

ANIKA THERAPEUTICS INC  
Form 10-K  
March 09, 2009

Use these links to rapidly review the document

[ANIKA THERAPEUTICS, INC. TABLE OF CONTENTS](#)  
[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)  
[PART III](#)

[Table of Contents](#)

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

---

**FORM 10-K**

(Mark  
One)

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

**For the fiscal year ended December 31, 2008**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 000-21326**

**Anika Therapeutics, Inc.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Massachusetts**

**04-3145961**

*(State or Other Jurisdiction of Incorporation or  
Organization)*

*(IRS Employer Identification No.)*

**32 Wiggins Avenue, Bedford, Massachusetts 01730**

*(Address of Principal Executive Offices) (Zip Code)*

**(781) 457-9000**

*(Registrant's Telephone Number, Including Area Code)*

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

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

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### 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 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 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer <input type="radio"/>	Accelerated filer <input checked="" type="radio"/>	Non-accelerated filer <input type="radio"/>	Smaller reporting company <input type="radio"/>
		(Do not check if a 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, 2008, the last day of the Registrant's most recently completed second fiscal quarter, was \$97,648,741 based on the close price per share of Common Stock of \$8.59 as of such date as reported on the NASDAQ Global Select Market. Shares of our Common Stock held by each executive officer, director and each person or entity known to the registrant to be an affiliate have been excluded in that such persons may be deemed to be affiliates; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. At March 1, 2009, there were issued and outstanding 11,377,623 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, 2008. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

Table of Contents

**ANIKA THERAPEUTICS, INC.**  
**TABLE OF CONTENTS**

		<b>Page</b>
<u>Part I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>3</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>11</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>21</u>
<u>Item 2.</u>	<u>Properties</u>	<u>21</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>22</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	<u>22</u>
<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>	<u>23</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>24</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>26</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>40</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>41</u>
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>66</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>66</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>66</u>
<u>Part III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>67</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>67</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>67</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>67</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>67</u>
<u>Part IV</u>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>67</u>
<u>Signatures</u>		<u>72</u>

---

Table of Contents

**FORM 10-K**  
**ANIKA THERAPEUTICS, INC.**  
**For Fiscal Year Ended December 31, 2008**

*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 revenues, 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;

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, and our ability to remain the exclusive global supplier for AMVISC and AMVISC Plus to Bausch & Lomb;

our expectations regarding ORTHOVISC sales, including intention to increase market share for ORTHOVISC in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals, and commercial launches;

our expectations regarding HYVISC sales;

our ability to license ELEVESS to a new distribution partner on terms favorable to the Company, if at all, or our ability to market ELEVESS on our own;

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

our expectations regarding product gross margin;

our expectations regarding the commencement of our clinical trial for CINGAL;

Table of Contents

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;

our expectations regarding our existing manufacturing facility and the new 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 plans to address the FDA's Warning Letter and Form 483 Notice of Observations; and

our abilities to successfully defend our ELEVESS trademark.

*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.*

Table of Contents

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Anika Therapeutics, Inc. ("Anika," 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. Our currently manufactured and marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans; AMVISC®, AMVISC® Plus, STAARVISC -II, and ShellGel , each an injectable ophthalmic viscoelastic HA product. HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT®, an HA based anti-adhesive for surgical applications. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints is available in Europe. MONOVISC , a single-injection osteoarthritis product based on our proprietary cross-linking technology is available in Europe and Turkey. In the U.S., ORTHOVISC is marketed by DePuy Mitek, Inc. ("DePuy Mitek"), a subsidiary of Johnson & Johnson (collectively, "JNJ"), under the terms of a licensing, distribution, supply and marketing agreement. Outside the U.S., ORTHOVISC has been approved for sale since 1996 and is marketed by distributors in approximately 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. INCERT® is currently marketed in three countries outside of the U.S. ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. Our initial ELEVESS product is approved in the U.S., the European Union ("EU"), Canada and certain countries in South America, and is manufactured by Anika. We are currently seeking new distribution partners for ELEVESS both domestically and internationally. Products in development include next generation joint health related products and ELEVESS line extension products.

In 2008, revenue from the sale of our products contributed 92% of our total revenue. Licensing, milestone and contract revenue contributed 8% of our total revenue in 2008. Revenue from the sale of ophthalmic viscoelastic products was 32% of product revenue. Our joint health products contributed 57% of our product revenue, and HYVISC contributed 9% of our product revenue in 2008.

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

*Osteoarthritis 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 some international markets for the treatment of

Table of Contents

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 for all joints, and is available in Europe and Turkey. 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 38% in 2008 from 2007.

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, and Asia. We will continue to seek to establish long-term 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*."

*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. 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. 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 Cytosol Ophthalmics, Inc.) who currently receive such products from us. See also Item 1A. "*Risk Factors*."

*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.

*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



Table of Contents

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. We commenced INCERT sales during the second quarter of 2006. 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. There are currently no plans at this time to distribute INCERT in the U.S.

Anika co-owns issued U.S. patents covering the use of INCERT for adhesion prevention. See the section captioned "*Patent and Proprietary Rights.*"

*Aesthetic Dermatology Business*

ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA. We received European, Canadian, and United States FDA approvals for our initial commercial product in 2007. In July 2008, we entered into a distributor agreement with Artes Medical, Inc. ("Artes") for distribution of ELEVESS in the U.S. Shipments of commercial product and sample units commenced shortly after the signing of the distribution agreement, with product launch initiated in early August 2008. Our distribution agreement with Artes was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

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**

Our research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. Our development focus includes chemically modified formulations of HA designed for longer residence time in the body. For the years ended December 31, 2008, 2007 and 2006, these expenses were \$7.4 million, \$4.4 million, and \$3.6 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

Products in development include next generation joint health products. Our next generation osteoarthritis products include 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. This product has been branded as MONOVISC. We received *Conformité Européene* (CE) Mark approval for the MONOVISC product in October 2007. We launched MONOVISC in Europe during the second quarter of 2008, following a small clinical study. In the U.S., we filed an investigational device exemption, or an IDE application, with the FDA, and completed patient enrollment for our U.S. clinical trial in December of 2008. 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. We expect to commence a clinical trial and file an application for CE Mark for CINGAL in 2009.

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

Table of Contents

our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We may not be able to obtain regulatory approval for any new applications we develop. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that we will achieve meaningful sales of such products or applications.

**Patent and Proprietary Rights**

Our products and trademarks, including our Company name, product names and logos, are proprietary. We rely on a combination of patent protection, trade secrets and trademark laws, license agreements, 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 2009 and 2023. We co-own 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. We also solely own patents covering composition of matter and certain manufacturing processes. 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.

Table of Contents

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. ELEVESS 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.

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

Table of Contents

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

Table of Contents

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. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter by early 2009. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems. 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. 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;

Table of Contents

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 HA-based products for use in ophthalmic surgery, orthopedics, surgical adhesion prevention, 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, 2008, we had 84 employees. We consider our relations with our employees to be good. None of our employees are represented by labor unions.

**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.

Table of Contents

**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 next generation joint health related products. Monovisc is 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. We are conducting a pivotal trial in the U.S. for a PMA application. 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. We expect to commence a clinical trial and file an application for CE Mark for CINGAL in 2009.

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;

Table of Contents

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.

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



Table of Contents

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. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter by early 2009. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems. 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



Table of Contents

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 seven 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, if completed, will ultimately demonstrate these products to be safe and efficacious. Our current products in clinical trial include 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.

***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,

Table of Contents

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 copy right, 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

Table of Contents

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 for the new manufacturing space is expected to be completed in 2009. 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

Table of Contents

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.

***If we engage in any acquisition as a part our growth strategy, we will incur a variety of costs, and may never realize the anticipated benefits of the acquisition.***

Our business strategy may include the future acquisition of businesses, technologies, services or products that we believe are a strategic fit with our business. If we undertake any acquisition, the process of integrating an acquired business, technology, service or product 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. Moreover, we may fail to realize the anticipated benefits of any acquisition as rapidly as expected or at all. Future acquisitions could reduce stockholders' ownership, cause us to incur debt, expose us to future 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 experienced distribution alliances 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. We may not be able to identify suitable acquisition candidates in the future or consummate future acquisitions.

***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

Table of Contents

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 \$43.2 million at December 31, 2008. 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;

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

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



Table of Contents

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. The Credit Agreement was entered into to finance the construction and validation of our new 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 2009. 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

Table of Contents

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.

***Our future operating results may be harmed by economic, political and other risks relating to international sales.***

During the years ended December 31, 2008 and 2007, approximately, 27% and 25%, respectively, of our product sales were to international distributors. Our representatives, agents and distributors who sell products in international markets are subject to the laws and regulations of the foreign jurisdictions in which they operate and in which our products are sold. A number of risks are inherent in international sales and operations. For example, the volume of international sales may be limited by the imposition of government controls, export license requirements, political and/or economic instability, trade restrictions, changes in tariffs, difficulties in managing international operations, import restrictions and fluctuations in foreign currency exchange rates. Such changes in the volume of sales may have a material adverse effect on our business, financial condition, and results of operations.

***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.

Table of Contents

*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, 2008, four customers accounted for 85% 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 2008 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 2009. 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 February 28, 2010. For the year ended December 31, 2008, we had aggregate facility lease expenses of approximately \$1,486,000.

We intend to spend approximately \$32 million to build out the Bedford facility that will serve as our corporate headquarters and manufacturing facility for the foreseeable future. Through December 31, 2008, approximately \$29 million has already been spent in connection with the buildout. Our plan is to fund the project with cash on hand and debt. We have borrowed \$16 million under our Credit Agreement which we

Table of Contents

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. The only potential relief available in this proceeding is the denial of the Company's trademark application; no damages or injunctive relief are possible. 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. The Company believes Colbar's claim and recent petition are without merit, and has denied all substantive allegations in the notice of opposition, and the parties are exploring settlement possibilities. As of December 31, 2008, the carrying value of the intangible asset related to ELEVESS was \$936,275. The Company does not believe any impairment of the asset has occurred.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matter was submitted to a vote of the security holders during the fourth quarter of the fiscal year covered by this report.

Table of Contents**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.

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

<b>Year Ended December 31, 2007</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 14.24	\$ 12.31
Second Quarter	15.85	12.32
Third Quarter	21.80	15.08
Fourth Quarter	21.21	13.13

At December 31, 2008, the closing price per share of our common stock was \$3.04 as reported on the NASDAQ Global Select Market and there were approximately 308 holders of record.

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.

**EQUITY COMPENSATION PLAN INFORMATION**

The following table sets forth information concerning the Company's equity compensation plan as of December 31, 2008.

<b>Plan category</b>	<b>Equity Compensation Plan Information</b>		
	<b>Number of securities to be issued upon exercise of outstanding options, stock appreciation rights, and restricted stock</b>	<b>Weighted Average exercise price of outstanding options, stock appreciation rights, and restricted stock</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b>
	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
Equity compensation plans approved by security holders	1,178,078	\$ 9.12	364,200
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>1,178,078</b>	<b>\$ 9.12</b>	<b>364,200</b>

Table of Contents**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, 2008 and 2007 and the Statement of Operations Data for each of the three years ended December 31, 2008 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Annual Report on Form 10-K. The Balance Sheet Data at December 31, 2006, 2005 and 2004, and the Statement of Operations Data for each of the two years in the period ended December 31, 2005 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,				
	2008	2007	2006	2005	2004
Product revenue	\$33,055	\$26,905	\$23,953	\$20,534	\$22,286
Licensing, milestone and contract revenue	2,725	3,925	2,887	9,301	4,180
<b>Total revenue</b>	<b>35,780</b>	<b>30,830</b>	<b>26,840</b>	<b>29,835</b>	<b>26,466</b>
Cost of product revenue	13,189	11,881	11,118	11,144	9,949
Product gross profit	19,866	15,024	12,835	9,390	12,337
Product gross margin	60%	56%	54%	46%	55%
Total operating expenses	31,553	24,242	21,413	21,284	20,078
Net income	\$ 3,629	\$ 6,035	\$ 4,604	\$ 5,893	\$11,190
Diluted net income per common share	\$ 0.32	\$ 0.53	\$ 0.41	\$ 0.52	\$ 0.98
Diluted common shares outstanding	11,461	11,454	11,155	11,428	11,384

**Balance Sheet Data**  
(In thousands)

	December 31,				
	2008	2007	2006	2005	2004
Cash, cash equivalents and short-term investments	\$43,194	\$39,406	\$47,167	\$44,747	\$39,339
Working capital	46,798	41,805	52,145	46,584	42,135
Total assets	95,821	79,497	68,114	62,618	59,538
Retained earnings (accumulated deficit)	17,782	14,153	8,118	3,514	(2,379)
Stockholders' equity	60,757	54,961	45,488	37,892	30,363

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

Table of Contents

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.

In the first quarter of 2004, based on our expectations regarding future profitability, we released the previously established valuation allowance against our deferred tax assets and recorded a one-time income tax benefit of \$7.0 million.

Table of Contents**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," 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. Our currently manufactured and marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans; AMVISC®, AMVISC® Plus, STAARVISC -II, and ShellGel , each an injectable ophthalmic viscoelastic HA product; HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT® is an HA based anti-adhesive for surgical applications. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints is available in Europe. MONOVISC , a single-injection osteoarthritis product based on our proprietary cross-linking technology is available in Europe and Turkey. In the U.S., ORTHOVISC® is marketed by DePuy Mitek, Inc., a subsidiary of Johnson & Johnson, under the terms of a licensing, distribution, supply and marketing agreement. Outside the U.S., ORTHOVISC® has been approved for sale since 1996 and is marketed by distributors in approximately 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. INCERT® is currently marketed in three countries outside of the U.S. ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. Our initial ELEVESS product is approved in the U.S., EU, Canada and certain countries in South America, and is manufactured by Anika. We are currently seeking new distribution partners for ELEVESS both domestically and internationally. Products in development include next generation joint health related products and ELEVESS line extension products.

*Osteoarthritis Business*

Our osteoarthritis business contributed 57% to our product revenue reflecting an increase in sales of 38% compared to 2007. 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 for all joints, and is available in Europe and Turkey. ORTHOVISC *mini*, and MONOVISC are our two newest joint health products and became available during the second quarter of 2008.



Table of Contents

We have marketed ORTHOVISC, our product for the treatment of osteoarthritis of the knee, internationally since 1996 through various distribution agreements. International sales of ORTHOVISC contributed 15% of product revenue for the year ended December 31, 2008 and increased 36% compared to 2007. 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 57% of our product revenue in 2008. We continue to seek new distribution partnerships around the world and we expect total joint health product sales to increase in 2009 compared to 2008.

*Ophthalmic Business*

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2008, sales of ophthalmic products contributed 32% of our product revenue reflecting an increase in sales of ophthalmic products of 2% compared to 2007. Sales to Bausch & Lomb accounted for 92% of ophthalmic sales for 2008 and contributed 30% of product revenue for the period.

*Veterinary Business*

U.S. sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 9% to product revenue for the year ended December 31, 2008 and increased 28% from 2007. We expect HYVISC sales to be relatively flat in 2009. We continue to look at other veterinary applications and opportunities to expand geographic territories.

*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. We commenced INCERT sales during the second quarter of 2006. 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 \$134,780 and \$190,332 for the years 2008 and 2007, respectively. There are currently no plans to distribute INCERT in the U.S.

*Aesthetic Dermatology Business*

ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our 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 our initial product in April and July of 2007, respectively. We recorded \$505,273 and \$224,220 of ELEVESS revenue in 2008 and 2007, respectively. ELEVESS 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. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

*Research and Development*

Products in development include next generation joint health related products. Our next generation osteoarthritis products include 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. This product has

Table of Contents

been branded as MONOVISC. 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 patient enrollment for our U.S. clinical trial in December of 2008. 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. We expect to commence a clinical trial and file an application for CE Mark for CINGAL in 2009.

**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, 2008.

*Revenue Recognition.*

Our revenue recognition policies are in accordance with the Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

*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

Table of Contents

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 EITF 00-21. Under EITF 00-21, 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.

*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.*

On January 1, 2008, we adopted SFAS No. 157, Fair Value Measurements ("SFAS No. 157"), for our financial assets and liabilities. Our adoption of SFAS No. 157 did not impact our financial position, results of operations or liquidity. In accordance with FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157 ("FSP FAS 157-2"), we elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is currently evaluating the potential impact of adopting FSP FAS 157-2.

SFAS No. 157 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, Level 1, of our cash equivalents was \$34,197,953 at December 31, 2008.

*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

Table of Contents

period the asset will be utilized, forecasted cash flows, and customer demand. Our intangible asset consists of our ELEVESS trade name. Significant assumptions underlying the recoverability of the intangible asset 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. Recoverability of the carrying value of the asset may also be impacted by the outcome of the pending trade name opposition. Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible asset. Refer to Note 18 to Consolidated Financial Statements for additional disclosure on our pending trade name opposition.

*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 SFAS No. 34, "Capitalization of Interest Costs" ("SFAS 34"). 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.

*Stock-based Compensation.*

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, ("SFAS 123R") "Share-Based Payment," which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123R, 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.

Table of Contents*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 FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109" (FIN 48). 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 FIN 48 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 FIN 48 liability and record the expense in the provision for income taxes. As of December 31, 2008, income tax related interest and penalties were immaterial. Our U.S. federal income tax returns for the years 2005 through 2007 remain subject to examination, and our state income tax returns for 2006 and 2007 remain 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, 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.

**Results of Operations***Year ended December 31, 2008 compared to year ended December 31, 2007**Statement of Operations Detail*

	<b>Year Ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Product revenue	\$ 33,054,787	\$ 26,905,100
Licensing, milestone and contract revenue	2,725,000	3,924,721
<b>Total revenue</b>	<b>35,779,787</b>	<b>30,829,821</b>
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
<b>Total operating expenses</b>	<b>31,553,058</b>	<b>24,242,390</b>
<b>Income from operations</b>	<b>4,226,729</b>	<b>6,587,431</b>
Interest income, net	498,512	2,100,663
<b>Income before income taxes</b>	<b>4,725,241</b>	<b>8,688,094</b>
Provision for income taxes	1,096,046	2,652,840
<b>Net income</b>	<b>\$ 3,629,195</b>	<b>\$ 6,035,254</b>
Product gross profit		
	\$ 19,866,271	\$ 15,024,111
<b>Product gross margin</b>	<b>60%</b>	<b>56%</b>

*Total Revenue.* Total revenue for the year ended December 31, 2008 increased by \$4,949,966 to \$35,779,787 compared to \$30,829,821 for 2007. The increase in total revenue was primarily due to increased ORTHOVISC revenue and the introduction of new joint health products in 2008.

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

*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 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 \$5,105,175, or 38%, in 2008. The improvement in joint health product revenue was 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 in the 2008 increased 36% to \$4,806,082, from \$3,530,717, in 2007. The increase in international revenue was due to increased product shipments to Turkey, Germany, Italy, Egypt, Hungary and Austria. We expect joint health product revenue to increase in 2009 compared to 2008, both domestically and internationally.

Ophthalmic products sales increased \$161,459, or 2%, to \$10,678,615. 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 revenue increased \$657,552, or 28%, to \$3,028,450 in 2008 as compared with \$2,370,898 in 2007. 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 2009 compared to 2008.

ELEVESS revenue increased \$281,053, or 125%, to \$505,273 in 2008 from \$224,220 in 2007. ELEVESS 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. ELEVESS revenue in 2007 represented sales of samples to a former distributor. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

*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 related to the development and commercialization of ELEVESS. As a result the Company recorded \$1,199,722 of revenue 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

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

year ended December 31, 2007. The improvement in product gross margin was primarily related to unit growth and a more favorable product mix in 2008 than 2007. We expect product gross margin to remain at the current level in 2009.

*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 was primarily 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 ELEVESS, as well as the development of our next-generation osteoarthritis product, CINGAL, and additional headcount. We expect research and development expenses will increase in the future related to next generation joint health products, ELEVESS post-approval and line extensions development activity, and other research and development programs in the pipeline.

*Selling, general and administrative.* Selling, general and administrative expenses for the year ended December 31, 2008 increased by \$2,968,712 or 37%, to \$10,965,493 from \$7,996,781 in the prior year. 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, shareholders rights plan, and strategic programs. We expect that general and administrative expenses will increase in 2009.

*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 off set 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:

	<b>Years ended</b>	
	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Computed expected tax expense	34.0%	34.0%
State tax expense (net of federal benefit)	4.6%	4.2%
State deferred tax assets rate change	2.6%	
Permanent items, including nondeductible expenses	0.6%	(1.1)%
State investment tax credit	(11.1)%	(3.9)%
Federal and state research and development credits	(5.8)%	(2.4)%
Other	(1.9)%	(0.3)%
Tax expense	23.0%	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

Table of Contents

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. Our U.S. federal income tax returns for the years 2005, 2006, and 2007 remain subject to examination, and our state income tax returns for the years 2006 and 2007 remain subject to examination.

*Net income.* For the year ended December 31, 2008 net income for 2008 was \$3,629,195 or \$0.32 per diluted share compared to \$6,035,254 or \$.53 per diluted share for the same period last year. The primary drivers for the decrease in net income was an increase in operating expenses, a decrease in net interest income, partially offset by increases in joint health revenue and a reduction in effective tax due to our new manufacturing facility investment.

***Year ended December 31, 2007 compared to year ended December 31, 2006****Statement of Operations Detail*

	<b>Year Ended December 31,</b>	
	<b>2007</b>	<b>2006</b>
Product revenue	\$ 26,905,100	\$ 23,953,285
Licensing, milestone and contract revenue	3,924,721	2,887,329
<b>Total revenue</b>	<b>30,829,821</b>	<b>26,840,614</b>
Operating Expenses:		
Cost of product revenue	11,880,989	11,117,861
Research and development	4,364,620	3,616,435
Selling, general and administrative	7,996,781	6,678,845
<b>Total operating expenses</b>	<b>24,242,390</b>	<b>21,413,141</b>
<b>Income from operations</b>	<b>6,587,431</b>	<b>5,427,473</b>
Interest income, net	2,100,663	2,100,749
<b>Income before income taxes</b>	<b>8,688,094</b>	<b>7,528,222</b>
Provision for income taxes	2,652,840	2,924,006
<b>Net income</b>	<b>\$ 6,035,254</b>	<b>\$ 4,604,216</b>
Product gross profit		
	\$ 15,024,111	\$ 12,835,424
<b>Product gross margin</b>	<b>56%</b>	<b>54%</b>

*Total Revenue.* Total revenue for the year ended December 31, 2007 increased by \$3,989,207 to \$30,829,821 compared to \$26,840,614 for 2006 primarily due to an increase in U.S. ORTHOVISC product sales and milestone revenue in connection with the termination of the Galderma agreements. Product revenue for 2007 increased by \$2,951,815 to \$26,905,100 primarily due to increased ORTHOVISC revenue from our U.S. distributor, Depuy Mitek. See below for further details.



## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

*Product revenue by product line.* Product revenue for the year ended December 31, 2007 was \$26,905,100, an increase of \$2,951,815, or 12%, compared with \$23,953,285 for the year ended December 31, 2006.

	Year Ended December 31,	
	2007	2006
Joint Health	\$ 13,602,494	\$ 11,340,433
Ophthalmic	10,517,156	10,748,765
Veterinary	2,370,898	1,820,617
Others	414,552	43,470
	\$26,905,100	\$23,953,285

Joint health revenue was from sales of ORTHOVISC which increased \$2,262,061, or 20%, to \$13,602,494 in 2007 as compared with \$11,340,433 in 2006. The increase in ORTHOVISC sales for 2007 was primarily due to an increase in domestic sales by Depuy Mitek. Depuy Mitek's sales increased by 94% in 2007 compared to 2006 thereby gaining market share. This resulted in a significant increase in our U.S. revenue which totaled \$10,071,776, or 37% of product sales, in 2007 compared to \$5,232,589, or 22% of product sales, in 2006. International sales of ORTHOVISC decreased to \$3,530,717 or 42% from \$6,107,844, in 2007 compared to the same period last year. The decrease in international sales was due to a reimbursement change in Turkey. In the third quarter of 2006, the government of Turkey eliminated reimbursement for over 100 drugs including ORTHOVISC and its competing products. We did not ship product to our Turkish distributor during the 10 months ended May 2007. Started in June 2007, sales to Turkey had been at a lower level reflective of a private pay business. Sales to Turkey represented 6% of product sales in 2007 versus 17% in 2006.

Ophthalmic products sales decreased \$231,609, or 2%, to \$10,517,156. The decrease was primarily attributable to a decrease in sales to Bausch & Lomb in 2007 compared to 2006 due to their inventory management efforts in 2007.

HYVISC sales increased \$550,281, or 30%, to \$2,370,898 in 2007 as compared with \$1,820,617 in 2006. Sales of HYVISC were made to a single customer under an exclusive agreement which was extended in April 2006 to December 31, 2010.

Sales of INCERT increased \$146,862 to \$190,332 in 2007 as compared with \$43,470 in 2006, as interest in the product as an anti-adhesive for use in surgical procedures grows.

ELEVESS sales of \$224,220 in 2007 represent sales of samples to our former distributor, Galderma, during the year. The Company is currently seeking new distribution partners.

*Licensing, milestone and contract revenue.* Licensing, milestone and contract revenue for the year ended December 31, 2007 was \$3,924,721, compared to \$2,887,329 for 2006. 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, 2007 was \$15,024,111, or 56% of product revenue, compared with \$12,835,424, or 54% of product revenue, for the year ended December 31, 2006. The improvement in product gross margin was primarily related to a more favorable product mix.

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

*Research and development.* Research and development expenses for the year ended December 31, 2007 increased by \$748,185, or 21%, to \$4,364,620 from \$3,616,435 for the prior year. Research and development expenses include those costs associated with our in-house and external research and development efforts for the development of ELEVESS product enhancements, next generation osteoarthritis products, the costs of clinical trials, manufacturing process improvements, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. The increase in research and development expenses during 2007 was primarily attributable to an increase in clinical trial expenses, engineering related expenses for the scale up of ELEVESS for commercial sales and additional headcount compared to 2006.

*Selling, general and administrative.* Selling, general and administrative expenses for the year ended December 31, 2007 increased by \$1,317,936 or 20%, to \$7,996,781 from \$6,678,845 in the prior year. The increase was primarily due to rent and operating expenses at our new facility located in Bedford, Massachusetts. Our facility lease for the Bedford facility commenced in May 2007. The Company expects that selling, general and administrative expenses will increase in the future related to headcount increases, and infrastructure expansion. Operating expense related to the new facility will be mostly recorded in general and administrative expenses until manufacturing operations occupies the building, which is currently expected to occur in 2009.

*Interest income, net.* Net interest income of \$2,100,663 for the year ended December 31, 2007, was essentially flat compared with \$2,100,749 in 2006.

*Income taxes.* Income tax provision was \$2,652,840 and \$2,924,006 for 2007 and 2006, respectively. The reduction in effective tax rate in 2007 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, a domestic manufacturing deduction, an increase in state and federal research and development credits, and the tax benefits realized from disqualifying events related to incentive stock option exercises.

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

	2007	2006
Computed expected tax expense	34.0%	34.0%
State tax expense (net of federal benefit)	4.2%	3.8%
Permanent items, including nondeductible expenses	(1.1)%	1.8%
State investment tax credit	(3.9)%	
Federal and state research and development credits	(2.4)%	(1.6)%
Other	(0.3)%	0.8%
<b>Tax expense</b>	<b>30.5%</b>	<b>38.8%</b>

### **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 expands. Historically we have funded our cash requirements from available cash and investments on hand. Most recently in 2008, we have financed our long-term facility project with a long-term debt. We expect that our existing capital resources, together with cash from operations and interest income, will be sufficient to fund our operations for the foreseeable future. At December 31, 2008, cash, cash equivalents and short-term investments totaled \$43,193,655 compared to \$39,405,543 at December 31, 2007.

Cash provided by operating activities was \$3,407,231, \$4,492,642 and \$2,001,172 for 2008, 2007, and 2006 respectively. Cash provided by operating activities decreased by \$1,085,411 in 2008 from 2007. This

Table of Contents

decrease in operating cash was primarily due to a \$2,406,059 decrease in net income, a \$182,214 net increase in assets and liabilities, and an increase in non-cash expenses of approximately \$1,138,434.

Cash used in investing activities was \$12,804,552, \$18,282,467 and \$1,305,801 in 2008, 2007 and 2006 respectively. Cash used for investing activities in 2008 and 2007 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 \$32 million in total (including interior construction, equipment, furniture and fixtures). Through December 31, 2008, approximately \$29 million has been spent in connection with the buildout. We have borrowed \$16 million from a line of credit with Bank of America to fund the build out of our Bedford facility. Buildout at the new facility commenced in May 2007 and was substantially completed in mid-2008. Validation of the manufacturing space is expected to continue into 2009. There can also be no assurance that we will be successful in qualifying the new facility under the FDA and European Union regulations.

Cash provided by financing activities of \$16,687,407, \$2,525,962 and \$1,725,405 for 2008, 2007 and 2006, respectively. On January 31, 2008, the Company entered into an unsecured credit facility for up to \$16 million to finance its new facility project. We have borrowed the maximum amount allowed under the agreement as of 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.

*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*

In October 2008, the Financial Accounting Standards Board ("FASB") issued FSP No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for the Asset is Not Active" ("FSP 157-3"). This FSP clarifies the application of SFAS 157, "Fair Value Measurements", in a market that is not active and provides examples of key considerations in determining the fair value of a financial asset when the market for the financial asset is not active. FSP 157-3 is effective upon issuance. The Company has elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is currently evaluating the potential impact of FSP-157-3.

In June 2008, the FASB issued Financial Accounting Standards Board Staff Position ("FSP") Emerging Issues Task Force ("EITF") Issue 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities". FSP EITF 03-6-1 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 should be included in the calculation of basic earnings per share. FSP EITF 03-6-1 is effective for the Company in 2009. The Company does not expect a material effect from the adoption of this standard.

In April 2008, the FASB issued FSP No. 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). This FSP 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 SFAS No. 142, "Goodwill and Other Intangible Assets". The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), "Business Combinations," and other U.S. generally accepted accounting principles. This FSP is effective for the Company on

Table of Contents

January 1, 2009 and early adoption is prohibited. The Company is evaluating the impact of this standard on its financial statements.

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS No. 161"), an amendment of FASB Statement No. 133 ("SFAS No. 133"). SFAS No. 161 requires enhanced disclosures regarding an entity's derivative and hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, and its related interpretations; and how derivative instruments and related hedge items affect an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. SFAS No. 161 will not have an impact on the Company's financial position, results of operations or liquidity as the Company does not have or expect to have derivative instruments or to engage in hedging activities.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 ("EITF 07-1"), "Accounting for Collaborative Arrangements". EITF 07-1 is effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 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 analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9. The Company is assessing the impact of adoption of EITF 07-1 on its financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS No. 141(R)"), which replaces SFAS No 141. The statement 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. SFAS No. 141(R) is effective for us beginning January 1, 2009 and will apply prospectively to business combinations completed on or after that date.

*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. 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;



## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

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; and

the contractual obligation to make principal and interest debt payments.

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 based on our current strategy, our cash and investments on hand will be sufficient to meet our cash flows requirements beyond 2009. 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, 2008:

	Total	Payments due by period			
		Less than 1 year	2-3 years	4-5 years	More than 5 years
Operating Leases <sup>(1)</sup>	\$ 8,823,751	\$ 1,460,317	\$ 1,741,018	\$ 1,898,333	\$ 3,724,083
New Facility Build-out	2,858,980	2,858,980			
Clinical Trials	2,636,291	2,636,291			
Purchase Commitments	1,984,264	1,984,264			
Long Term Debt <sup>(2)</sup>	17,626,242	1,937,068	3,769,075	3,628,995	8,291,104
	\$ 33,929,528	\$ 10,876,920	\$ 5,510,093	\$ 5,527,328	\$ 12,015,187

(1)

Included in this line is a new 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

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

Table of Contents

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 2009.

(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 has 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. Interest on periodic loans and term loans will be payable at a rate based upon (at the Company's election) either Bank of America's prime rate or LIBOR plus 75 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. 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, 2008, throughout the life of the obligation.

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

As of December 31, 2008, 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 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 were immaterial in 2008. Our investment portfolio of cash equivalents and long-term debt are subject to interest rate fluctuations. As of December 31, 2008, the Company is subject to interest rate risk on \$16 million of variable rate debt. The interest payable on our debt is determined based on either an interest rate based on LIBOR plus 0.75% 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, 2008, we would have a decrease in future annual cash flows of approximately \$150,000 for every 1% increase in the interest rate.



Table of Contents

**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>	<u>42</u>
<u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>	<u>43</u>
<u>Consolidated Statements of Operations for the Years Ended December 31, 2008, 2007 and 2006</u>	<u>44</u>
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2008, 2007 and 2006</u>	<u>45</u>
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2008, 2007 and 2006</u>	<u>46</u>
<u>Notes to Consolidated Financial Statements</u>	<u>47</u>

Table of Contents

**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 subsidiary at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 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, 2008, 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.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 9, 2009

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Consolidated Balance Sheets**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 43,193,655	\$35,903,569
Short-term investments		3,501,974
Accounts receivable, net of reserves of \$60,000 at December 31, 2008 and 2007	5,418,421	5,795,973
Inventories	5,519,754	4,390,118
Current portion of deferred income taxes	1,235,364	1,657,007
Prepaid expenses and other	463,284	1,194,081
<b>Total current assets</b>	<b>55,830,478</b>	<b>52,442,722</b>
Property and equipment, at cost	42,436,827	28,101,422
Less: accumulated depreciation	(10,190,144)	(8,731,706)
	32,246,683	19,369,716
Long-term deposits and other	506,787	433,081
Intangible asset, net	936,275	995,098
Deferred income taxes	6,300,665	6,256,067
<b>Total Assets</b>	<b>\$ 95,820,888</b>	<b>\$79,496,684</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,375,340	\$ 4,866,619
Accrued expenses	2,325,219	2,760,010
Deferred revenue	2,732,293	2,806,778
Current portion of long-term debt	1,600,000	
Income taxes payable		203,954
<b>Total current liabilities</b>	<b>9,032,852</b>	<b>10,637,361</b>
Other long-term liabilities	831,051	398,365
Long-term deferred revenue	10,800,001	13,500,001
Long-term debt	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, 2008 and 2007		
Common stock, \$.01 par value; 30,000,000 shares authorized, 11,377,623 shares issued and outstanding at December 31, 2008, 11,223,273 shares issued and outstanding at December 31, 2007	113,776	112,233
Additional paid-in-capital	42,861,229	40,695,940
Retained earnings	17,781,979	14,152,784
<b>Total stockholders' equity</b>	<b>60,756,984</b>	<b>54,960,957</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 95,820,888</b>	<b>\$79,496,684</b>

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



Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Consolidated Statements of Operations**

	<b>For the Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Product revenue	\$33,054,787	\$26,905,100	\$23,953,285
Licensing, milestone and contract revenue	2,725,000	3,924,721	2,887,329
<b>Total revenue</b>	<b>35,779,787</b>	<b>30,829,821</b>	<b>26,840,614</b>
Operating expenses:			
Cost of product revenue	13,188,516	11,880,989	11,117,861
Research & development	7,399,049	4,364,620	3,616,435
Selling, general & administrative	10,965,493	7,996,781	6,678,845
<b>Total operating expenses</b>	<b>31,553,058</b>	<b>24,242,390</b>	<b>21,413,141</b>
<b>Income from operations</b>	<b>4,226,729</b>	<b>6,587,431</b>	<b>5,427,473</b>
Interest income, net	498,512	2,100,663	2,100,749
<b>Income before income taxes</b>	<b>4,725,241</b>	<b>8,688,094</b>	<b>7,528,222</b>
Provision for income taxes	1,096,046	2,652,840	2,924,006
<b>Net income</b>	<b>\$ 3,629,195</b>	<b>\$ 6,035,254</b>	<b>\$ 4,604,216</b>
Basic net income per share:			
Net income	\$ 0.32	\$ 0.55	\$ 0.43
Basic weighted average common shares outstanding	11,308,124	11,059,582	10,639,028
Diluted net income per share:			
Net income	\$ 0.32	\$ 0.53	\$ 0.41
Diluted weighted average common shares outstanding	11,460,801	11,453,600	11,155,249

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

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Consolidated Statements of Stockholders' Equity**

	Common Stock				Total
	Number of	\$.01 Par	Additional	Retained	Stockholders'
	Shares	Value	Paid-in	Earnings	Equity
Balance, December 31, 2005	10,500,393	\$ 105,004	\$ 34,272,881	\$ 3,513,314	\$ 37,891,199
Issuance of common stock for employee equity awards	272,261	2,723	1,216,751		1,219,474
Tax benefit related to stock based compensation			505,931		505,931
FAS 123R stock based compensation expense			1,267,205		1,267,205
Net income				4,604,216	4,604,216
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
FAS 123R 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
FAS 123R 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

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

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Consolidated Statements of Cash Flows**

	<b>For the Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities:</b>			
Net income	\$ 3,629,195	\$ 6,035,254	\$ 4,604,216
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization	1,433,012	793,716	384,055
Loss on fixed asset disposals		6,906	
Amortization of premium on short-term investment	1,974	25,011	
Stock-based compensation expense	1,391,704	911,716	1,267,205
Deferred income taxes	377,045	696,516	659,976
Provision for inventory reserve	138,290	154,931	56,380
Tax benefit from exercise of stock options	(258,146)	(643,351)	(505,931)
<b>Changes in operating assets and liabilities:</b>			
Accounts receivable	377,552	(2,286,465)	(1,443,268)
Inventories	(1,267,926)	850,547	(2,181,298)
Prepaid expenses and other	876,576	(973,636)	805,036
Long-term deposits and other	(73,706)	(240,031)	(49,990)
Accounts payable	(129,662)	1,133,278	(312,602)
Accrued expenses	(733,070)	562,370	(145,081)
Deferred revenue	(2,774,485)	(3,698,032)	(1,725,235)
Income taxes payable	54,192	830,072	523,184
Other long-term liabilities	364,686	333,840	64,525
<b>Net cash provided by operating activities</b>	<b>3,407,231</b>	<b>4,492,642</b>	<b>2,001,172</b>
<b>Cash flows from investing activities:</b>			
Proceeds from maturity of short-term investment	3,500,000		
Purchase of short-term investment		(3,526,985)	
Purchase of property and equipment, net	(16,246,494)	(13,755,482)	(1,305,801)
Purchase of intangible		(1,000,000)	
Other assets	(58,058)		
<b>Net cash used in investing activities</b>	<b>(12,804,552)</b>	<b>(18,282,467)</b>	<b>(1,305,801)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from long-term debt	16,000,000		
Debt issuance costs	(87,721)		
Proceeds from exercise of stock options	516,982	1,882,611	1,219,474
Tax benefit from exercise of stock options	258,146	643,351	505,931
<b>Net cash provided by financing activities</b>	<b>16,687,407</b>	<b>2,525,962</b>	<b>1,725,405</b>
<b>Increase (decrease) in cash and cash equivalents</b>	<b>7,290,086</b>	<b>(11,263,863)</b>	<b>2,420,776</b>
Cash and cash equivalents at beginning of year	35,903,569	47,167,432	44,746,656
<b>Cash and cash equivalents at end of year</b>	<b>\$ 43,193,655</b>	<b>\$ 35,903,569</b>	<b>\$ 47,167,432</b>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for income taxes	\$ 10,000	\$ 1,813,278	\$ 1,077,506

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

Interest paid	\$	191,137	\$	\$
---------------	----	---------	----	----

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



Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**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. The Company's currently manufactured and marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans; AMVISC®, AMVISC® Plus, STAARVISC -II, and ShellGel , each an injectable ophthalmic viscoelastic HA product; HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT®, which is an HA based anti-adhesive for surgical applications. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints is available in Europe. MONOVISC , a single-injection osteoarthritis product based on our proprietary cross-linking technology is available in Europe and Turkey. In the U.S., ORTHOVISC® is marketed by DePuy Mitek, Inc., a subsidiary of Johnson & Johnson, under the terms of a licensing, distribution, supply and marketing agreement. Outside the U.S., ORTHOVISC® has been approved for sale since 1996 and is marketed by distributors in approximately 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. We also produce STAARVISC -II, which is distributed by STAAR Surgical Company and ShellGel for Cytosol Ophthalmics, Inc. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. INCERT® is currently marketed in three countries outside of the U.S. ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. Our initial ELEVESS product is approved in the U.S., EU, Canada and certain countries in South America, and is manufactured by Anika. The Company is currently seeking new distribution partners for ELEVESS both domestically and internationally. Products in development include next generation ELEVESS line extension, and joint health related products.

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 subsidiary, Anika Securities, Inc. (a Massachusetts Securities Corporation). All intercompany balances and transactions have been eliminated in consolidation.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Cash, Cash Equivalents and Short-term Investments**

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 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, 2008, cash equivalents consisted of funds invested in U.S. Treasury obligations and repurchase agreements secured by U.S. Treasury obligations, which approximates fair market value.

**Fair Value Measurements**

On January 1, 2008, the Company adopted SFAS No. 157, Fair Value Measurements ("SFAS No. 157"), for its financial assets and liabilities. The adoption of SFAS No. 157 did not impact the Company's financial position, results of operations or liquidity. In accordance with FASB Staff Position No. FAS 157-2, Effective Date of FASB Statement No. 157 ("FSP FAS 157-2"), the Company elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is currently evaluating the potential impact of adopting FSP FAS 157-2.

SFAS No. 157 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 \$34,197,953 at December 31, 2008 based on Level 1 inputs.

**Revenue Recognition**

The Company's revenue recognition policies are in accordance with the Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, and Emerging Issues Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21").

**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.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

***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 EITF 00-21. Under EITF 00-21, 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.

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 EITF 00-21. 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 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.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**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 SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 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, 2008, long-lived assets consisted of machinery, equipment, leasehold improvements and an intangible asset. The Company's intangible asset consists of its ELEVESS trade name. Significant assumptions underlying the recoverability of the intangible asset include: future cash flow, growth projections, product life cycle and useful life assumptions. The ultimate recoverability of the asset is dependent on the Company securing additional distributors, or directly commercializing the product. Recoverability of the carrying value of the asset may also be impacted by the outcome of the pending trade name opposition. Changes in these assumptions could materially impact the Company's ability to realize the value of its intangible asset. Refer to Note 18 for additional disclosure on the Company's pending trade name opposition.

During the years ended December 31, 2008, 2007, and 2006, the Company did not record losses on impairment.

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 SFAS No. 34, "Capitalization of Interest Costs" ("SFAS 34"). 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.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Research and Development**

Research and development costs consists 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 SFAS No. 109, "Accounting for Income Taxes." SFAS No. 109 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 FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109" (FIN 48). 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 FIN 48 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 FIN 48 liability and record the expense in the provision for income taxes.

**Stock-Based Compensation**

Effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, ("SFAS 123R"), "Share-Based Payment," which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS No. 123R, 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, 2008, Bausch & Lomb, JNJ, Biomeks, Plasmaconcept AG, and Rivex, combined, represented 90% of the Company's accounts receivable balance. As of December 31, 2007, Bausch & Lomb, Biomeks, Boehringer Ingelheim Vetmedica, JNJ, and Staar Surgical, combined, represented 93% of the Company's accounts receivable balance.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Reporting Comprehensive Income**

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, 2008, 2007, and 2006 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 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. All of the operations and assets of the Company have been derived from and are located in the United States.

**Recent Accounting Pronouncements**

In October 2008, the Financial Accounting Standards Board ("FASB") issued FSP No. 157-3, "Determining the Fair Value of a Financial Asset When the Market for the Asset is Not Active" ("FSP 157-3"). This FSP clarifies the application of SFAS 157, "Fair Value Measurements", in a market that is not active and provides examples of key considerations in determining the fair value of a financial asset when the market for the financial asset is not active. FSP 157-3 is effective upon issuance. The Company has elected to defer until January 1, 2009 the adoption of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities that are not recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is currently evaluating the potential impact of FSP-157-3.

In June 2008, the FASB issued Financial Accounting Standards Board Staff Position ("FSP") Emerging Issues Task Force ("EITF") Issue 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities". FSP EITF 03-6-1 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 should be included in the calculation of basic earnings per share. FSP EITF 03-6-1 is effective for the Company in 2009. The Company does not expect a material effect from the adoption of this standard.

In April 2008, the FASB issued FSP No. 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). This FSP 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 SFAS No. 142, "Goodwill and Other Intangible Assets". The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R), "Business Combinations," and other U.S. generally accepted accounting principles. This FSP is effective for the Company on January 1, 2009 and early adoption is prohibited. The Company is evaluating the impact of this standard on its financial statements.

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

In March 2008, the FASB issued SFAS No. 161, "Disclosures about Derivative Instruments and Hedging Activities" ("SFAS No. 161"), an amendment of FASB Statement No. 133 ("SFAS No. 133"). SFAS No. 161 requires enhanced disclosures regarding an entity's derivative and hedging activities. These enhanced disclosures include information regarding how and why an entity uses derivative instruments; how derivative instruments and related hedge items are accounted for under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, and its related interpretations; and how derivative instruments and related hedge items affect an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. SFAS No. 161 will not have an impact on the Company's financial position, results of operations or liquidity as the Company does not have or expect to have derivative instruments or to engage in hedging activities.

In December 2007, the FASB ratified the consensus reached by the EITF on Issue No. 07-1 ("EITF 07-1"), "Accounting for Collaborative Arrangements". EITF 07-1 is effective for the Company beginning January 1, 2009 and will be applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 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 analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarifies that the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF 01-9. The Company is assessing the impact of adoption of EITF 07-1 on its financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS No. 141(R)"), which replaces SFAS No 141. The statement 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. SFAS No. 141(R) is effective for us beginning January 1, 2009 and will apply prospectively to business combinations completed on or after that date.

**3. Net Income per Common Share**

The Company reports earnings per share in accordance with 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.

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****3. Net Income per Common Share (Continued)**

Shares used in calculating basic and diluted earnings per share for each of the years ended December 31, 2008, 2007 and 2006, are as follows:

	2008	2007	2006
Net income	\$ 3,629,195	\$ 6,035,254	\$ 4,604,216
Basic weighted average common shares outstanding	11,308,124	11,059,582	10,639,028
Dilutive potential common shares	152,677	394,018	516,221
Diluted weighted average common and potential common shares outstanding	11,460,801	11,453,600	11,155,249

Options to purchase approximately 757,153, 85,000 and 193,075 shares were outstanding at December 31, 2008, 2007 and 2006, 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, 2008, 2007 and 2006, 83,395, 17,225 and 23,900 shares of issued and outstanding unvested restricted stock were excluded from the basic earnings per share calculation in accordance with SFAS No. 128.

**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 of Statement of Financial Accounting Standards ("SFAS") No. 115, "Accounting For Certain Investments in Debt and Equity Securities." The tax exempt municipal bond is classified as held-to-maturity because the Company intends, and has the ability, to hold the securities 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:

	December 31,		
	2008	2007	2006
Balance, beginning of the year	\$60,000	\$49,724	\$22,558
Amounts provided		10,276	27,166
Amounts written off			
Balance, end of the year	\$60,000	\$60,000	\$49,724



Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****6. Inventories**

Inventories consist of the following:

	December 31,	
	2008	2007
Raw Materials	\$2,556,588	\$2,689,358
Work-in-Process	2,354,736	1,541,968
Finished Goods	608,430	158,792
Total	\$5,519,754	\$4,390,118

**7. Property & Equipment**

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

	December 31,	
	2008	2007
Machinery and equipment	\$ 8,674,679	\$ 7,939,465
Furniture and fixtures	579,824	497,955
Leasehold improvements	11,552,091	11,552,091
Construction in progress	21,630,233	8,111,911
	42,436,827	28,101,422
Less accumulated depreciation	(10,190,144)	(8,731,706)
Total	\$ 32,246,683	\$ 19,369,716

Depreciation expense was \$1,374,189, \$788,814 and \$384,055 for the years ended December 31, 2008, 2007 and 2006, respectively.

**8. Intangible Asset**

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 reviews 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. 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, 2008, amortization expense on the intangible asset for the next five years is expected to be \$58,824 annually. Amortization expenses were \$58,823, \$4,902 and \$0 for the years ended

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****8. Intangible Asset (Continued)**

December 31, 2008, 2007 and 2006, respectively. Intangible assets are at stated cost and consist of the following:

	December 31,	
	2008	2007
ELEVESS trade name	\$ 1,000,000	\$ 1,000,000
Accumulated amortization	(63,725)	(4,902)
<b>Total</b>	<b>\$ 936,275</b>	<b>\$ 995,098</b>

**9. Accrued Expenses**

Accrued expenses consist of the following:

	December 31,	
	2008	2007
Payroll and benefits	\$ 1,380,901	\$ 1,339,145
Professional fees	332,570	365,578
Facility construction costs	24,723	623,805
Clinical trial costs	285,500	146,921
Other	301,525	284,561
<b>Total</b>	<b>\$ 2,325,219</b>	<b>\$ 2,760,010</b>

**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 \$13,500,000 and \$16,200,000 at December 31, 2008 and 2007, respectively.

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****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 2009. 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 February 28, 2010. Rental expense in connection with the various facility leases totaled \$1,486,472, \$1,319,160 and \$791,137, for the years ended December 31, 2008, 2007, and 2006, respectively. The Company's future lease commitments as of December 31, 2008 are as follows:

2009	\$ 1,460,317
2010	866,130
2011	874,888
2012	926,833
2013 and thereafter	4,695,583
	\$ 8,823,751

*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 SFAS 123R, 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

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****12. Stock Option Plan (Continued)**

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 2008, 2007 and 2006 was estimated on the grant date using the Black-Scholes option-pricing model with the following assumptions:

	Twelve Months Ended		
	December 31, 2008	December 31, 2007	December 31, 2006
Risk-free interest rate	1.44% - 2.82%	3.11% - 4.80%	4.32% - 5.03%
Expected volatility	58.15% - 63.37%	56.67% - 64.11%	63.92% - 65.82%
Expected lives (years)	4 - 5	4	4
Expected dividend yield	0.00%	0.00%	0.00%

The Company recorded \$1,391,704, \$911,716 and \$1,267,205 of share-based compensation expense for the years ended December 31, 2008, 2007 and 2006, 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.

The Company had reserved 3,485,000 shares of common stock for the grant of stock options to employees, directors, consultants and advisors under the Anika Therapeutics, Inc. 1993 Stock Option Plan, as amended (the "1993 Plan"). In addition, the Company also established the Directors' Stock Option Plan (the "Directors' Plan") and reserved 40,000 shares of the Company's common stock for issuance to the Board of Directors. On March 3, 2003, the 1993 Plan expired in accordance with its terms and approximately 662,000 shares reserved under the plan were released. On April 4, 2003 the Board of Directors approved the 2003 Anika Therapeutics, Inc. Stock Option and Incentive Plan (the "2003 Plan"). The Company has 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. The Company issues new shares upon share option exercise from its authorized shares 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 conditions and generally vest annually over 3 or 4 year terms. Awards have 10-year contractual terms. There are 364,200 options available for future grant at December 31, 2008.

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****12. Stock Option Plan (Continued)**

Combined stock options and stock appreciation rights activity under the three plans is summarized as follows for the years end December 31, 2008, 2007, and 2006:

	2008		2007		2006	
	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	1,093,479	\$ 7.93	1,547,412	\$ 6.39	1,795,394	\$ 5.80
Granted	179,130	\$ 10.50	115,000	\$ 19.22	274,550	\$ 11.54
Cancelled	(29,126)	\$ 6.43	(134,714)	\$ 10.83	(249,604)	\$ 9.85
Expired			(3,295)	\$ 12.06	(667)	\$ 4.75
Exercised	(148,800)	\$ 3.47	(430,924)	\$ 4.48	(272,261)	\$ 4.48
Outstanding at end of year	1,094,683	\$ 9.00	1,093,479	\$ 7.93	1,547,412	\$ 6.39
Options exercisable at end of year	713,453	\$ 7.06	772,154	\$ 5.43	1,022,262	\$ 4.55
Weighted average fair value of options granted at fair value		\$ 5.22		\$ 9.31		\$ 6.05

The restricted stock activity for the years ended December 31, 2008, 2007 and 2006 are as follows:

	2008		2007		2006	
	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	17,225	\$ 11.82	23,900	\$ 11.80		
Granted	77,170	\$ 10.58	200	\$ 13.09	27,200	\$ 11.65
Cancelled	(5,850)	\$ 11.39	(1,100)	\$ 11.86	(3,300)	\$ 10.51
Vested	(5,150)	\$ 11.76	(5,775)	\$ 11.78		
Expired						
Nonvested at end of year	83,395	\$ 10.71	17,225	\$ 11.82	23,900	\$ 11.80

The aggregate intrinsic value of stock options and stock appreciation rights fully vested at December 31, 2008, 2007 and 2006 were \$482,853, \$7,042,267 and \$8,921,023, respectively. The aggregate intrinsic value of stock options and stock appreciation rights outstanding at December 31, 2008, 2007 and 2006, were \$482,853, \$7,797,706 and \$10,653,459, respectively. The total intrinsic value of options and stock appreciation rights exercised were \$729,313, \$4,204,142 and \$2,130,816 for the years ended December 31, 2008, 2007 and 2006, respectively. The total fair value of options and stock appreciation rights vested during the years ended December 31, 2008, 2007, and 2006 were \$727,765, \$889,256, and \$1,125,195 respectively. The Company received \$516,982, \$1,882,611 and \$1,219,474 for exercises of stock options during the years ended December 31, 2008, 2007 and 2006, respectively. As of December 31, 2008 the weighted average remaining contractual life of the outstanding and vested shares, for options and stock appreciation rights, were 5.96 years and 4.65 years, respectively.

As of December 31, 2008, the weighted average fair value per share for options and stock appreciation rights for shares outstanding and vested were \$4.97 and \$4.24, respectively. As of December 31, 2008, there

Table of Contents

**Anika Therapeutics, Inc. and Subsidiary**

**Notes to Consolidated Financial Statements (Continued)**

**12. Stock Option Plan (Continued)**

was approximately \$3,307,895, 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 2.1 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**

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, 2008, 2007, and 2006, the Company made matching contributions of \$301,155, \$241,982 and \$223,185 respectively.

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****15. Revenue by Product Group, by Significant Customer and by Geographic Region**

Product revenue by product group is as follows:

	Years Ended December 31,		
	2008	2007	2006
Joint Health	\$ 18,707,669	\$ 13,602,494	\$ 11,340,433
Ophthalmic	10,678,615	10,517,156	10,748,765
Veterinary	3,028,450	2,370,898	1,820,617
Aesthetics	505,273	224,220	
Others	134,780	190,332	43,470
	\$ 33,054,787	\$ 26,905,100	\$ 23,953,285

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

	Percent of Product Revenue Years Ended December 31,		
	2008	2007	2006
Depuy Mitek / Ortho Biotech	40.0%	37.4%	21.8%
Bausch & Lomb Incorporated	29.8%	35.4%	40.8%
Boehringer Ingelheim Vetmedica	9.2%	8.8%	7.6%
Pharmaren AG / Biomeks	5.7%	6.1%	16.7%
	84.7%	87.7%	86.9%

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

	Years Ended December 31,					
	2008		2007		2006	
Geographic location:	Revenue	Percent of Revenue	Revenue	Percent of Revenue	Revenue	Percent of Revenue
United States	\$ 26,789,515	74.9%	\$ 22,759,765	73.8%	\$ 17,743,274	66.1%
Europe	5,667,215	15.8%	5,462,266	17.7%	3,668,479	13.7%
Turkey	1,946,081	5.4%	1,666,696	5.4%	3,998,226	14.9%
Other	1,376,976	3.9%	941,094	3.1%	1,430,635	5.3%
Total	\$ 35,779,787	100.0%	\$ 30,829,821	100.0%	\$ 26,840,614	100.0%

The Company recorded licensing, milestone and contract revenue of \$2,725,000, \$3,924,721 and \$2,887,329 for the year ended December 31, 2008, 2007, and 2006, respectively. Substantially all licensing, milestone and contract revenue was derived in the United States for 2008 and 2006. In 2007, approximately \$1,200,000 of milestone revenue was derived in Europe.

**16. Income Taxes**

Income tax expense was \$1,096,046, \$2,652,840 and \$2,924,006 for the years ended December 31, 2008, 2007, and 2006, respectively. Prepaid taxes of \$112,950 and \$693,661 were included in the prepaid expenses at December 31, 2008 and 2007. The Company receives a tax deduction upon the exercise of





Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****16. Income Taxes (Continued)**

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, \$643,351 and \$505,931 were not recorded through the tax provision; rather, they were credited directly to additional paid in capital in 2008, 2007 and 2006, respectively. The components of the provision for income taxes are as follows:

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Current:</b>			
Federal	\$ 765,578	\$ 1,792,556	\$ 1,991,829
State	(46,577)	163,768	272,201
	719,001	1,956,324	2,264,030
<b>Deferred:</b>			
Federal	693,732	849,573	580,694
State	(316,687)	(153,057)	79,282
	377,045	696,516	659,976
<b>Tax expense</b>	<b>\$ 1,096,046</b>	<b>\$ 2,652,840</b>	<b>\$ 2,924,006</b>

The Company's effective tax rate varied from the U.S. federal statutory rate due, principally, to a state investment tax credit as a result of the new facility project, a domestic manufacturing deduction, state and federal research and development credits, and the tax benefits realized from disqualifying events related to incentive stock option exercises during the period. 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:

	<b>Years ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
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%		
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	(1.9)%	(0.3)%	0.8%
<b>Tax expense</b>	<b>23.0%</b>	<b>30.5%</b>	<b>38.8%</b>

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, 2008 and 2007, management determined that it



Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****16. Income Taxes (Continued)**

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:

	<b>Years ended December 31,</b>	
	<b>2008</b>	<b>2007</b>
Deferred tax assets:		
Deferred revenue	\$5,155,800	\$6,300,645
Stock-based compensation expense	930,492	474,670
Tax credit carryforwards	788,915	270,888
Accrued expenses and other	449,632	351,322
Depreciation	163,565	480,106
Inventory reserve	47,625	35,443
Deferred tax asset	\$7,536,029	\$7,913,074

The Company adopted the provisions of FIN 48 on January 1, 2007. As a result of the implementation of FIN 48, 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 as of January 1, 2007, December 31, 2007 and December 31, 2008. Total amount of unrecognized tax benefits that would affect our effective tax rate if recognized is \$40,900, \$203,954 and \$228,938 as of December 31, 2008 and 2007 and January 1, 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 FIN 48 tax reserves and a related income tax benefit of approximately \$100,000. Our U.S. federal income tax returns for the years 2005 to 2007 remain subject to examination, and our state income tax returns for 2006 and 2007 remain 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

**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



Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****17. Long-term Debt (Continued)**

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 75 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, 2008, the Company had an outstanding debt balance of \$16,000,000, at a blended interest rate of 2.19%. 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, 2008, the Company capitalized interest expense of \$227,076 as part of construction in progress related to the Company's new facility build-out. Interest capitalization was recorded in accordance with SFAS No. 34, "Capitalization of Interest Costs." Long-term debt principal payments over the next five years are \$1,600,000 per year. At December 31, 2008, the long-term debt's fair value approximates its cost.

**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. The only potential relief available in this proceeding is the denial of the Company's trademark application; no damages or injunctive relief are possible. 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. The Company believes Colbar's claim and recent petition are without merit, and has denied all substantive allegations in the notice of opposition, and the parties are exploring settlement possibilities. As of December 31, 2008, the carrying value of the intangible asset related to ELEVESS was \$936,275. The Company does not believe any impairment of the asset has occurred.

**19. Quarterly Financial Data (Unaudited)**

	Quarter ended December 31,	Quarter ended September 30,	Quarter ended June 30,	Quarter ended March 31,
<b>Year 2008</b>				
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

Table of Contents**Anika Therapeutics, Inc. and Subsidiary****Notes to Consolidated Financial Statements (Continued)****19. Quarterly Financial Data (Unaudited) (Continued)**

	Quarter ended	Quarter ended	Quarter ended	Quarter ended
Year 2007	December 31,	September 30,	June 30,	March 31,
Product revenue	\$ 7,915,967	\$ 7,283,129	\$ 6,331,966	\$ 5,374,038
Total revenue	9,626,833	7,965,380	7,099,562	6,138,046
Cost of product revenue	3,225,979	3,138,307	3,023,781	2,492,922
Gross profit on product revenue	4,689,988	4,144,822	3,308,185	2,881,116
Net income	\$ 1,673,396	\$ 1,796,230	\$ 1,364,851	\$ 1,200,777
Per common share information				
Basic net income per share	\$ 0.15	\$ 0.16	\$ 0.12	\$ 0.11
Basic common shares outstanding	11,177,521	11,152,686	11,018,053	10,878,448
Diluted net income per share	\$ 0.15	\$ 0.16	\$ 0.12	\$ 0.11
Diluted common shares outstanding	11,511,862	11,568,074	11,376,673	11,281,322

65

Table of Contents

**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 2008 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, 2008. 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, 2008.

The effectiveness of our internal control over financial reporting as of December 31, 2008 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.





Table of Contents

**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, 2008.

**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, 2008.

**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, 2008.

**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, 2008.

**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, 2008.

**PART IV**

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

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

(1) Financial Statements

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

Table of Contents

- (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**

(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.
- 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

Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

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.

Table of Contents

<b>(b) Exhibit No.</b>	<b>Description</b>
<b>(10) Material Contracts</b>	
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.

## Edgar Filing: ANIKA THERAPEUTICS INC - Form 10-K

### Table of Contents

#### (b) Exhibit

No.	Description
10.11	2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit A to the Company's Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 30, 2003.
10.12	First Amendment to the Company's 2003 Stock Option and Incentive Plan, incorporated herein by reference to Exhibit 4.9 of the Company's Registration Statement on Form S-8 (File no. 333-110326), filed with the Securities and Exchange Commission on November 7, 2003.
10.13	Form of Incentive Stock Option Agreement under the Company's 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.
10.14	Form of Non-Qualified Stock Option Agreement under the Company's 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.
10.15	Form of Stock Appreciation Right Agreement for Employees under the Company's 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.
10.16	Form of Stock Appreciation Right Agreement for Non-Employee Directors under the Company's 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.
10.17	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.
10.18	Credit Agreement, dated January 31, 2008, among the Company, Anika Securities, Inc., Bank of America, N.A., and the other lenders party thereto, 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.
10.19	Anika 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.
10.20	Form of Performance Share Award Agreement under the Anika Therapeutic, Inc. 2003 Stock Option and Incentive Plan, as amended, 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.
10.21	Employment 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



Table of Contents

**(b) Exhibit**

<b>No.</b>	<b>Description</b>
10.22	Employment 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.
10.23	Form of Restricted Stock Agreement for Employees under the Anika Therapeutic, Inc. 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.
10.24	Anika 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.
* 10.25	Form of Restricted Deferred Stock Unit Award Agreement for Non-Employee Directors under the Company's 2003 Stock Option and Incentive Plan.
(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)	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.
***32.1	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.

