.” for additional information regarding the acquisition).

FAB has over 20 products currently commercialized, primarily in Europe. These products are 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 patents. With the acquisition of FAB, beginning in 2010, the Company will be offering therapeutic products in the following areas:

	AnikaFAB	
Orthopedic/joint health	X	X
Advanced wound care		X
Ophthalmic surgery	X	
Surgical/Anti-adhesion	X	X
Ear, nose & throat care (Otolaryngology)		X
Aesthetic dermatology	X	
Veterinary	X	

## Orthopedic/Joint Health Business

Anika's joint health business contributed 61% to our product revenue in the year ended December 31, 2009 compared to 57% in the year ended December 31, 2008, reflecting an increase in sales of 22% in 2009 compared to 2008. Our 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 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 14% of product revenue for the year ended December 31, 2009 and increased \$385,013, or 8% compared to 2008. This increase in many countries is reflective of our continued focus in this therapeutic area, an area with favorable demographics of an aging population looking to remain active. 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 39% of our product revenue in 2005 to 61% of our product revenue in 2009. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2010 compared to 2009.

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. FAB's 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 be a major focus area for the Company.

#### Advanced Wound Care Business

With the FAB acquisition, the Company has now entered the field of advanced wound care products. FAB offers 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 Hyalomatrix 3D, for the regeneration of skin; and Hyalomatrix, for treatment of burns and ulcers and the only product not contra-indicated for 3rd 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, and the Company is exploring distribution opportunities.

#### Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2009, sales of ophthalmic products contributed 28% of our product revenue reflecting a decrease in sales of ophthalmic products of 1% compared to 2008. Sales to Bausch & Lomb accounted for 94% of ophthalmic sales for 2009 and contributed 27% of product revenue for the period.

#### Surgical/Anti-adhesion Business

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. INCERT is currently marketed in three 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 aesthetic products. Sales of INCERT® were \$121,445 and \$134,780 for the years 2009 and 2008, respectively. There are currently no plans to distribute INCERT in the U.S.

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.



#### Ear, Nose and Throat Care Business

FAB offers eight 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.

#### Aesthetic Dermatology Business

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. We received European and United States FDA approvals for this product in April and July of 2007, respectively. We recorded \$1,471,465 and \$505,273 of aesthetic dermatology revenue in 2009 and 2008, respectively. Aesthetic dermatology revenue in 2008 was primarily from Artes Medical, Inc., our former U.S. ELEVESS distributor. Our distribution agreement with Artes was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. This product is now marketed in the U.S. by Coapt Systems, Inc. under the name of HYDRELLE™. Coapt began selling the product in the third quarter of 2009. Internationally, this product is marketed under the ELEVESS™ name, and in 2010 expected to also be marketed under the HYDRELLE™ brand. We continue to focus on the development and expansion of the product in additional countries and added distributors in Poland, Egypt, and Korea during the fourth quarter of 2009.

#### Veterinary Business

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 6% to product revenue for the year ended December 31, 2009, reflecting a decrease of 25% from 2008. We believe the decrease for these periods was primarily due to inventory management by our partner, Boehringer Ingelheim Vetmedica. We expect HYVISC sales to be relatively flat in 2010. We continue to look at other veterinary applications and opportunities to expand geographic territories.

#### Research and Development

Products in development include MONOVISC for U.S. marketing approval, and additional next generation joint health related products. Our first next generation osteoarthritis product is MONOVISC, a single-injection treatment product that uses a non-animal source HA, and is 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 completed a PMA filing with the FDA in December 2009 which is currently under review. Our second single-injection osteoarthritis product 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.

Our new subsidiary, FAB, has a number of research and development projects underway. Key projects include obtaining FDA approval to market FAB's suite of orthopedic products in the U.S. These products consist of Hyalofast®, Hyaloglide®, Hyalograft® and Hyalonect®. A key objective for 2010 will be to integrate our research and development activities, and to prioritize the many projects currently underway at both companies.

#### 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 financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these 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, 2009.

## Business Combinations

The Company assigns the value of the consideration transferred to acquire a business to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets such as in-process research and development, using a variety of methods including present-value models. Each asset is measured at fair value from the perspective of a market participant. The establishment of fair value for intangible assets in a stock purchase transaction frequently results in a different treatment for tax return purposes. Under Italian tax law, the tax basis of the assets may not be stepped-up to fair value, and the additional depreciation and amortization expense is not deductible, which creates a deferred tax liability over the amortization period that is recorded on the opening balance sheet.

In-process research and development assets acquired in a business combination are recorded as of the acquisition date at fair value and accounted for as indefinite-lived intangible assets. These assets are maintained on the Company's consolidated balance sheet until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. In-process research and development assets are tested for impairment on an annual basis, or earlier, if impairment indicators are present.

The method used to estimate the fair values of in-process research and development assets incorporates significant assumptions regarding the estimates market participants would make in order to evaluate an asset. These include assumptions regarding the probability of completing development projects, obtaining regulatory approval for marketing, estimates regarding the timing of and the expected costs to complete, and estimates of future cash flows from potential product sales.

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis, or earlier if impairment indicators are present.

## Revenue Recognition

Our revenue recognition policies are in accordance with Accounting Standards Codification 605, Revenue Recognition (ASC 605), and Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (formerly the SEC SAB No. 101, Revenue Recognition in Financial Statements, as amended by SEC SAB No. 104, Revenue Recognition, and EITF No. 00-21, Revenue Arrangements with Multiple Deliverables, and EITF No. 07-1 Accounting for Collaborative Arrangements), which became effective on January 1, 2009. Adoption of ASC 808 did not impact our financial statements for the year ended December 31, 2009.

### Product Revenue

We recognize revenue from the sales of products we manufacture upon confirmation of regulatory compliance and shipment to the customer as long as there is (1) persuasive evidence of an arrangement, (2) delivery has occurred and risk of loss has passed, (3) the sales price is fixed or determinable and (4) collection of the related receivable is reasonably assured. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. When determining whether risk of loss has transferred to customers on product sales or if the sales price is fixed or determinable we evaluate both the contractual terms and conditions of our distribution and supply agreements as well as our business practices. Product revenue also includes royalties. Royalties earned are recorded as product revenue

and is based on our distributor's sales and recognized in the same period our distributor records their sale of the product.



### 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, supply of products and royalties on product sales. The Company evaluates each agreement and elements within each agreement in accordance with ASC 605. Under ASC 605, in order to account for an element as a separate unit of accounting, the element must have stand-alone value and there must be objective and reliable evidence of fair value of the undelivered elements. In general, non-refundable upfront fees and milestone payments are recognized as revenue over the term of the arrangement as the Company completes its performance obligations. In October 2009 the FASB issued Accounting Standards Update 2009-13, Revenue Recognition (Topic 605), a new accounting standard for the recognition of revenue arrangements with multiple deliverables. This standard provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and how the consideration should be allocated. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. While we do not expect the adoption of this standard to have a material impact on our financial position and results of operations, this standard may impact us in the event we complete future transactions or modify existing collaborative relationships. See the accompanying notes to the Financial Statements in the Form 10-K under Recent Accounting Pronouncements for additional discussion of this standard and its impact on us.

### Grant Research Revenue

With the FAB acquisition, the Company assumed two grant contracts with the European Community related to cell-based tissue engineered products and disc regeneration research. FAB coordinates the fiscal activities for a group of participating companies and universities, and accounts for these contracts by recording an account receivable for the reimbursable expenses incurred under the contract, and records a liability for any amounts due to the other participants. Expenses are recorded as incurred.

### Reserve for Obsolete/Excess Inventory

Inventories are stated at the lower of cost or market. We regularly review our inventories and record a provision for excess and obsolete inventory based on certain factors that may impact the realizable value of our inventory including, but not limited to, technological changes, market demand, inventory cycle time, regulatory requirements and significant changes in our cost structure. If ultimate usage varies significantly from expected usage or other factors arise that are significantly different than those anticipated by management, additional inventory write-down or increases in obsolescence reserves may be required.

We generally produce finished goods based upon specific orders or in anticipation of specific orders. As a result, we generally do not establish reserves against finished goods. We evaluate the value of inventory on a quarterly basis and may, based on future changes in facts and circumstances, determine that a write-down of inventory is required in future periods.

### Fair Value Measurements

Effective January 1, 2009, the Company adopted the authoritative guidance for fair value measurements and the fair value option for financial assets and financial liabilities in accordance with Accounting Standards Codification 820, Fair Value Measurements and Disclosures (ASC 820), (Formerly SFAS No. 157, Fair Value Measurements and

Disclosures). ASC 820 establishes a three-level hierarchy which prioritizes the inputs used in measuring fair value. In general, fair value determined by Level 1 inputs utilize quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability. The fair value of our cash equivalents was \$20,212,992 and \$34,197,953 at December 31, 2009 and December 31, 2008, respectively, based on Level 1 inputs. Effective January 1, 2009, the Company adopted the provisions under ASC 820 for valuation of nonfinancial assets and nonfinancial liabilities. The adoption of such provisions did not impact the Company's financial position, results of operations, or cash flows.

During the second quarter of 2009, the Company implemented Accounting Standards Codification 825, Financial Instruments (ASC 825), (Formerly FSP 107-1 and APB 28-1 Interim Disclosures about Fair Value of Financial Instruments). ASC 825 requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The adoption of this standard has resulted in the disclosure of the fair value of the Company's long term debt instrument on a quarterly basis. Since ASC 825 addresses disclosure requirements, the adoption of this ASC did not impact our financial position or results of operations. The carrying value of our debt instrument was \$14,400,000 at December 31, 2009. The estimated fair value of our debt instrument was approximately \$13,800,000 using market observable inputs and interest rate measurements.

## Asset Valuation

Asset valuation includes assessing the recorded value of certain assets, including accounts receivable, investments, inventories, and intangible assets. We use a variety of factors to assess valuation, depending upon the asset. Accounts receivable are evaluated based upon the credit-worthiness of our customers, our historical experience, and the age of the receivable. The determination of whether unrealized losses on investments are other than temporary is based upon the type of investments held, market conditions, length of the impairment, magnitude of the impairment and ability to hold the investment to maturity. Should current market and economic conditions deteriorate, our ability to recover the cost of our investments may be impaired. The recoverability of inventories is based upon the types and levels of inventory held and forecasted demand. Should current market and economic conditions deteriorate, our actual recovery could be less than our estimate. Intangible assets are evaluated based upon the expected period the asset will be utilized, forecasted cash flows, and customer demand. Our intangible assets consist of our ELEVESS trade name, as well as Developed Technology, IPR&D, Goodwill and other items related to the FAB acquisition. Significant assumptions underlying the recoverability of the intangible assets include: future cash flow, growth projections, product life cycle and useful life assumptions. The ultimate recoverability of the asset is dependent on us securing additional distributors, or directly commercializing the product. Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible asset. Refer to Note 19 on the acquisition of FAB.

## Property and equipment

Property and equipment are carried at cost less accumulated depreciation, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Costs of major additions and improvements are capitalized; maintenance and repairs that do not improve or extend the life of the respective assets are charged to operations. On disposal, the related accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in results of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful life or the expected term of the respective lease. Machinery and equipment are depreciated from 5 to 10 years, furniture and fixtures from 5 to 7 years and computer software and hardware from 3 to 5 years. Interest costs incurred during the construction of major capital projects are capitalized in accordance with Accounting Standards Codification 835-20, Capitalization of Interest (ASC 835-20), (Formerly SFAS No. 34, "Capitalization of Interest Costs"). The interest is capitalized until the underlying asset is ready for its intended use, at which point the interest cost is amortized as interest expense over the life of the underlying assets. The Company began expensing all interest costs incurred commencing after July 1, 2009. We capitalize certain direct and incremental costs associated with the validation effort related to FDA approval of our manufacturing facility and equipment for the production of our commercial products. These costs include construction costs, equipment costs, direct labor and materials incurred in preparing the facility and equipment for their intended use. The validation costs are amortized over the life of the related facility and equipment. We will commence depreciation upon receiving FDA approval to manufacture our products.

## Stock-based Compensation

The Company accounts for stock-based compensation under the provisions of Accounting Standards Codification 718, Compensation – Stock Compensation (ASC 718), (Formerly SFAS No. 123R, Share-Based Payment), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant). For awards with a performance condition vesting feature, when achievement of the performance condition is deemed probable, the Company recognizes compensation cost on a graded-vesting basis over the awards' expected vesting periods. The Company assesses probability on a quarterly basis.

The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, the expected award term, the expected volatility of the Company's stock over the option's expected term, the risk-free interest rate over the award's expected term, and the Company's expected annual dividend yield. The Company uses historical data on exercise of stock options and other factors to estimate the expected term of share-based awards. The Company also evaluates forfeitures periodically and adjusts accordingly. The expected volatility assumption is based on the unadjusted historical volatility of the Company's common stock. The risk-free interest rate assumption is based on U.S. Treasury interest rates at the time of grants. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

## Income Taxes

Beginning January 1, 2007, the Company began accounting for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement in accordance with Accounting Standards Codification 740, Income Taxes (ASC 740), (Formerly FIN 48, "Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109"). If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit will be recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. As a result of the adoption of ASC 740 there was no change to the tax reserve for unrecognized tax benefits. As such, there was no change to retained earnings as of January 1, 2007. It is the Company's policy to classify accrued interest and penalties as part of the accrued ASC 740 liability and record the expense in the provision for income taxes. As of December 31, 2009, income tax related interest and penalties were immaterial. The DOR is currently auditing the Company's taxes for the years ended December 31, 2007 and December 31, 2006. Our U.S. federal income tax returns for the years 2006 to 2008 remain subject to examination, and our state income tax return for 2008 remains subject to examination.

We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates assumed to be in effect when these differences reverse. As of December 31, 2009, management determined that it is more likely than not that the deferred tax assets will be realized and, therefore, a valuation allowance has not been recorded.

## Results of Operations

Year ended December 31, 2009 compared to year ended December 31, 2008

The historical results of operations discussion below 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,	
	2009	2008
Product revenue	\$37,320,906	\$33,054,787
Licensing, milestone and contract revenue	2,814,798	2,725,000
Total revenue	40,135,704	35,779,787
Operating Expenses:		
Cost of product revenue	13,670,228	13,188,516
Research and development	8,181,532	7,399,049
Selling, general and administrative	10,545,351	10,965,493
Acquisition-related expenses	2,151,854	—
Total operating expenses	34,548,965	31,553,058
Income from operations	5,586,739	4,226,729
Interest income (expense), net	(74,480 )	498,512
Income before income taxes	5,512,259	4,725,241
Provision for income taxes	1,824,692	1,096,046
Net income	\$3,687,567	\$3,629,195
Product gross profit	\$23,650,678	\$19,866,271
Product gross margin	63 %	60 %

**Total Revenue.** Total revenue for the year ended December 31, 2009 increased by \$4,355,917 to \$40,135,704. The increase in total revenue was primarily due to increased Joint Health and Aesthetic Dermatology product revenue in 2009.

Product revenue by product line. Product revenue for the year ended December 31, 2009 was \$37,320,906, an increase of \$4,266,119, or 13%, compared to the prior year.

	Year Ended December 31,	
	2009	2008
Joint Health	\$22,879,899	\$18,707,669
Ophthalmic	10,573,915	10,678,615
Veterinary	2,274,482	3,028,450
Aesthetics	1,471,165	505,273
Others	121,445	134,780
	\$37,320,906	\$33,054,787

Our joint health products consist of ORTHOVISC, ORTHOVISC mini and MONOVISC, the latter two of which are currently only available outside the United States. Revenue from joint health products increased \$4,172,230, or 22%, in 2009. The improvement in joint health product revenue was due to increases in both international and domestic ORTHOVISC revenue, as well as increased sales of MONOVISC and ORTHOVISC mini in Europe, Turkey and Canada in 2009 compared with only a partial period during 2008. Our U.S. joint health product revenue for 2009 totaled \$16,930,420, compared to \$13,222,454 in 2008, an increase of 28%. This increase reflects DePuy Mitek's underlying volume driven sales increases to end-users as a result of their continued marketing efforts. International joint health product revenue in 2009 increased 8% to \$5,949,479, from \$5,485,215, in 2008. The increase in international revenue was due to increased product shipments to Canada, France, Egypt, Hungary and Austria. We expect joint health product revenue to increase in 2010 compared to 2009, both domestically and internationally.

Ophthalmic products sales decreased \$104,700, or 1%, to \$10,573,915. The decrease was primarily attributable to order timing and inventory management by our partners.

HYVISC revenue decreased \$753,968, or 25%, to \$2,274,482 in 2009 as compared with \$3,028,450 in 2008. We believe the decrease for the period was primarily due to inventory management by our partner, Boehringer Ingelheim Vetmedica. Sales of HYVISC are made to a single customer under an exclusive agreement which was extended in April 2006 to December 31, 2010. We expect HYVISC revenue to be relatively flat in 2010 compared to 2009.

AESTHETICS revenue increased \$965,892, or 191%, to \$1,471,165 in 2009 from \$505,273 in 2008. The increase was primarily due to the commencement of sales in the third quarter of 2009 by our new United States distributor, Coapt Systems, Inc. Coapt is marketing the product in the U.S. under the brand name HYDRELLE™. AESTHETICS revenue in 2008 was primarily from Artes Medical, Inc., our former U.S. ELEVESS distributor. Our distribution agreement with Artes Medical, Inc. was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. We added several additional international distributors in the second half of 2009, and we continue to seek additional marketing and distribution partners to commercialize our aesthetic products outside the U.S. The aesthetics' market is crowded with many large companies, and our growth expectations in this area are modest.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the year ended December 31, 2009 was \$2,814,798, compared to \$2,725,000 for 2008. The increase was due to a short term product development contract with an existing partner. Licensing and milestone revenue includes the ratable recognition of the \$27,000,000 in up-front and milestone payments related to the JNJ agreement. These amounts are being recognized in income ratably over the ten-year expected life of the agreement, or \$2,700,000 per year.

Product gross profit and margin. Product gross profit for the year ended December 31, 2009 was \$23,650,678, or 63% of product revenue, compared with \$19,866,271, or 60% of product revenue, for the year ended December 31, 2008. The increase in product gross profit dollars and margin was primarily due to increased sales of our more profitable

joint health products resulting in a more favorable product mix compared to 2008, and increased manufacturing activity in our Woburn facility to build inventory in preparation for moving our operations to the Bedford facility. We expect a small decline in gross margin in 2010 due to lower manufacturing activity during the time we transition operations to our Bedford facility. The transition will take place by product line and result in manufacturing activities occurring in both facilities for a significant portion of the year. The Bedford facility is expected to add in excess of \$2.2 million to annual depreciation once completely on-line.

Research and development. Research and development expenses for the year ended December 31, 2009 increased by \$782,483, or 11%, to \$8,181,532 from \$7,399,049 for the prior year. The increase in research and development expenses was primarily related to our ongoing U.S.-based clinical trials for MONOVISC, the post-marketing aesthetics dermatology “people of color” study, manufacturing validation activities at our Bedford facility, as well as other continuing new product development projects. We expect research and development expenses will increase significantly in the future with the addition of FAB’s activities.



**Selling, general and administrative.** Selling, general and administrative expenses for the year ended December 31, 2009, excluding acquisition-related expense, decreased by \$420,142 or 4%, to \$10,545,351 from \$10,965,493 in the prior year. The decrease was primarily due to a decrease in marketing expenses. The prior year's spending included additional marketing expenses as a result of the MONOVISC and ORTHOVISC mini product launches in Europe. We expect that general and administrative expenses will increase modestly in 2010, but selling expenses to significantly increase as we prepare for the direct commercialization of MONOVISC in the U.S.

**Acquisition-related Expenses.** We incurred \$2.2 million of acquisition-related non-recurring expenses in 2009 in connection with our acquisition of FAB. We did not have corresponding acquisition-related expenses in 2008 or 2007.

**Interest income, net.** Net interest expense was \$74,480 for the year ended December 31, 2009, compared to a net interest income of \$498,512 in 2008. The decrease was primarily attributable to lower interest rates as a result of the current rate environment, and lower available cash and invested balances in 2009 compared to 2008. The net interest expense for 2009 represents interest expense for facility related asset retirement obligations, and the interest expense on our outstanding debt balance, which was capitalized during the construction/validation stages prior to July 1, 2009.

**Income taxes.** Provisions for income taxes were \$1,824,692 and \$1,096,046 for 2009 and 2008, respectively. The increase in effective tax rate in 2009 of 9.9% and difference from the U.S. federal statutory rate is primarily due to two factors: approximately \$1.3 million of the FAB acquisition expenses are non-deductible for income tax purposes, and lower capital spending on the Bedford facility as the project spending peaked in 2008, resulting in lower state investment tax credits in 2009. Partially offsetting this increase was greater state and federal research and development spending resulting in higher credits in 2009 compared to 2008.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	Years ended December 31,					
	2009		2008		2007	
Computed expected tax expense	34.0	%	34.0	%	34.0	%
State tax expense (net of federal benefit)	6.2	%	4.6	%	4.2	%
State deferred tax assets rate change	(0.8)	)%	2.6	%	-	
Permanent items, including nondeductible expenses	8.8	%	0.6	%	(1.1)	)%
State investment tax credit	(5.6)	)%	(11.1)	)%	(3.9)	)%
Federal and state research and development credits	(8.4)	)%	(5.8)	)%	(2.4)	)%
Other	(1.1)	)%	(1.7)	)%	(0.3)	)%
Tax expense	33.1	%	23.2	%	30.5	%

During the third quarter of 2008, the Company concluded its audit by the Massachusetts Department of Revenue ("DOR") for its 2004 and 2005 tax returns, which resulted in a reduction to its FIN 48 tax reserves and a related income tax benefit of approximately \$100,000. In 2008, the Company recorded additional provision of approximately \$121,000 related to the reduction of its deferred tax assets as a result of newly enacted changes in the Commonwealth of Massachusetts to gradually reduce future corporate income tax rates. The DOR is currently auditing the Company's taxes for the years ended December 31, 2007 and December 31, 2006. Our U.S. federal income tax returns for the years 2006 to 2008 remain subject to examination, and our state income tax return for 2008 remains subject to examination.

**Net income.** For the year ended December 31, 2009 net income was \$3,687,567 or \$0.32 per diluted share compared to \$3,629,195 or \$0.32 per diluted share for the same period last year. The primary driver for the increase in net income was an increase in product sales with a more favorable product mix.



Year ended December 31, 2008 compared to year ended December 31, 2007

Statement of Operations Detail

	Year Ended December 31,	
	2008	2007
Product revenue	\$33,054,787	\$26,905,100
Licensing, milestone and contract revenue	2,725,000	3,924,721
Total revenue	35,779,787	30,829,821
Operating Expenses:		
Cost of product revenue	13,188,516	11,880,989
Research and development	7,399,049	4,364,620
Selling, general and administrative	10,965,493	7,996,781
Total operating expenses	31,553,058	24,242,390
Income from operations	4,226,729	6,587,431
Interest income, net	498,512	2,100,663
Income before income taxes	4,725,241	8,688,094
Provision for income taxes	1,096,046	2,652,840
Net income	\$3,629,195	\$6,035,254
Product gross profit	\$19,866,271	\$15,024,111
Product gross margin	60 %	56 %

Total Revenue. Total revenue for the year ended December 31, 2008 increased by \$4,949,996 to \$35,779,787 compared to \$30,829,821 for the year ended December 31, 2007 primarily due to increased ORTHOVISC revenue and the introduction of new joint health products in 2008. Product revenue for 2008 increased by \$6,149,687 to \$33,054,787 primarily due to increased ORTHOVISC revenue from our U.S. distributor, Depuy Mitek. See below for further details.

Product revenue by product line. Product revenue for the year ended December 31, 2008 was \$33,054,787, an increase of \$6,149,687, or 23%, compared with \$26,905,100 for the year ended December 31, 2007.

	Year Ended December 31,	
	2008	2007
Joint Health	\$18,707,669	\$13,602,494
Ophthalmic	10,678,615	10,517,156
Veterinary	3,028,450	2,370,898
Aesthetics	505,273	224,220
Others	134,780	190,332
	\$33,054,787	\$26,905,100

Our Joint health revenue was from sales of ORTHOVISC, ORTHOVISC mini and MONOVISC, the latter two of which were only available outside the United States. Revenue from joint health products increased \$5,105,175, or 38%, to \$18,707,669 in 2008. The improvement in joint health product revenue for 2008 was primarily due to increases in both international and domestic ORTHOVISC revenue, as well as the launch of MONOVISC and ORTHOVISC mini in Europe and Turkey during the second quarter of 2008. Our U.S. joint health product revenue for 2008 totaled \$13,222,454, compared to \$10,071,776 in 2007, an increase of 31%. This increase reflects DePuy Mitek's underlying sales increases to end-users of 26% in 2008 compared to 2007. International joint health product revenue increased 36% to \$4,806,082 from \$3,530,717 in 2008 compared to the same period in 2007. The increase in

international sales was due to increased product shipments to Turkey, Germany, Italy, Egypt, Hungary and Austria.

Ophthalmic products sales increased \$161,459, or 2%, to \$10,678,615 in 2008 compared with \$10,517,156 in 2007. The increase was primarily attributable to an increase in sales to Bausch & Lomb in 2008 compared to 2007 due to their inventory management efforts.

HYVISC sales increased \$657,552, or 28%, to \$3,028,450 in 2008 as compared with \$2,370,898 in 2007. Sales of HYVISC were made to a single customer under an exclusive agreement which was extended in April 2006 to December 31, 2010.

AESTHETIC product sales increased \$281,053, or 125%, to \$505,273 in 2008 as compared with \$224,220 in 2007. AESTHETICS revenue in 2008 was primarily from Artes Medical, Inc., our former U.S. ELEVESS distributor. Our distribution agreement with Artes Medical, Inc. was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. AESTHETICS revenue in 2007 represented sales of samples to a former distributor.

Licensing, milestone and contract revenue. Licensing, milestone and contract revenue for the year ended December 31, 2008 was \$2,725,000, compared to \$3,924,721 for 2007. Licensing and milestone revenue includes the ratable recognition of the \$27,000,000 in up-front and milestone payments from Ortho Biotech. These amounts are being recognized in income ratably over the ten-year expected life of the agreement, or \$2,700,000 per year. On November 16, 2007, the Company, Galderma and Galderma S.A. entered into a Termination Agreement. As a result the Company recorded non-recurring revenue of \$1,199,722 in 2007 primarily from the balance of the upfront and milestone payments made that were recorded as deferred revenue at the time of receipt. All amounts due and contractual obligations by both parties have been satisfied.

Product gross profit and margin. Product gross profit for the year ended December 31, 2008 was \$19,866,271, or 60% of product revenue, compared with \$15,024,111, or 56% of product revenue, for the year ended December 31, 2007. The improvement in product gross margin was primarily related to a more favorable product mix in 2008 than 2007.

Research and development. Research and development expenses for the year ended December 31, 2008 increased by \$3,034,429, or 70%, to \$7,399,049 from \$4,364,620 for the prior year. The increase in research and development expenses during 2008 related to our U.S.-based clinical trials for MONOVISC, and post-approval clinical studies for MONOVISC and ORTHOVISC mini in Europe, manufacturing scale-up and related activities for MONOVISC and AESTHETICS, the development of our next generation osteoarthritis product, CINGAL, and additional personnel.

Selling, general and administrative. Selling, general and administrative expenses for the year ended December 31, 2008 increased by \$2,928,712 or 37%, to \$10,965,493 from \$7,996,781 in 2007. The increase was primarily the result of duplicate expense related to the Company's new manufacturing facility and existing manufacturing facility, as well as marketing expenses associated with the launch of our new products, increased personnel costs, and higher legal and consulting costs related to corporate governance, trademark matters, shareholder rights plan, and strategic programs.

Interest income, net. Net interest income was \$498,512 for the year ended December 31, 2008, a decrease of \$1,602,151, or 76%, compared to \$2,100,663 in 2007. The decrease in net interest income was primarily attributable to lower interest rates as a result of Federal Reserve Bank reductions, movement to conservative U.S. treasury securities in mid-2007, and lower available cash and invested balances in 2008 compared to 2007.

Income taxes. Income tax provision was \$1,096,046 and \$2,652,840 for 2008 and 2007, respectively. The reduction in effective tax rate in 2008 and difference from the U.S. federal statutory rate is primarily due to a favorable impact of a state investment tax credit as a result of the new facility project, and increases in state and federal research and development credits. These favorable factors were partially offset by an increase in provision due to a State of Massachusetts law change to gradually reduce future corporate income tax rates.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	Year Ended December 31,					
	2008		2007		2006	
Computed expected tax expense	34.0	%	34.0	%	34.0	%
State tax expense (net of federal benefit)	4.6	%	4.2	%	3.8	%
State deferred tax assets rate change	2.6	%	—		—	

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

Permanent items, including nondeductible expenses	0.6	%	(1.1	)%	1.8	%
State investment tax credit	(11.1	)%	(3.9	)%	—	
Federal and state research and development credits	(5.8	)%	(2.4	)%	(1.6	)%
Other	(1.7	)%	(0.3	)%	0.8	%
Tax expense	23.2	%	30.5	%	38.8	%

38

---

## Liquidity and Capital Resources

We require cash to fund our operating expenses and to make capital expenditures. We expect that our requirements for cash to fund these uses will increase as the scope of our operations expand, particularly as a result of our acquisition of FAB. Historically we have funded our cash requirements from available cash and investments on hand. In 2008, we financed a portion of our long-term facility project with long-term debt of \$16 million. On December 30, 2009, we utilized \$17,055,000 of cash to acquire 100% of the equity of Fidia Advanced Biopolymers S.r.l. (see Management Overview above), thereby significantly reducing our cash balance. We believe that our existing cash and cash equivalents and future cash provided by operating activities will be sufficient to meet our working capital and capital expenditure needs over the next 12 months.

At December 31, 2009, cash, cash equivalents and short-term investments totaled \$24,426,990 compared to \$43,193,655 at December 31, 2008.

Cash provided by operating activities was \$3,094,705, \$3,407,231 and \$4,492,642 for 2009, 2008, and 2007 respectively. Cash provided by operating activities decreased by \$312,526 in 2009 from 2008. This decrease in operating cash was primarily due to a \$1,597,330 net decrease in assets and liabilities, offset by an increase in non-cash expenses of \$1,226,432, and an increase in net income of \$58,372.

Cash used in investing activities was \$20,217,869, \$12,804,552 and \$18,282,467 in 2009, 2008 and 2007 respectively. Cash used for investing activities in 2009 was primarily due to the acquisition of FAB, as well as additional capital expenditures related to the buildout of our new facility. Cash used in investing activities in 2008 was primarily the result of an increase in capital expenditures related to the buildout of our new facility. We expect the new facility capital project to cost approximately \$34 million in total (including interior construction, equipment, furniture and fixtures). Through December 31, 2009, approximately \$33 million has been spent in connection with the buildout. Buildout at the new facility commenced in May 2007 and validation of the facility is expected to be completed in 2010. There can also be no assurance that we will be successful in qualifying the new facility under the FDA and European Union regulations.

Cash used in financing activities was \$1,643,501 for 2009, compared to cash provided by financing activities of \$16,687,407 and \$2,525,962 for 2008, and 2007 respectively. Cash used in financing activities in 2009 was primarily due to our principal payments on long-term debt in the amount of \$1.6 million. On January 31, 2008, the Company entered into an unsecured credit facility and during 2008 borrowed \$16 million to finance its new facility project. The credit facility was converted to a 7 year term loan on December 31, 2008. Also reflected in the cash provided by financing activities were proceeds from the exercise of stock options, including any associated tax benefits, as well as debt issuance costs related to our loan amendment with Bank of America.

## Off Balance Sheet Arrangements

We do not use special purpose entities or other off-balance sheet financing techniques except for operating leases as disclosed in the contractual obligations table below that we believe have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity or capital resources.

## Recent Accounting Pronouncements

During 2009, we adopted the following new accounting pronouncements:

Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (Formerly EITF No. 07-1 Accounting for Collaborative Arrangements). ASC 808 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. ASC 808 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogous authoritative accounting literature, or a reasonable, rational, and consistently applied accounting policy election. Further, ASC 808 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to ASC 605 (Formerly EITF No. 01-9). ASC 808 was applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. Adoption of ASC 808 did not impact our financial statements for the year ended December 31, 2009.

Accounting Standards Codification 260-10, Earnings Per Share (ASC 260), (Formerly FSP EITF 03-6-1 Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities). The standard clarifies that share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments are included in the calculation of basic earnings per share. ASC 260 is effective for the Company in 2009. The adoption of ASC 260-10 did not have a material impact on the Company's earnings per share calculations.



Accounting Standards Codification 805, Business Combinations (ASC 805), (Formerly SFAS No. 141(R), Business Combinations, which revised SFAS No. 141, Business Combinations). The standard retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred.

Accounting Standards Codification 350, Intangibles – Goodwill and Other (ASC 350), (Formerly FSP No.142-3, Determination of the Useful Life of Intangible Assets), amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under former SFAS No. 142, Goodwill and Other Intangible Assets. The intent of this standard is to improve the consistency between the useful life of a recognized intangible asset under former SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under ASC 805, Business Combinations, and other U.S. generally accepted accounting principles. The adoption of this pronouncement did not impact our financial statements in years ended December 31, 2009 and 2008.

On June 3, 2009, the FASB approved the FASB Accounting Standards Codification, (the "Codification"), as the single source of authoritative nongovernmental Generally Accepted Accounting Principles, or GAAP, in the United States. The Codification is effective for interim and annual periods ending after September 15, 2009. Upon the effective date, the Codification will be the single source of authoritative accounting principles to be applied by all nongovernmental U.S. entities. All other accounting literature not included in the Codification will be nonauthoritative. The Codification does not change or alter existing GAAP and there was no impact on our consolidated financial position or results of operations.

Effective during the third quarter of 2009, we implemented Accounting Standards Codification 855, Subsequent Events (ASC 855), (Formerly SFAS No. 165, Subsequent Events). This standard establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of ASC 855 did not impact our financial position or results of operations. We evaluated all events or transactions that occurred through March 16, 2010, the date we issued these financial statements. During this period we did not have any material recognizable subsequent events.

Effective during the third quarter of 2009, the Company also implemented Accounting Standards Codification 825, Financial Instruments (ASC 825), (Formerly FSP 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments). The adoption of this standard has resulted in the disclosure of the fair value of the Company's long term debt instrument on a quarterly basis. Since ASC 825 addresses disclosure requirements, the adoption of this ASC did not impact our financial position or results of operations. The carrying value of our debt instrument was \$14,400,000 at December 31, 2009. The estimated fair value of our debt instrument was approximately \$13,800,000 at December 31, 2009 using market observable inputs and interest rate measurements.

In August 2009, the FASB issued Accounting Standards Update 2009-05, Fair Value Measurements and Disclosures (Topic 820). The purpose of this Update is to clarify that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses either the quoted price of the identical liability when traded as an asset or quoted prices for similar liabilities or similar liabilities when traded as assets or another valuation technique that is consistent with the principles of Topic 820. This guidance is effective upon issuance. There was no material impact to the Company from the adoption of this update.

In October 2009, the FASB issued Accounting Standards Update 2009-13, Revenue Recognition (Topic 605). The purpose of this Update is to provide updated guidance (1) on whether multiple deliverables exist, how the deliverables

in a revenue arrangement should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Anika means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The Company is currently evaluating the impact this guidance will have, if any, on our financial statements, but does not anticipate that this updated guidance will have a material impact on our financial statements.

### Contractual Obligations and Other Commercial Commitments

To-date, we have limited commitments for purchases of inventories. We have incurred significant capital investments related to the buildout of our new facility in Bedford, Massachusetts, as well as the FAB acquisition. Our future capital requirements and the adequacy of available funds will depend, on numerous factors, including:

- market acceptance of our existing and future products;
- the success and sales of our products under current and future distribution agreements;
- the successful commercialization of products in development;
- progress in our product development efforts;
- the magnitude and scope of such efforts;
- any potential acquisitions of products, technologies or businesses;
- progress with pre-clinical studies, clinical trials and product clearances by the FDA and other agencies;
- the cost of maintaining adequate manufacturing capabilities;
- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- 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;
- the cost of maintaining adequate inventory levels to meet current and future product demands;
- the contractual obligation to make principal and interest debt payments;
- our success with respect to our recently announced plan to utilize a direct sales force; and
- the successful integration of our subsidiary FAB.

We cannot assure you that we will record profits in future periods. To the extent that 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, or through other sources. 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. However, we believe that our existing cash and cash equivalents and future cash provided by operating activities will be sufficient to meet our working capital and capital expenditure needs over the next 12 months. See Item 1A. "Risk Factors."

The terms of any future equity financings may be dilutive to our stockholders and the terms of any debt financings may contain restrictive covenants, which could 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 may be made available to us or may be available on acceptable terms should such a need arise.

The table below summarizes our non-cancelable operating leases and contractual obligations at December 31, 2009:

	Total	Payments due by period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Leases(1)	\$ 11,769,422	\$ 1,744,690	\$ 2,988,342	\$ 3,113,403	\$ 3,922,987
New Facility Build-out	1,337,442	1,337,442	—	—	—
Clinical Trials	2,235,762	2,235,762	—	—	—
Purchase Commitments	2,971,184	2,971,184	—	—	—
Long Term Debt(2)	15,284,499	1,807,587	3,542,969	3,446,697	6,487,246
Total	\$ 33,598,309	\$ 10,096,665	\$ 6,531,311	\$ 6,560,100	\$ 10,410,233

(1) Included in this line is a lease we entered into on January 4, 2007, pursuant to which we lease a corporate 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 May 1, 2007. 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. The lease covering the Company's existing manufacturing facility located in Woburn, Massachusetts is also included in the table above. Our administrative, research and development personnel began occupying the Bedford facility in November of 2007, and the buildout and validation for the new manufacturing space is expected to be completed in 2010. Also included in the table above is the lease entered into in Italy related to FAB. The lease commenced on December 30, 2009 and is for the next 6 years.

(2) On January 31, 2008, the Company entered into an unsecured Credit Agreement (the "Agreement") with Bank of America. Pursuant to the terms of the Agreement, our lender has agreed to provide the Company with an unsecured revolving credit facility through December 31, 2008 of up to a maximum principal amount at any time outstanding of \$16,000,000. The Company borrowed the maximum amount as of December 31, 2008. On December 31, 2008, all outstanding revolving credit loans were converted into a term loan with quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. In connection with the acquisition of FAB, the Company entered into a Consent and First Amendment to our original loan with Bank of America. As part of this amendment, the interest rate for Eurodollar based loans was increased and is payable at a rate based upon (at the Company's election) either Bank of America's prime rate or LIBOR plus 125 basis points. This increased from the original loan amount of prime rate or LIBOR plus 75 basis points. In addition, the Company has pledged to the lender sixty-five percent (65%) of the stock of FAB. The Agreement contains customary representations and warranties of the Company, affirmative and negative covenants regarding the Company's operations, financial covenants regarding the maintenance by the Company of a specified quick ratio and consolidated fixed charge coverage ratio, and events of default. The table includes expected principal and interest payments. For the purpose of this calculation, interest payments are based on the carrying rate of the debt at December 31, 2009, throughout the life of the obligation.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2009, we did not utilize any derivative financial instruments, market risk sensitive instruments or other financial and commodity instruments for which fair value disclosure would be required under Accounting Standards Codification 825, Financial Instruments (ASC 825), (Formerly SFAS No. 107). Our investments consist of money market funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by

U.S. Treasury obligations, and municipal bonds that are carried on our books at amortized cost, which approximates fair market value.

#### Primary Market Risk Exposures

Our primary market risk exposures are in the areas of interest rate risk and currency rate risk. We have two supplier contracts denominated in foreign currencies. Unfavorable fluctuations in exchange rates would have a negative impact on our financial statements. The impact of changes in currency exchange rates for the two contracts on our financial statements was immaterial in 2009. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of December 31, 2009, the Company is subject to interest rate risk on \$14.4 million of variable rate debt. The interest payable on our debt is determined based (at the Company's election) on either an interest rate based on LIBOR plus 1.25% or the lender's prime rate, therefore, is affected by changes in market interest rates. Based on the outstanding debt amount as of December 31, 2009, we would have a decrease (increase) in future annual cash flows of approximately \$137,000 for every 1% increase (decrease) in the interest rate.

A significant portion of FAB revenue and all operating expenses are denominated in Euro's, which leaves the Company vulnerable to foreign exchange risk.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	45
<u>Consolidated Balance Sheets as of December 31, 2009 and 2008</u>	46
<u>Consolidated Statements of Operations for the Years Ended December 31, 2009, 2008 and 2007</u>	47
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2009, 2008 and 2007</u>	48
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2009, 2008 and 2007</u>	49
<u>Notes to Consolidated Financial Statements</u>	50



Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Anika Therapeutics, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Anika Therapeutics, Inc. and its subsidiaries at December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2009 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

As described in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, in 2009 the Company has excluded Fidia Advanced Biopolymers S.r.l. from its assessment of internal control over financial reporting as of December 31, 2009 as it was acquired by the Company in a purchase business combination on December 30, 2009. We have also excluded Fidia Advanced Biopolymers S.r.l. from our audit of internal control over financial reporting. Fidia Advanced Biopolymers S.r.l. is a wholly-owned subsidiary whose total assets (excluding amounts resulting from the purchase price allocation) represent 7% of the consolidated total assets as of December 31,

2009.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 16, 2010

45

---

## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Balance Sheets

	December 31,	
	2009	2008
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$24,426,990	\$43,193,655
Accounts receivable, net of reserves of \$29,261 and \$60,000 at December 31, 2009 and 2008, respectively	11,831,438	5,418,421
Inventories	8,441,079	5,519,754
Current portion of deferred income taxes	2,183,827	1,235,364
Prepaid expenses and other	2,921,283	463,284
Total current assets	49,804,617	55,830,478
Property and equipment, at cost	47,172,403	42,436,827
Less: accumulated depreciation	(11,424,788 )	(10,190,144)
	35,747,615	32,246,683
Long-term deposits and other	413,228	506,787
Intangible assets, net	33,577,451	936,275
Deferred income taxes	3,506,362	6,300,665
Goodwill	7,652,253	—
Total Assets	\$130,701,526	\$95,820,888
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$6,366,944	\$2,375,340
Accrued expenses	5,816,170	2,325,219
Deferred revenue	2,751,467	2,732,293
Current portion of long-term debt	1,600,000	1,600,000
Total current liabilities	16,534,581	9,032,852
Other long-term liabilities	1,818,383	831,051
Long-term deferred revenue	8,099,996	10,800,001
Deferred tax liability	9,305,064	—
Long-term debt	12,800,000	14,400,000
Commitments and contingencies (Notes 11 and 18)		
Stockholders' equity		
Preferred stock, \$.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at December 31, 2009 and 2008	—	—
Common stock, \$.01 par value; 30,000,000 shares authorized, 13,418,772 shares issued and outstanding at December 31, 2009, 30,000,000 shares authorized, 11,377,623 shares issued and outstanding at December 31, 2008	134,188	113,776
Additional paid-in-capital	60,539,768	42,861,229
Retained earnings	21,469,546	17,781,979
Total stockholders' equity	82,143,502	60,756,984
Total Liabilities and Stockholders' Equity	\$130,701,526	\$95,820,888

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



## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Operations

	For the Years Ended December 31,		
	2009	2008	2007
Product revenue	\$37,320,906	\$33,054,787	\$26,905,100
Licensing, milestone and contract revenue	2,814,798	2,725,000	3,924,721
Total revenue	40,135,704	35,779,787	30,829,821
Operating expenses:			
Cost of product revenue	13,670,228	13,188,516	11,880,989
Research & development	8,181,532	7,399,049	4,364,620
Selling, general & administrative	10,545,351	10,965,493	7,996,781
Acquisition-related expenses	2,151,854	—	—
Total operating expenses	34,548,965	31,553,058	24,242,390
Income from operations	5,586,739	4,226,729	6,587,431
Interest income (expense), net	(74,480 )	498,512	2,100,663
Income before income taxes	5,512,259	4,725,241	8,688,094
Provision for income taxes	1,824,692	1,096,046	2,652,840
Net income	\$3,687,567	\$3,629,195	\$6,035,254
Basic net income per share:			
Net income	\$0.32	\$0.32	\$0.55
Basic weighted average common shares outstanding	11,386,989	11,308,124	11,059,582
Diluted net income per share:			
Net income	\$0.32	\$0.32	\$0.53
Diluted weighted average common shares outstanding	11,562,304	11,460,801	11,453,600

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

## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Stockholders' Equity

	Common Stock				Total
	Number of Shares	\$.01 Par Value	Additional Paid-in Capital	Retained Earnings	Stockholders' Equity
Balance, December 31, 2006	10,772,654	\$ 107,727	\$ 37,262,768	\$ 8,117,530	\$ 45,488,025
Issuance of common stock for employee equity awards	450,619	4,506	1,878,105	—	1,882,611
Tax benefit related to stock based compensation	—	—	643,351	—	643,351
Stock based compensation expense	—	—	911,716	—	911,716
Net income	—	—	—	6,035,254	6,035,254
Balance, December 31, 2007	11,223,273	112,233	40,695,940	14,152,784	54,960,957
Issuance of common stock for employee equity awards	154,350	1,543	515,439	—	516,982
Tax benefit related to stock based compensation	—	—	258,146	—	258,146
Stock based compensation expense	—	—	1,391,704	—	1,391,704
Net income	—	—	—	3,629,195	3,629,195
Balance, December 31, 2008	11,377,623	113,776	42,861,229	17,781,979	60,756,984
Issuance of common stock for employee equity awards	59,957	600	2,550	—	3,150
Acquisition of Fidia Advanced Biopolymers S.r.l.	1,981,192	19,812	16,800,508	—	16,820,320
Tax shortfall related to stock based compensation	—	—	(82,544 )	—	(82,544 )
Stock based compensation expense	—	—	958,025	—	958,025
Net income	—	—	—	3,687,567	3,687,567
Balance, December 31, 2009	13,418,772	\$ 134,188	\$ 60,539,768	\$ 21,469,546	\$ 82,143,502

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

## Anika Therapeutics, Inc. and Subsidiaries

## Consolidated Statements of Cash Flows

	For the Years Ended December 31,		
	2009	2008	2007
Cash flows from operating activities:			
Net income	\$3,687,567	\$3,629,195	\$6,035,254
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	1,293,468	1,433,012	793,716
Loss on fixed asset disposals	—	—	6,906
Amortization of premium on short-term investment	—	1,974	25,011
Stock-based compensation expense	958,025	1,391,704	911,716
Deferred income taxes	1,735,947	377,045	696,516
Provision for inventory write downs	350,220	138,290	154,931
Tax benefit from exercise of stock options	(27,349 )	(258,146 )	(643,351 )
Changes in operating assets and liabilities, net of effect of acquisition:			
Accounts receivable	(1,697,673 )	377,552	(2,286,465 )
Inventories	(1,871,545 )	(1,267,926 )	850,547
Prepaid expenses and other	(774,764 )	876,576	(973,636 )
Long-term deposits and other	93,559	(73,706 )	(240,031 )
Accounts payable	141,083	(129,662 )	1,133,278
Accrued expenses	1,718,307	(733,070 )	562,370
Deferred revenue	(2,680,831 )	(2,774,485 )	(3,698,032 )
Income taxes payable	—	54,192	830,072
Other long-term liabilities	168,691	364,686	333,840
Net cash provided by operating activities	3,094,705	3,407,231	4,492,642
Cash flows from investing activities:			
Proceeds from maturity of short-term investment	—	3,500,000	—
Purchase of short-term investment	—	—	(3,526,985 )
Purchase of property and equipment, net	(3,962,232 )	(16,246,494)	(13,755,482)
Purchase of intangible	—	—	(1,000,000 )
Payment for the acquisition of FAB, net of cash acquired	(16,255,637)	—	—
Other assets	—	(58,058 )	—
Net cash used in investing activities	(20,217,869)	(12,804,552)	(18,282,467)
Cash flows from financing activities:			
Principal payments on debt	(1,600,000 )	—	—
Proceeds from long-term debt	—	16,000,000	—
Debt issuance costs	(74,000 )	(87,721 )	—
Proceeds from exercise of stock options	3,150	516,982	1,882,611
Tax benefit from exercise of stock options	27,349	258,146	643,351
Net cash provided by (used in) financing activities	(1,643,501 )	16,687,407	2,525,962
Increase (decrease) in cash and cash equivalents	(18,766,665)	7,290,086	(11,263,863)
Cash and cash equivalents at beginning of year	43,193,655	35,903,569	47,167,432
Cash and cash equivalents at end of year	\$24,426,990	\$43,193,655	\$35,903,569
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	\$1,210,000	\$10,000	\$1,813,278
Interest paid	\$208,053	\$191,137	\$—

Supplemental disclosure of non-cash investing and financing activities:

Fair value of common stock issued to acquire FAB	\$ 16,820,320	\$—	\$—
Non-cash activities:			
Fair value of assets of FAB and product lines	\$ 50,539,846	\$—	\$—
Cash paid for FAB and product lines	17,055,000	—	—
Fair value of common stock issued to acquire FAB	16,820,320	—	—
Liabilities assumed of acquired businesses and product lines	\$ 16,664,611	\$—	\$—

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



Anika Therapeutics, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Nature of Business

Anika Therapeutics, Inc. (“Anika,” the “Company,” “we,” “us,” or “our”) 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.

On December 30, 2009, Anika Therapeutics, Inc. entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A., a privately held Italian corporation, pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l. (“FAB”), a privately held Italian corporation, for a purchase price consisting of \$17.1 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.

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

2. Summary of Significant Accounting Policies

Use of Estimates

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

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiaries, Anika Securities, Inc. (a Massachusetts Securities Corporation), and Fidia Advanced Biopolymers S.r.l. All intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

Cash and cash equivalents consists of cash and highly liquid investments with original maturities of 90 days or less. The Company accounts for short-term investments in accordance with Accounting Standards Codification 320, Investments - Debt and Equity Securities (ASC 320), (Formerly SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities). The Company determines the appropriate classification of all short-term investments as held-to-maturity, available-for-sale or trading at the time of purchase and re-evaluates such classifications as of each balance sheet date. At December 31, 2009, cash equivalents consisted of funds primarily invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, which approximates fair market value.

## Fair Value Measurements

Effective January 1, 2009, the Company adopted the authoritative guidance for fair value measurements and the fair value option for financial assets and financial liabilities in accordance with Accounting Standards Codification 820, Fair Value Measurements and Disclosures (ASC 820), (Formerly SFAS No. 157, Fair Value Measurements and Disclosures). ASC 820 establishes a three-level hierarchy which prioritizes the inputs used in measuring fair value. In general, fair value determined by Level 1 inputs utilize quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability. The fair value of our cash equivalents were \$20,212,992 and \$34,197,953 at December 31, 2009 and December 31, 2008, respectively, based on Level 1 inputs. Effective January 1, 2009, the Company adopted the provisions under ASC 820 for valuation of nonfinancial assets and nonfinancial liabilities. The adoption of such provisions did not impact the Company's financial position, results of operations, or cash flows.

Accounting Standards Codification 825, Financial Instruments (ASC 825) requires disclosures about the fair value of financial instruments in interim as well as in annual financial statements. The carrying value of our debt instrument was \$14,400,000 at December 31, 2009. The estimated fair value of our debt instrument was approximately \$13,800,000 at December 31, 2009 using market observable inputs and interest rate measurements.

### Revenue Recognition

The Company's revenue recognition policies are in accordance with the Accounting Standards Codification 605, Revenue Recognition (ASC 605), and Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (Formerly SEC SAB No. 101, Revenue Recognition in Financial Statements, as amended by SEC SAB No. 104, Revenue Recognition, and EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables, and EITF No. 07-1 Accounting for Collaborative Arrangements, which became effective on January 1, 2009).

### Product Revenue

The Company recognizes revenue from the sales of products it manufactures upon confirmation of regulatory compliance and shipment to the customer as long as there is (1) persuasive evidence of an arrangement, (2) delivery has occurred and risk of loss has passed, (3) the sales price is fixed or determinable and (4) collection of the related receivable is reasonably assured. 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 distributor's sales and recognized in the same period our distributor records their sale of the product.

On May 15, 2009, the Company entered into a Distribution Agreement ("the Agreement") with Coapt Systems, Inc. ("Coapt"). The agreement grants Coapt an exclusive, non-transferable right to market HYDRELLE™ in the United States. The Company will receive payments for the supply of HYDRELLE™ to Coapt and royalties on future Coapt net product sales to its customers. Per unit prices are determined based on contractual rates which vary based on volumes levels measured annually. Initial royalty rates include reimbursement for the Company's ongoing research and development expenditures for the Company's aesthetic dermatology product, up to a maximum of \$1,000,000. All royalties will be recognized as product revenue by the Company in the period Coapt makes sales to its customers. The Company concluded that the agreement contains one unit of accounting for revenue recognition purposes.

### Licensing, Milestone and Contract Revenue

Licensing, milestone and contract revenue consist of revenue recognized on initial and milestone payments, as well as contractual amounts received from partners. The Company's business strategy includes entering into collaborative license, development and/or supply agreements with partners for the development and commercialization of the Company's products. 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 Accounting Standards Codification 605-25, Multiple Element Arrangements (ASC 605-25), (Formerly EITF No. 00-21). 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.



On June 30, 2006, the Company entered into a License and Development Agreement with Galderma Pharma S.A., a joint venture between Nestlé and L'Oréal, and a Supply Agreement with Galderma Pharma S.A. and Galderma S.A., an affiliate of Galderma Pharma S.A., for the exclusive worldwide development and commercialization of hyaluronic acid based ELEVESS products used in aesthetic dermatology, formerly referenced as cosmetic tissue augmentation. Galderma Pharma S.A. and Galderma S.A. are hereinafter jointly referred to as Galderma. Under the agreements, the Company was responsible for the development and manufacturing of aesthetic dermatology products, and Galderma was responsible for the commercialization, including distribution and marketing, of aesthetic dermatology products worldwide. The agreements included an upfront payment, milestones upon achievement of predefined regulatory goals, funding of certain ongoing development activities, payments for the supply of aesthetic dermatology products, royalties on sales and sales threshold achievement payments for meeting certain net sales targets. The Company accounted for the agreements in accordance with ASC 605. Under the terms of the agreements, the Company received on June 30, 2006 a non-refundable, upfront payment of \$1,000,000 which the Company was amortizing over a 10 year period. During the third quarter of 2007, the Company received \$3,500,000 in milestone payments under the agreements related to regulatory approvals of ELEVESS in the United States and Europe. In November 2007, the agreements were terminated and the Company reacquired the worldwide rights and control of the future development and marketing of ELEVESS. In connection with the termination, the Company paid Galderma \$4,250,000 for the ELEVESS trade name and an expedited exit from the June 30, 2006 agreements. The ELEVESS trade name was valued at approximately \$1,000,000. See footnotes 2 and 8 for more information on the intangible asset acquired. After consideration of Accounting Standards Codification 605-50, Revenue Recognition – Customer Payments and Incentives (ASC 605-50), (Formerly EITF 01-09 Accounting for Consideration Given by Vendor to a Customer (Including a Reseller of the Vendor's Products)), the termination of the Galderma agreements contributed approximately \$1,200,000 to licensing, milestone and contract revenue for 2007.

#### Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company determines the allowance based on specific identification. The Company reviews its allowance for doubtful accounts at least quarterly. Past due balances over 90 days are reviewed individually for collectibility. Account balances are charged off against the allowance when the Company feels it is probable the receivable will not be recovered.

#### 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.

#### Long Lived Assets

The Company accounts for impairment of long-lived assets in accordance with Accounting Standards Codification 360, Property, Plant and Equipment, (Formerly SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets). ASC 360 establishes a uniform accounting model for long-lived assets to be disposed of. This Statement also requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by comparing the carrying amount of an asset to estimated undiscounted future net cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. As of December 31, 2009, long-lived assets consisted of machinery, equipment, leasehold improvements and intangible assets. The Company's intangible assets consist of its ELEVESS trade name, as well as the Developed

Technology, IPR&D, Goodwill and other items related to the acquisition of FAB. Significant assumptions underlying the recoverability of the intangible assets include: future cash flow, growth projections, product life cycle and useful life assumptions. The ultimate recoverability of the assets is dependent on the Company securing additional distributors, or directly commercializing the product. Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible assets. Refer to Note 19 on the acquisition of FAB.

During the years ended December 31, 2009, 2008, and 2007, the Company did not record impairment losses.

Property and equipment are carried at cost less accumulated depreciation, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Costs of major additions and improvements are capitalized; maintenance and repairs that do not improve or extend the life of the respective assets are charged to operations. On disposal, the related accumulated depreciation or amortization is removed from the accounts and any resulting gain or loss is included in results of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the useful life or the expected term of the respective lease. Machinery and equipment are depreciated from 5 to 10 years, furniture and fixtures from 5 to 7 years and computer software and hardware from 3 to 5 years. Interest costs incurred during the construction of major capital projects are capitalized in accordance with Accounting Standards Codification 835-20, Capitalization of Interest (ASC 835-20), (Formerly SFAS No. 34, Capitalization of Interest Costs). The interest is capitalized until the underlying asset is ready for its intended use, at which point the interest cost is amortized as interest expense over the life of the underlying assets. We capitalize certain direct and incremental costs associated with the validation effort related to FDA approval of our manufacturing facility and equipment for the production of our commercial products. These costs include construction costs, equipment costs, direct labor and materials incurred in preparing the facility and equipment for their intended use. The validation costs are amortized over the life of the related facility and equipment.

#### Research and Development

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

#### Income Taxes

The Company provides for income taxes in accordance with Accounting Standards Codification 740, Income Taxes (ASC 740), (Formerly SFAS No. 109, Accounting for Income Taxes). ASC 740 requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis of assets and liabilities.

Beginning January 1, 2007, the Company began accounting for uncertain income tax positions using a benefit recognition model with a two-step approach, a more-likely-than-not recognition criterion and a measurement attribute that measures the position as the largest amount of tax benefit that is greater than 50% likely of being ultimately realized upon ultimate settlement in accordance with Accounting Standards Codification 740, Income Taxes (ASC 740), (Formerly FIN 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109). If it is not more likely than not that the benefit will be sustained on its technical merits, no benefit will be recorded. Uncertain tax positions that relate only to timing of when an item is included on a tax return are considered to have met the recognition threshold. As a result of adoption of ASC 740 there was no change to the tax reserve for unrecognized tax benefits. As such, there was no change to retained earnings as of January 1, 2007. It is the Company's policy to classify accrued interest and penalties as part of the accrued ASC 740 liability and record the expense in the provision for income taxes.

#### Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of Accounting Standards Codification 718, Compensation – Stock Compensation (ASC 718), (Formerly SFAS 123R, Share-Based Payment), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of ASC 718, share-based

compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant). For awards with a performance condition vesting feature, when achievement of the performance condition is deemed probable, the Company recognizes compensation cost on a graded-vesting basis over the awards' expected vesting periods. The Company assesses probability on a quarterly basis. See Note 12 for additional disclosures.

#### Concentration of Credit Risk and Significant Customers

The Company has no significant off-balance sheet risks related to foreign exchange contracts, option contracts or other foreign hedging arrangements. The Company currently maintains its cash equivalent balance with one major national financial institution. The Company, by policy, routinely assesses the financial strength of its customers. As a result, the Company believes that its accounts receivable credit risk exposure is limited and has not experienced significant write-downs in its accounts receivable balances. As of December 31, 2009, Bausch & Lomb, Johnson and Johnson, Boehringer Ingelheim Vetmedica, Coapt, and Rivex, combined, represented 53% of the Company's accounts receivable balance. As of December 31, 2008, Bausch & Lomb, Johnson and Johnson, Biomeks, Plasmaconcept AG, and Rivex, combined, represented 90% of the Company's accounts receivable balance.



## Reporting Comprehensive Income

Accounting Standards Codification 220, Comprehensive Income (ASC 220), (Formerly SFAS No. 130, Reporting Comprehensive Income), establishes standards for reporting and display of comprehensive income and its components in the financial statements. Comprehensive income is the total of net income and all other non-owner changes in equity including such items as unrealized holding gains/losses on securities, foreign currency translation adjustments and minimum pension liability adjustments. The Company had no such items for the years ended December 31, 2009, 2008, and 2007, and as a result, comprehensive income is the same as reported net income for all periods presented.

## Disclosures About Segments of an Enterprise and Related Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding how to allocate resources and assess performance. The Company's chief operating decision maker is its Chief Executive Officer. Based on the criteria established by Accounting Standards Codification 280, Segment Reporting (ASC 280), (Formerly SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information), the Company has one reportable operating segment, the results of which are disclosed in the accompanying consolidated financial statements. As a result of the acquisition of FAB on December 30, 2009, the Company is currently evaluating its segments.

## Business Combinations

The Company assigns the value of the consideration transferred to acquire a business to the tangible and identifiable intangible assets acquired and liabilities assumed on the basis of their fair values at the date of acquisition. The Company assesses the fair value of assets, including intangible assets such as in-process research and development, using a variety of methods including present-value models. Each asset is measured at fair value from the perspective of a market participant. The establishment of fair value for intangible assets in a stock purchase transaction frequently results in a different treatment for tax return purposes. Under Italian tax law, the tax basis of the assets may not be stepped-up to fair value, and the additional depreciation and amortization expense is not deductible, which creates a deferred tax liability over the amortization period that is recorded on the opening balance sheet.

## In-process Research and Development Assets

In-process research and development assets acquired in a business combination are recorded as of the acquisition date at fair value and accounted for as indefinite-lived intangible assets. These assets are maintained on the Company's consolidated balance sheet until either the project underlying them is completed or the assets become impaired. If a project is completed, the carrying value of the related intangible asset is amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset is written down to its fair value and an impairment charge is taken in the period in which the impairment occurs. In-process research and development assets are tested for impairment on an annual basis, or earlier, if impairment indicators are present.

The method used to estimate the fair values of in-process research and development assets incorporates significant assumptions regarding the estimates market participants would make in order to evaluate an asset. These include assumptions regarding the probability of completing development projects, obtaining regulatory approval for marketing, estimates regarding the timing of and the expected costs to complete, and estimates of future cash flows from potential product sales.

## Goodwill

The difference between the purchase price and the fair value of assets acquired and liabilities assumed in a business combination is allocated to goodwill. Goodwill is evaluated for impairment on an annual basis, or earlier if impairment indicators are present.

## Foreign Currency Translation

The functional currency of the Company's foreign subsidiary is the euro. Assets and liabilities of the foreign subsidiary are translated into U.S. dollars at rates of exchange in effect at the end of the year. Revenue and expense amounts are translated using the average exchange rates for the period. Net unrealized gains and losses resulting from foreign currency translation are included in other comprehensive income (loss), which is a separate component of stockholders' equity. As a result of FAB being acquired on December 30, 2009, the foreign currency effect is immaterial for the year ended December 31, 2009. All assets and liabilities of the Company's foreign subsidiary are translated at year-end exchange rates.

## Recent Accounting Pronouncements

During 2009, we adopted the following new accounting pronouncements:

Accounting Standards Codification 808, Collaborative Arrangements (ASC 808), (Formerly EITF No. 07-1 Accounting for Collaborative Arrangements). ASC 808 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. ASC 808 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogous authoritative accounting literature, or a reasonable, rational, and consistently applied accounting policy election. Further, ASC 808 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to ASC 605 (Formerly EITF No. 01-9). ASC 808 was applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. Adoption of ASC 808 did not impact our financial statements for the year ended December 31, 2009.

Accounting Standards Codification 260-10, Earnings Per Share (ASC 260), (Formerly FSP EITF 03-6-1 Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities) clarifies that share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments are included in the calculation of basic earnings per share. ASC 260 is effective for the Company in 2009. The adoption of ASC 260-10 did not have a material impact on the Company's earnings per share calculations.

Accounting Standards Codification 805, Business Combinations (ASC 805), (Formerly SFAS No. 141(R), Business Combinations, which revised SFAS No. 141, Business Combinations) retains the purchase method of accounting for acquisitions, but requires a number of changes, including changes in the way assets and liabilities are recognized in the purchase accounting. It also changes the recognition of assets acquired and liabilities assumed arising from contingencies, requires the capitalization of in-process research and development at fair value, and requires the expensing of acquisition-related costs as incurred. The adoption of this was taken into account during the purchase accounting related to the acquisition of FAB during 2009. Please refer to Note 19 for further discussion.

Accounting Standards Codification 350, Intangibles – Goodwill and Other (ASC 350), (Formerly FSP No. 142-3, Determination of the Useful Life of Intangible Assets), amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under former SFAS No. 142, Goodwill and Other Intangible Assets. The intent of this standard is to improve the consistency between the useful life of a recognized intangible asset under former SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under ASC 805, Business Combinations, and other U.S. generally accepted accounting principles. The adoption did not have a material impact on our financial statements.

On June 3, 2009, the Financial Accounting Standards Board (FASB) approved the FASB Accounting Standards Codification, or the Codification, as the single source of authoritative nongovernmental Generally Accepted Accounting Principles, or GAAP, in the United States. The Codification is effective for interim and annual periods ending after September 15, 2009. Upon the effective date, the Codification will be the single source of authoritative accounting principles to be applied by all nongovernmental U.S. entities. All other accounting literature not included in the Codification will be nonauthoritative. The Codification does not change or alter existing GAAP and there was no impact on our consolidated financial position or results of operations.

Effective during the third quarter of 2009, we implemented Accounting Standards Codification 855, Subsequent Events (ASC 855), (Formerly SFAS No. 165, Subsequent Events). This standard establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued. The adoption of ASC 855 did not impact our financial position or results of operations. We evaluated all events or transactions that occurred through March 16, 2010, the date we issued these financial statements. During this period we did not have any material recognizable subsequent events.

In August 2009, the FASB issued Accounting Standards Update 2009-05, Fair Value Measurements and Disclosures (Topic 820). The purpose of this Update is to clarify that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using a valuation technique that uses either the quoted price of the identical liability when traded as an asset or quoted prices for similar liabilities or similar liabilities when traded as assets or another valuation technique that is consistent with the principles of Topic 820. This guidance is effective upon issuance. There was no material impact to the Company from the adoption of this update.

In October 2009, the FASB issued Accounting Standards Update 2009-13, Revenue Recognition (Topic 605). The purpose of this Update is to provide updated guidance (1) on whether multiple deliverables exist, how the deliverables in a revenue arrangement should be separated, and how the consideration should be allocated; (2) requiring an entity to allocate revenue in an arrangement using estimated selling prices of deliverables if a vendor does not have vendor-specific objective evidence or third-party evidence of selling price; and (3) eliminating the use of the residual method and requiring an entity to allocate revenue using the relative selling price method. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, which for Anika means no later than January 1, 2011. Early adoption is permitted; however, adoption of this guidance as of a date other than January 1, 2011, will require us to apply this guidance retrospectively effective as of January 1, 2010 and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The Company is currently evaluating the impact this guidance will have, if any, on our financial statements, but does not anticipate that this updated guidance will have a material impact on our financial statements.

### 3. Net Income per Common Share

The Company reports earnings per share in accordance with Accounting Standards Codification 260, Earnings Per Share (Formerly SFAS No. 128, Earnings per Share), which establishes standards for computing and presenting earnings per share. Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted average number of common shares outstanding and the number of dilutive potential common share equivalents during the period. Under the treasury stock method, unexercised “in-the-money” stock options are assumed to be exercised at the beginning of the period or at issuance, if later. The assumed proceeds are then used to purchase common shares at the average market price during the period.

Effective January 1, 2009, the Company adopted Accounting Standards Codification 260-10, Earnings Per Share (ASC 260-10), (formerly FSP EITF 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities). ASC 260-10 clarifies that share-based payment awards that entitle their holders to receive non-forfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments are included in the calculation of basic and diluted earnings per share. Adoption of this pronouncement is retroactive to prior reporting periods. Basic and diluted earnings per share for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009	2008	2007
Basic earnings per share			
Net income	\$ 3,687,567	\$ 3,629,195	\$ 6,035,254
Income allocated to participating securities	(14,961 )	(21,304 )	(9,685 )
Income available to common stockholders	\$ 3,672,606	\$ 3,607,891	\$ 6,025,569
Basic weighted average common shares outstanding	11,386,989	11,308,124	11,059,582
Basic earnings per share	\$ 0.32	\$ 0.32	\$ 0.54

Diluted earnings per share			
Net income	\$ 3,687,567	\$ 3,629,195	\$ 6,035,254
Income allocated to participating securities	(14,375 )	(21,022 )	(9,353 )
Income available to common stockholders	\$ 3,673,192	\$ 3,608,173	\$ 6,025,901
Weighted average common shares outstanding	11,386,989	11,308,124	11,059,582
Diluted potential common shares	175,315	152,677	394,018
Diluted weighted average common shares and potential common shares	11,562,304	11,460,801	11,453,600
Diluted earnings per share	\$ 0.32	\$ 0.31	\$ 0.53

Options to purchase approximately 924,007, 757,153 and 85,000 shares were outstanding at December 31, 2009, 2008 and 2007, respectively, but not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price during the period. At December 31, 2009, 2008 and 2007, 46,965, 83,395 and 17,225 shares of issued and outstanding unvested restricted stock were excluded from the basic earnings per share calculation in accordance with ASC 260.

#### 4. Short-term Investment

In February 2007, the Company purchased a tax exempt municipal bond with a par value of \$3,500,000 and an interest rate of 4.25%, which matured on February 1, 2008 for a cost of \$3,526,985. The Company classifies its investments in debt and equity securities into held-to-maturity, available-for-sale or trading categories in accordance with the provisions Accounting Standards Codification 320, Investments – Debt and Equity Securities (ASC 320), (Formerly SFAS No. 115, Accounting For Certain Investments in Debt and Equity Securities). The tax exempt municipal bond was classified as held-to-maturity in 2007 because the Company intended, and held the security to maturity. Held-to-maturity securities are stated at amortized cost.

## 5. Allowance for Doubtful Accounts

A summary of the allowance for doubtful account activity is as follows:

	2009	December 31, 2008	2007
Balance, beginning of the year	\$60,000	\$60,000	\$49,724
Amounts provided	62,745	—	10,276
Amounts written off	(93,484 )	—	—
Balance, end of the year	\$29,261	\$60,000	\$60,000

## 6. Inventories

Inventories consist of the following:

	December 31, 2009	2008
Raw materials	\$2,535,496	\$2,556,588
Work-in-process	3,188,241	2,354,736
Finished goods	2,717,342	608,430
Total	\$8,441,079	\$5,519,754

The above amounts include \$232,484 of raw materials and \$1,167,516 of finished goods from the FAB acquisition.

## 7. Property &amp; Equipment

Property and equipment is stated at cost and consists of the following:

	December 31, 2009	2008
Machinery and equipment	\$9,859,867	\$8,674,679
Furniture and fixtures	608,361	579,824
Leasehold improvements	12,117,091	11,552,091
Construction in progress	24,587,084	21,630,233
	47,172,403	42,436,827
Less accumulated depreciation	(11,424,788)	(10,190,144)
Total	\$35,747,615	\$32,246,683

Depreciation expense was \$1,234,644, \$1,374,189 and \$788,814 for the years ended December 31, 2009, 2008 and 2007, respectively. The above amounts include \$1,109,000 of machinery and equipment, \$17,000 of furniture and fixtures, and \$565,000 of leasehold improvements from the FAB acquisition.

## 8. Intangible Assets

In November 2007, in connection with the termination of the Galderma agreements, the Company purchased an intangible asset related to the ELEVESS trade name, which is being amortized over its estimated useful life of seventeen years. The Company periodically reviews its long-lived assets for impairment. The Company initiates a review for impairment whenever 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 the assets are no longer appropriate, such as a significant reduction in cash flows associated with the assets. Each impairment test will be based on a comparison of the undiscounted cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value.



As of December 31, 2009, amortization expense on the intangible asset for the next five years is expected to be \$58,824 annually. Amortization expenses were \$58,824, \$58,823 and \$4,902 for the years ended December 31, 2009, 2008 and 2007, respectively. The ELEVESS intangible asset is at stated cost and consists of the following:

	December 31,	
	2009	2008
ELEVESS trade name	\$1,000,000	\$1,000,000
Accumulated amortization	(122,549 )	(63,725 )
Total	\$877,451	\$936,275

On December 30, 2009, in connection with the acquisition of FAB, the Company purchased various intangible assets. The Company is currently finalizing the purchase price allocation, and evaluating the useful lives and amortization methods related to these intangibles. The in-process research and development intangible assets initially have indefinite lives and will be reviewed periodically to assess the project status, valuation and disposition including write-off for abandoned projects. Until such determination, they are not amortized. See Note 2 "Summary of Significant Accounting Policies" for further details on the treatment of in-process research and development. Intangible assets related to FAB are at stated cost and consist of the following:

	December 31, 2009
Developed Technology.	\$ 15,700,000
In-Process Research & Development	11,300,000
Distributor Relationships	4,700,000
Patents	1,000,000
Accumulated amortization	—
Total	\$ 32,700,000

#### 9. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2009	2008
Payroll and benefits	\$2,137,067	\$1,380,901
Professional fees	1,470,007	332,570
Clinical trial costs	129,509	285,500
Advanced payments received and due to participants under FAB research grants	1,625,044	—
Other	454,543	326,248
Total	\$5,816,170	\$2,325,219

#### 10. Deferred Revenue

In December 2003, the Company entered into a ten-year licensing and supply agreement (the "JNJ Agreement") with Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies, to market ORTHOVISC in the U.S. In mid-2005, the agreement was assigned to DePuy Mitek, Inc., a subsidiary of Johnson & Johnson. Under the JNJ Agreement, DePuy Mitek performs sales, marketing and distribution functions and licensed the right to further develop and commercialize ORTHOVISC as well as other new products for the treatment of pain associated with osteoarthritis based on the Company's viscosupplementation technology. In support of the license, the JNJ Agreement

provides that DePuy Mitek will fund post-marketing clinical trials for new indications of ORTHOVISC. The Company received an initial payment of \$2,000,000 upon entering into the JNJ Agreement, a milestone payment of \$20,000,000 in February 2004, as a result of obtaining FDA approval of ORTHOVISC and a milestone payment of \$5,000,000 in December 2004 for planned upgrades to our manufacturing operations. The Company evaluated the terms of the JNJ Agreement and determined that the upfront fee and milestone payments did not meet the conditions to be recognized separately from the supply agreement, therefore, the Company has deferred non-refundable payments received of \$27,000,000 which we are recognizing ratably over the expected ten year term of the JNJ Agreement. Current and long-term deferred revenue related to the JNJ Agreement were \$10,799,996 and \$13,500,000 at December 31, 2009 and 2008, respectively.

## 11. Commitments and Contingencies

The Company's corporate headquarters is located in Bedford, Massachusetts, where the Company leases approximately 134,000 square feet of administrative and research and development space. This lease was entered into on January 4, 2007, and the lease commenced on May 1, 2007 for an initial term of ten and a half years. The Company has 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. The Company's administrative, research and development personnel moved into the Bedford facility in November of 2007, and the buildout and validation for the manufacturing space will be completed during 2010. The Company's 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, for our manufacturing facility and warehouse. The Woburn manufacturing lease is scheduled to end on May 31, 2010. 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. Rental expense in connection with the various facility leases totaled \$1,651,713, \$1,486,472 and \$1,319,160, for the years ended December 31, 2009, 2008, and 2007, respectively. The Company's future lease commitments as of December 31, 2009 are as follows:

2010	\$1,744,690
2011	1,473,063
2012	1,515,278
2013	1,556,702
2014 and thereafter	5,479,689
	\$11,769,422

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

## 12. Stock Option Plan

Effective January 1, 2006, the Company adopted the provisions of Accounting Standards Codification 718, Compensation – Stock Compensation (ASC 718), (Formerly SFAS 123R, Share-Based Payment), which established accounting for equity instruments exchanged for employee services. The Company estimates the fair value of stock options and stock appreciation rights using the Black-Scholes valuation model. Fair value of restricted stock is measured by the grant-date price of the Company's shares. Key input assumptions used to estimate the fair value of stock options and stock appreciation rights include the exercise price of the award, the expected award term, the expected volatility of the Company's stock over the option's expected term, the risk-free interest rate over the award's expected term, and the Company's expected annual dividend yield. The Company uses historical data on exercise of stock options and other factors to estimate the expected term of share-based awards. The Company also evaluates forfeitures periodically and adjusts accordingly. The expected volatility assumption is based on the unadjusted

historical volatility of the Company's common stock. The risk-free interest rate assumption is based on U.S. Treasury interest rates at the time of grant. The fair value of each stock option and stock appreciation rights award during 2009, 2008 and 2007 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Twelve Months Ended					
	December 31, 2009		December 31, 2008		December 31, 2007	
Risk-free interest rate	1.54% - 1.89	%	1.44% - 2.82	%	3.11% - 4.80	%
Expected volatility	59.35% - 61.03	%	58.15% - 63.37	%	56.67% - 64.11	%
Expected lives (years)	4		4 - 5		4	
Expected dividend yield	0.00	%	0.00	%	0.00	%

The Company recorded \$958,025, \$1,391,704 and \$911,716 of share-based compensation expense for the years ended December 31, 2009, 2008 and 2007, respectively, for stock options, stock appreciation rights and restricted stock awards. The Company presents the expenses related to stock-based compensation awards in the same expense line items as cash compensation paid to the same employees. Equity awards were granted under the 2003 Stock Option and Incentive Plan approved by the Board of Directors on April 4, 2003.

On April 4, 2003 the Board of Directors approved the 2003 Anika Therapeutics, Inc. Stock Option and Incentive Plan (the “2003 Plan”). The Company initially reserved 1,500,000 shares of common stock for grant of equity-based awards to employees, directors, consultants and advisors under the 2003 Plan, which was approved by stockholders on June 4, 2003. On May 29, 2009, the Board of Directors approved changes to the 2003 Plan and adopted the Amended and Restated 2003 Stock Option and Incentive Plan (the “Amended 2003 Plan”), to increase the number of shares available to grant by 850,000. The Amended 2003 Plan was approved by the Company’s shareholders on June 5, 2009, and resulted in a total of 2,350,000 shares of common stock being reserved for issuance under the Amended 2003 Plan. The Company issues new shares from its authorized common stock upon share option exercises or satisfaction of vesting requirements for other equity-based awards. Stock-based awards are granted with an exercise price equal to the market price of the Company’s stock on the date of grant. Awards contain service or performance conditions and generally vest annually over 3-or-4 year terms. Awards have 10-year contractual terms. As of December 31, 2009, there were 307,118 shares still outstanding under the Company’s original 1993 Stock Option Plan included in the total outstanding options of 1,372,933. There are 887,840 options available for future grant at December 31, 2009.

Combined stock options and stock appreciation rights activity under the three plans is summarized as follows for the years end December 31, 2009, 2008, and 2007:

	2009		2008		2007	
	Number of Shares	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share	Number of Shares	Weighted Average Exercise Price per Share
Outstanding at beginning of year	1,094,683	\$9.00	1,093,479	\$7.93	1,547,412	\$6.39
Granted	365,000	\$4.33	179,130	\$10.50	115,000	\$19.22
Cancelled	(76,750 )	\$20.93	(29,126 )	\$6.43	(134,714 )	\$10.83
Expired	(7,000 )	\$4.80	—	—	(3,295 )	\$12.06
Exercised	(3,000 )	\$1.05	(148,800 )	\$3.47	(430,924 )	\$4.48
Outstanding at end of year	1,372,933	\$7.13	1,094,683	\$9.00	1,093,479	\$7.93
Options exercisable at end of year	824,598	\$7.46	713,453	\$7.06	772,154	\$5.43
Weighted average fair value of options granted at fair value		\$2.03		\$5.22		\$9.31

The restricted stock activity for the years ended December 31, 2009, 2008 and 2007 are as follows:

	2009		2008		2007	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at beginning of year	83,395	\$10.71	17,225	\$11.82	23,900	\$11.80

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

Granted	47,600	\$3.05	77,170	\$10.58	200	\$13.09
Cancelled	(7,082 )	\$9.62	(5,850 )	\$11.39	(1,100 )	\$11.86
Vested	(28,936 )	\$10.74	(5,150 )	\$11.76	(5,775 )	\$11.78
Expired	—	—	—	—	—	—
Nonvested at end of year	94,977	\$6.94	83,395	\$10.71	17,225	\$11.82

The aggregate intrinsic value of stock options and stock appreciation rights fully vested at December 31, 2009, 2008 and 2007 were \$1,646,441, \$482,853 and \$7,042,267, respectively. The aggregate intrinsic value of stock options and stock appreciation rights outstanding at December 31, 2009, 2008 and 2007, were \$2,880,716, \$482,853 and \$7,797,706, respectively. The total intrinsic value of options and stock appreciation rights exercised were \$12,770, \$729,313 and \$4,204,142 for the years ended December 31, 2009, 2008 and 2007, respectively. The total fair value of options and stock appreciation rights vested during the years ended December 31, 2009, 2008, and 2007 were \$812,732, \$727,765, and \$889,256 respectively. The Company received \$3,150, \$516,982 and \$1,882,611 for exercises of stock options during the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009 the weighted average remaining contractual life of the outstanding and vested shares, for options and stock appreciation rights, were 6.01 years and 4.15 years, respectively.

A total of 1,342,887 vested and expected to vest options were outstanding as of December 31, 2009. These vested and expected to vest options had a weighted average exercise price of \$7.16 and an aggregated intrinsic value of \$2,804,119. The weighted average remaining contractual term of vested and expected to vest options as of December 31, 2009 was 5.9 years.

For the year ended December 31, 2009, the weighted average fair value per share for options and stock appreciation rights for shares outstanding and vested were \$3.93 and \$4.38, respectively. As of December 31, 2009, there was approximately \$1,598,890, of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Company's stock plans. That cost is expected to be recognized over a weighted average period of 2.3 years.

### 13. Shareholder Rights Plan

On April 4, 2008 the Board of Directors of the Company adopted a Shareholder Rights Plan that replaced the Company's former Shareholder Rights Plan. Under the Shareholder Rights Plan, the Rights generally become exercisable if: (1) a person becomes an "Acquiring Person" by acquiring 15% or more of the Company's Common Stock, or (2) a person commences a tender offer that would result in that person owning 15% or more of the Company's Common Stock. In the event that a person becomes an "Acquiring Person," each holder of a Right (other than the Acquiring Person) would be entitled to acquire such number of shares of preferred stock which are equivalent to shares of the Company's Common Stock having a value of twice the exercise price of the Right. If, after any such event, the Company enters into a merger or other business combination transaction with another entity, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right. The current exercise price per Right is \$75.00. The Rights may be redeemed in whole, but not in part, at a price of \$0.01 per Right (payable in cash, shares of the Company's Common Stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (1) the time at which any person becomes an "Acquiring Person", or (2) the Expiration Date. At any time after any person becomes an "Acquiring Person", the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of the Company's Common Stock at an exchange ratio specified in the Rights Plan. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to affect such exchange at any time after any person becomes the beneficial owner of 50% or more of the Company's Common Stock.

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

### 14. Employee Benefit Plan

United States based employees are eligible to participate in the Company's 401(k) savings plan. Employees may elect to contribute a percentage of their compensation to the plan, and the Company will make matching contributions up to a limit of 5% of an employee's compensation. In addition, the Company may make annual discretionary contributions. For the years ended December 31, 2009, 2008, and 2007, the Company made matching contributions of \$323,876, \$301,155 and \$241,982 respectively.

## 15. Revenue by Product Group, by Significant Customer and by Geographic Region; Geographic Information

Product revenue by product group is as follows:

	Years Ended December 31,		
	2009	2008	2007
Joint Health	\$22,879,899	\$18,707,669	\$13,602,494
Ophthalmic	10,573,915	10,678,615	10,517,156
Veterinary	2,274,482	3,028,450	2,370,898
Aesthetics	1,471,165	505,273	224,220
Others	121,445	134,780	190,332
	\$37,320,906	\$33,054,787	\$26,905,100

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

	Percent of Product Revenue Years Ended December 31,					
	2009		2008		2007	
Depuy Mitek / Ortho Biotech	45.4	%	40.0	%	37.4	%
Bausch & Lomb Incorporated	26.6	%	29.8	%	35.4	%
Boehringer Ingelheim Vetmedica	6.1	%	9.2	%	8.8	%
Pharmaren AG / Biomeks	4.4	%	5.7	%	6.1	%
	82.5	%	84.7	%	87.7	%

Revenues by geographic location in total and as a percentage of total revenues are as follows:

	Years Ended December 31,					
	2009		2008		2007	
Geographic location:	Revenue	Percent of Revenue	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	\$30,196,213	75.2 %	\$26,789,515	74.9 %	\$22,759,765	73.8 %
Europe	6,536,835	16.3 %	5,667,215	15.8 %	5,462,266	17.7 %
Turkey	1,673,779	4.2 %	1,946,081	5.4 %	1,666,696	5.4 %
Other	1,728,877	4.3 %	1,376,976	3.9 %	941,094	3.1 %
Total	\$40,135,704	100.0 %	\$35,779,787	100.0 %	\$30,829,821	100.0 %

The Company recorded licensing, milestone and contract revenue of \$2,814,798, \$2,725,000 and \$3,924,721 for the year ended December 31, 2009, 2008, and 2007, respectively. Substantially all licensing, milestone and contract revenue was derived in the United States for 2009 and 2008. In 2007, approximately \$1,200,000 of milestone revenue was derived in Europe.

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

	Years Ended December 31,		
	2009	2008	2007
United States	\$34,056,615	\$32,246,683	\$19,369,716



Italy	1,691,000	—	—
	\$35,747,615	\$32,246,683	\$19,369,716

## 16. Income Taxes

Income tax expense was \$1,824,692, \$1,096,046 and \$2,652,840 for the years ended December 31, 2009, 2008, and 2007, respectively. Prepaid taxes of \$870,412, \$112,950, and \$643,351 were included in the prepaid expenses at December 31, 2009, 2008 and 2007. The Company receives a tax deduction upon the exercise of nonqualified stock options and disqualifying dispositions by employees for the difference between the exercise price and the market price of the underlying common stock on the date of exercise. The benefit of the related tax deduction in the amounts of \$258,146 and \$643,351 were not recorded through the tax provision; rather, were recorded as an increase to additional paid in capital in 2008 and 2007, respectively. During 2009, there was a tax shortfall which reduced additional paid in capital of \$82,544. The components of the provision for income taxes are as follows:

	Years Ended December 31,		
	2009	2008	2007
Current:			
Federal	\$(2,908 )	\$765,578	\$1,792,556
State	(18,237 )	(46,577 )	163,768
	(21,145 )	719,001	1,956,324
Deferred:			
Federal	2,010,097	693,732	849,573
State	(164,260 )	(316,687 )	(153,057 )
	1,845,837	377,045	696,516
Tax expense	\$1,824,692	\$1,096,046	\$2,652,840

The Company's effective tax rate varied from the U.S. federal statutory rate due to a state investment tax credit as a result of the new facility project, and state and federal research and development credits, offset by an increase in rate due to certain nondeductible transaction costs associated with the FAB acquisition. In 2008, the Company recorded additional provision of approximately \$121,000 related to the reduction of its deferred tax assets as a result of newly enacted changes to the Commonwealth of Massachusetts to gradually reduce future corporate income tax rates. A reconciliation of the U.S. federal statutory tax rate to the effective tax rate for the periods ending December 31 is as follows:

	Years ended December 31,					
	2009		2008		2007	
Computed expected tax expense	34.0	%	34.0	%	34.0	%
State tax expense (net of federal benefit)	6.2	%	4.6	%	4.2	%
State deferred tax assets rate change	(0.8)	)%	2.6	%	—	
Permanent items, including nondeductible expenses	8.8	%	0.6	%	(1.1)	)%
State investment tax credit	(5.6)	)%	(11.1)	)%	(3.9)	)%
Federal and state research and development credits	(8.4)	)%	(5.8)	)%	(2.4)	)%
Other	(1.1)	)%	(1.7)	)%	(0.3)	)%
Tax expense	33.1	%	23.2	%	30.5	%

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by the enacted tax rates assumed to be in effect when these differences reverse. As of December 31, 2009 and 2008, management determined that it is more likely than not that the deferred tax assets will be realized and, therefore, a valuation allowance has not been recorded. The Company has investment tax credits which will expire in 2017. The approximate income tax effect of each type of temporary difference and carryforward is as follows:

	Years ended December 31,	
	2009	2008
Deferred tax assets:		
Deferred revenue	\$4,161,014	\$5,155,800
Stock-based compensation expense	1,116,599	930,492
Tax credit carryforwards	1,646,935	788,915
Intangibles related to FAB acquisition	1,500,970	—
Accrued expenses and other	640,254	449,632
Depreciation	—	163,565
Inventory reserve	57,519	47,625
Deferred tax asset	\$9,123,291	\$7,536,029

	Years ended December 31,	
	2009	2008
Deferred tax liabilities:		
Intangibles related to FAB acquisition	\$10,806,034	—
Depreciation	1,932,133	—
Deferred tax liability	\$12,738,167	—

The Company adopted the provisions of Accounting Standards Codification 740, Income Taxes (ASC 740), (Formerly FIN 48), on January 1, 2007. As a result of the implementation of ASC 740, the Company recognized no adjustment in the liability for unrecognized income tax benefits. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense, which was immaterial. Total amount of unrecognized tax benefits that would affect our effective tax rate if recognized is \$40,900, \$40,900, and \$203,954 as of December 31, 2009, 2008 and 2007, respectively. During the third quarter of 2008, the Company concluded its audit by the Massachusetts Department of Revenue ("DOR") for its 2004 and 2005 tax returns, which resulted in a reduction to its ASC 740 tax reserves and a related income tax benefit of approximately \$100,000. The Company is in the process of completing an audit by the DOR for the years 2006 and 2007, and the Company does not expect a material change as a result of this audit. Our U.S. federal income tax returns for the years 2006 to 2008 remain subject to examination, and our state income tax return for 2008 remains subject to examination.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Unrecognized tax benefits at January 1, 2007	\$ 228,938
Gross increases for tax provision of prior years	34,211
Gross increases for tax provision of current year	69,206
Settlement	(128,401 )
Lapse of statute of limitations	—
Unrecognized tax benefits at December 31, 2007	\$ 203,954
Gross increases for tax provision of current year	6,249
Change in reserve related to Federal tax benefits	8,443
Settlements	(68,221 )
Lapse of statute of limitations	(109,525 )
Unrecognized tax benefits at December 31, 2008	\$ 40,900
Net Change	—
Unrecognized tax benefits at December 31, 2009	\$ 40,900

#### 17. Long-term Debt

On January 31, 2008, the Company entered into an unsecured Credit Agreement (the “Agreement”) with Bank of America, under which the Company was provided with a revolving credit line through December 31, 2008 of up to a maximum principal amount at any time outstanding of \$16,000,000. The Company borrowed the maximum amount of \$16,000,000 in 2008 to finance its new facility construction and validation capital project. On December 31, 2008, the outstanding revolving credit loans were converted into a term loan with quarterly principal payments of \$400,000 and a final installment of \$5,200,000 due on the maturity date of December 31, 2015. Interest on revolving credit loans and term loans are payable at a rate based upon (at the Company’s election) either Bank of America’s prime rate or LIBOR plus 125 basis points. The Agreement contains customary representations and warranties of the Company, affirmative and negative covenants regarding the Company’s operations, financial covenants regarding the maintenance by the Company of a specified quick ratio and consolidated fixed charge coverage ratio, and events of default. As of December 31, 2009, the Company had an outstanding debt balance of \$14,400,000, at a blended interest rate of 1.50%. The Company recorded approximately \$171,000 as deferred issuance costs, which is being amortized over the life of the long-term debt. For the year ended December 31, 2009, the Company capitalized interest expense of \$98,183 as part of construction in progress related to the Company’s new facility build-out. Interest capitalization was recorded in accordance with ASC 835-20, Capitalization of Interest Costs. The Company began expensing all interest costs incurred beginning after July 1, 2009. Long-term debt principal payments over the next five years are \$1,600,000 per year. The estimated fair value of our debt instrument was approximately \$13,800,000 at December 31, 2009 using market observable inputs and interest rate measurements.

In connection with the acquisition of FAB, the Company entered into a Consent and First Amendment to our original loan with Bank of America. As part of this amendment, the interest rate for Eurodollar based loans was increased and is payable at a rate based upon (at the Company’s election) either Bank of America’s prime rate or LIBOR plus 125 basis points. This increased from the original loan amount of prime rate or LIBOR plus 75 basis points. In addition, the Company has pledged to the lender sixty-five percent (65%) of the stock of FAB. We also incurred \$74,000 of fees from Bank of America which were capitalized in accordance with ASC 470-50, Debt – Modifications and Extinguishments, as the Consent and Amendment represents a debt modification. The fees will be amortized over the remaining life of the loan.

#### 18. Trademark Opposition

On December 12, 2007, Colbar Lifescience Ltd., a subsidiary of Johnson and Johnson, filed an opposition proceeding before the U.S. Patent & Trademark Office's Trademark Trial & Appeal Board ("Trademark Board"), objecting to one of the Company's applications to register the trademark ELEVESS, alleging that the mark is confusingly similar to Colbar's previous mark EVOLENCE. In October 2008, Colbar filed a petition with the Trademark Board requesting cancellation of the Company's second ELEVESS trademark that had been registered in September 2008. Throughout the discussions, the Company had maintained that Colbar's claim and petition are without merit, and has denied all substantive allegations in the notice of opposition. In November 2009, Colbar and Anika settled the matter and the parties signed a stipulation filed with the court, whereby Anika abandoned the US applications and registrations, and Colbar dismissed the opposition/cancellation proceedings. The Trademark Board has approved the stipulation and dismissed the case.

## 19. Acquisition of Fidia Advanced Biopolymers, S.r.l.

On December 30, 2009, Anika entered into a Sale and Purchase Agreement (the “Purchase Agreement”) with Fidia Farmaceutici S.p.A., a privately held Italian corporation pursuant to which the Company acquired 100% of the issued and outstanding stock of Fidia Advanced Biopolymers S.r.l., a privately held Italian corporation (“FAB”) for a purchase price consisting of \$17.1 million in cash and 1,981,192 shares of the Company’s common stock (the “Acquisition”). FAB’s operating results and cash flow changes were immaterial for the one day of post-acquisition activity. The completion of the Acquisition occurred simultaneously with the signing of the Purchase Agreement. FAB has over 20 products currently on the market, all manufactured from hyaluronic acid, the same basic material used by Anika. The acquisition complements Anika’s portfolio of products, broadens its pipeline of potential new products, and advances Anika’s vision to offer orthopedic doctors protective and regenerative products.

The 1,981,192 shares of the Company’s stock issued includes 800,000 shares to be held in escrow for a period of up to two years in order to satisfy any future indemnification claims under the Purchase Agreement. The issued shares are also subject to a one year holding period. The Purchase Agreement was based on an estimated closing balance sheet with a minimum working capital amount to be delivered. The Parties are currently in discussions to finalize the working capital amount, but it is not expected to be materially different than the estimated closing balance sheet.

The transaction will be accounted for under the acquisition method of accounting in accordance with Accounting Standards Codification 805, Business Combinations (“ASC 805”), (formerly Financial Accounting Standards Board Statement No. 141(revised 2007), “Business Combinations”). Under ASC 805, all of the assets acquired and liabilities assumed in the transaction are recognized at their acquisition-date fair values, while transaction costs and restructuring costs associated with the transaction are expensed as incurred. The purchase generated \$7.6 million of goodwill which is not expected to be deductible under Italian tax law.

### Purchase Price

The \$33.9 million purchase price for FAB is based on the acquisition-date fair value of the consideration transferred, which included cash and the issuance of shares of Anika stock, which was calculated based on the closing price of the Company's common stock of \$8.49 per share on December 30, 2009. The acquisition-date fair value of the consideration consisted of the following:

	Fair Value of Consideration
Cash	\$ 17,055,000
Common stock	16,820,320
Total	\$ 33,875,320

### Allocations of Assets and Liabilities

The Company allocated the purchase price for FAB, based on the acquired fair value of the net tangible assets and intangible assets, goodwill and a deferred tax liability. The difference between the aggregate purchase price and the fair value of assets acquired and liabilities assumed, after consideration of deferred taxes, was allocated to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed at the acquisition date:

### Preliminary Purchase Price Allocation

	December 31, 2009
Inventory	1,400,000
Other assets and liabilities, net	(253,869 )
Property and equipment	1,691,000
Intangible assets	32,700,000
Goodwill	7,652,253
Deferred tax liability	(9,305,064 )
Purchase price	\$33,875,320

The intangible assets identified in the purchase price allocation represent primarily developed technology, acquired in-process research and development (“IPR&D”), patents and distributor relationship assets. Under the acquisition method of ASC 805, \$21.4 million of these assets are recorded at their fair value and amortized over their estimated lives. The remaining amount represents IPR&D, which is accounted for as indefinite-lived intangible assets. The Company will periodically evaluate these IPR&D assets. If a project is completed, the carrying value of the related intangible asset would be amortized over the remaining estimated life of the asset beginning in the period in which the project is completed. If a project becomes impaired or is abandoned, the carrying value of the related intangible asset would be written down to its fair value and an impairment charge would be taken in the period in which the impairment occurs. These intangible assets will be tested for impairment on an annual basis, or earlier if impairment indicators are present.

The IPR&D projects primarily revolve around obtaining U.S. approval for several of FAB’s orthopedic products to gain access to this important market. Costs to complete the projects are estimated at \$4 million to \$7 million spread over the next four years, and involve primarily clinical studies and regulatory costs, which are deemed to be of moderate difficulty. IPR&D value was estimated using a multi-period excess earnings approach. The primary risks associated with the projects include generating sufficient data to support efficacy, and thereby gaining regulatory approval. There can be no assurance that the Company will be successful in completing development or obtaining regulatory approval; and if successful, that meaningful sales will occur.

#### Acquisition-related Expenses

In connection with the acquisition of FAB, the Company incurred \$2.2 million in expenses, which are reflected as acquisition-related expenses on the consolidated statements of operations in 2009. These costs include costs to investigate, document, close and complete regulatory compliance requirements.

#### FAB Financial Information

The FAB balance sheet amounts that have been included in the consolidated balance sheet consist of the following:

	December 31, 2009
<b>ASSETS</b>	
Cash and cash equivalents	\$ 799,363
Accounts receivable	4,715,344
Inventories	1,400,000
Prepaid expenses and other	1,581,886
Property and equipment	1,691,000
Intangible assets	32,700,000
Goodwill	7,652,253
Total Assets	\$ 50,539,846
<b>LIABILITIES AND STOCKHOLDERS’ EQUITY</b>	
Accounts Payable	\$ 4,092,596
Accrued expenses	2,448,225



Other long-term liabilities	818,641
Deferred tax liability	9,305,064
Stockholders' equity	33,875,320
Total Liabilities and Stockholders' Equity	\$ 50,539,846

The FAB operating results for 2009 were immaterial as the acquisition occurred on December 30, 2009. The Pro Forma (unaudited) combined Statement of Operations for the years ended December 31, 2009 and 2008 had FAB been included are as follows:

	December 31, 2009 Consolidated (unaudited)	2008 Consolidated (unaudited)
Total revenue	\$ 53,894,000	\$ 50,196,000
Net income (loss)	\$ (910,000 )	(317,000 )
Diluted net income per share:		
Net income	\$ (0.07 )	\$ (0.02 )
Diluted weighted average common shares outstanding	13,532,640	13,442,000

## 20. Related Party

In connection with the acquisition of FAB by Anika on December 30, 2009, Fidia Farmaceutici S.p.A ("Fidia") acquired ownership of 1,981,192 shares of the Company's common stock, or approximately 14.8% of the outstanding shares of the Company as of December 30, 2009, thus becoming a "related party" under the Securities and Exchange Commission regulations. See Note 19 to the consolidated financial statements for further description of the acquisition.

As part of the acquisition, the Company, primarily through FAB, entered into a series of operating agreements with Fidia as follows:

Agreement Type	Description	Term in Years
Lease	Rent of space in Abano Terme, Italy	Six
Finished goods supply	Manufacture and supply of goods	Three
Raw material supply	Hyaluronic acid powder	Five
Services	Finance, administrative, security	One to Six
Accounts Receivable Management	Collection of trade receivables outstanding as of December 30, 2009.	Two
Marketing and Promotion	Promote FAB products in Italy through Fidia sales force	Three

Historically FAB has relied on Fidia, its former parent company, for a several functional activities. In connection with the purchase of FAB, the Company has negotiated a lease for approximately 26,000 square feet of office, laboratory and warehouse space in Abano Terme, Italy, and a finished goods supply agreement. In addition, accounting and purchasing will be performed by Fidia on behalf of FAB during 2010 under a services agreement. Finally, Fidia has agreed to promote FAB's products in Italy through its existing 140 person sales force. At December 31, 2009, FAB had a net payable to Fidia for past products and services of \$2.9 million.

## 21. Quarterly Financial Data (Unaudited)

	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Year 2009				
Product revenue	\$ 9,943,940	\$ 10,087,130	\$8,770,763	\$8,519,073
Total revenue	10,618,940	10,792,764	9,523,676	9,200,324
Cost of product revenue	3,613,028	3,551,374	3,294,160	3,211,666
Gross profit on product revenue	6,330,912	6,535,756	5,476,603	5,307,407
Net income	\$ 697,148	\$ 1,511,925	\$955,774	\$522,720
Per common share information				
Basic net income per share	\$ 0.06	\$ 0.13	\$0.08	\$0.05
Basic common shares outstanding	11,408,790	11,385,679	11,384,949	11,366,545
Diluted net income per share	\$ 0.06	\$ 0.13	\$0.08	\$0.05
Diluted common shares outstanding	11,653,048	11,575,907	11,548,079	11,496,518
	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
Year 2008				
Product revenue	\$ 8,284,557	\$ 8,523,765	\$8,378,936	\$7,867,529
Total revenue	8,965,804	9,205,015	9,060,189	8,548,779
Cost of product revenue	2,822,930	3,504,986	3,644,530	3,216,070
Gross profit on product revenue	5,461,627	5,018,779	4,734,406	4,651,459
Net income	\$ 1,094,505	\$ 1,104,203	\$812,929	\$617,558
Per common share information				
Basic net income per share	\$ 0.10	\$ 0.10	\$0.07	\$0.06
Basic common shares outstanding	11,352,383	11,329,422	11,327,457	11,225,282
Diluted net income per share	\$ 0.10	\$ 0.10	\$0.07	\$0.05
Diluted common shares outstanding	11,456,691	11,485,989	11,516,177	11,612,720

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

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

(b) Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal year 2009 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control—Integrated Framework.

Based on our assessment and those criteria, our management believes that the Company maintained effective internal control over financial reporting as of December 31, 2009.

On December 30, 2009, the Company acquired Fidia Advanced Biopolymers S.r.l (“FAB”). As this acquisition occurred in late 2009, we have excluded FAB from our assessment of internal control over financial reporting as of December 31, 2009. FAB is a wholly-owned subsidiary of the Company whose total assets (excluding amounts resulting from the purchase price allocation) represent 7% of the consolidated financial statement total assets as of December 31, 2009.

The effectiveness of our internal control over financial reporting as of December 31, 2009 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

ITEM 9B. OTHER INFORMATION

None.

### PART III

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2009.

#### ITEM 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2009.

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

The information required under this item and Item 5 of this Annual Report on Form 10-K under the heading "Equity Compensation Plan Information" is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2009.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2009.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2009.

### PART IV

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

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

(1) Financial Statements

Report of Independent Registered Public Accounting Firm	[42]
Consolidated Balance Sheets	[43]
Consolidated Statements of Operations	[44]
Consolidated Statements of Stockholder's Equity	[45]
Consolidated Statements of Cash Flows	[46]
Notes to Consolidated Financial Statements	[47-65]

(2)

Schedules

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

(3)

Exhibits

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

(b) Exhibit No.	Description
(2) Plan of Acquisition, Reorganization, Arrangement, Liquidation or Succession:	
2.1	Sale and Purchase Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A., as Seller, and the Company, as Buyer, incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
(3) Articles of Incorporation and Bylaws:	
3.1	Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
3.2	Certificate of Vote of Directors Establishing a Series of Convertible Preferred Stock, incorporated herein by reference to the Exhibits to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
3.3	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-QSB for the quarterly period ended November 30, 1996 (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997.
3.4	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-QSB for the quarterly period ended June 30, 1998 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 1998.
3.5	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.3 of the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2002.
3.6	Amended and Restated Certificate of Vote of Directors Establishing a Series of Preferred Stock of the Company classifying and designating the Series B Junior Participating Cumulative Preferred Stock, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 2008.
3.7	Amendment to the Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File no. 001-14027), filed with the Securities and Exchange Commission on March 9, 2009.
3.8	Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.6 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2002.



(4) Instruments Defining the Rights of Security Holders

4.1 Shareholder Rights Agreement, dated as of April 7, 2008, between the Company and American Stock Transfer & Trust Company, incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 2008.

(10) Material Contracts

10.1 Commercial Lease, dated March 10, 1995, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.2 Amendment to Lease #1, dated December 11, 1997, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

- 10.3 Lease Extension, dated March 23, 1998, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
- 10.4 Amendment to Lease #2, dated September 27, 1999, between the Company and Cummings Properties Management, Inc., incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
- 10.5 Commercial Lease, dated July 9, 1999, between the Company and Cummings Properties LLC, incorporated herein by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
- 10.6 Stipulation and Agreement of Compromise, Settlement and Release, dated May 25, 2001, in connection with In Re Anika Therapeutics, Inc. Securities Litigation, incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2001.
- 10.7 Amendment to Lease #3, dated November 1, 2001, between the Company and Cummings Properties, LLC, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2001 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2001.
- 10.8 Lease Extension, dated October 8, 2003, between the Company and Cummings Properties, LLC, incorporated herein by reference to Exhibit 10.36 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2003 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2003.
- \*\*10.9 License Agreement, dated as of December 20, 2003, by and between the Company and Ortho Biotech Products, L.P., incorporated herein by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (File no. 001-14027), filed with the Securities and Exchange Commission on March 30, 2004.
- \*\*10.10 Supply Agreement, dated as of December 15, 2004, by and between the Company and Bausch & Lomb Incorporated, incorporated herein by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (File no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2005.
- †10.11 Form of Incentive Stock Option Agreement under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 5, 2004.
- †10.12 Form of Non-Qualified Stock Option Agreement under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 5, 2004.
- †10.13 Form of Stock Appreciation Right Agreement for Employees under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006 (File no. 001-14027), filed with the Securities and Exchange Commission on May 9, 2006.
- †10.14 Form of Stock Appreciation Right Agreement for Non-Employee Directors under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006 (File no. 001-14027), filed with the Securities and Exchange Commission on May 9, 2006.



- 10.15 Lease, dated January 3, 2007, between the Company and Farley White Wiggins, LLC, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 10, 2007.
- 10.16 Credit Agreement, dated January 31, 2008, among the Company, Anika Securities, Inc., Bank of America, N.A., and the other lenders party thereto (the "Credit Agreement"), incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
- †10.17Anika Therapeutic, Inc. Senior Executive Incentive Compensation Plan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
- †10.18Form of Performance Share Award Agreement under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on February 6, 2008.
- †10.19Employment Agreement, dated October 17, 2008, between the Company and Charles H. Sherwood, Ph.D., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 22, 2008.
- †10.20Employment Agreement, dated October 17, 2008, between the Company and Kevin Quinlan, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on October 22, 2008.
- †10.21Form of Restricted Stock Agreement for Employees under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File no. 001-14027), filed with the Securities and Exchange Commission on March 12, 2008.
- †10.22Anika Therapeutics, Inc. Non-Employee Director Compensation Policy, incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 (File no. 001-14027), filed with the Securities and Exchange Commission on March 12, 2008.
- †10.23Form of Restricted Deferred Stock Unit Award Agreement for Non-Employee Directors under the Company's Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 (File no. 001-14027), filed with the Securities and Exchange Commission on March 9, 2009.
- †10.24Letter Agreement, dated April 27, 2009, by and between the Company and Frank J. Luppino, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on May 29, 2009.
- †10.25Amended and Restated 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on June 11, 2009.
- †10.26Employment Agreement, dated September 10, 2009, between the Company and Frank J. Luppino, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
- †10.27Employment Agreement, dated September 10, 2009, between the Company and William J. Mrachek, incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on September 14, 2009.
- 10.28 Registration Rights Agreement, dated December 30, 2009, between the Company and Fidia Farmaceutici S.p.A., incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.



10.29	Lease Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l., incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
10.30	Tolling Agreement, dated December 30, 2009, between Fidia Farmaceutici S.p.A. and Fidia Advanced Biopolymers S.r.l., incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
10.31	Consent and First Amendment to the Credit Agreement, dated December 30, 2009, by and among the Company, Anika Securities, Inc., Bank of America, N.A. and each lender signatory thereto, incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on January 6, 2010.
*10.32	Pledge and Security Agreement, dated March 12, 2010, among the Company, Fidia Advanced Biopolymers S.r.l. and Bank of America, N.A.
(11) Statement Regarding the Computation of Per Share Earnings	
11.1	See Note 3 to the Financial Statements included herewith.
(21) Subsidiaries of the Registrant	
*21.1	List of Subsidiaries of the Registrant.
(23) Consent of Experts	
*23.1	Consent of PricewaterhouseCoopers llp.
(31) Rule 13a-14(a) / 15d-14(a) Certifications	
*31.1	Certification of Charles H. Sherwood, Ph.D. pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
*31.2	Certification of Kevin W. Quinlan pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
(32) Section 1350 Certification	
***32.1	Certification of Charles H. Sherwood, Ph.D. and Kevin W. Quinlan, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

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

\*\*\* Furnished herewith.

† Denotes compensatory plan or arrangement.



## SIGNATURES

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

Date: March 16, 2010	Anika Therapeutics, Inc. By:	/s/ Charles H. Sherwood, Ph.D.
		Charles H. Sherwood, Ph.D. Chief Executive Officer

## SIGNATURES

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

Signature	Title	Date
/s/ Charles H. Sherwood, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2010
Charles H. Sherwood, Ph.D.		
/s/ Kevin W. Quinlan	Chief Financial Officer (Principal Accounting Officer)	March 16, 2010
Kevin W. Quinlan		
/s/ Joseph L. Bower	Director	March 16, 2010
Joseph L. Bower		
/s/ Eugene A. Davidson, Ph.D.	Director	March 16, 2010
Eugene A. Davidson, Ph.D.		
/s/ Raymond J. Land	Director	March 16, 2010
Raymond J. Land		
/s/ John C. Moran	Director	March 16, 2010
John C. Moran		
/s/ Steven E. Wheeler	Director	March 16, 2010
Steven E. Wheeler		