ANIKA THERAPEUTICS INC
Form 10-K
March 09, 2006

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# Form 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2005**

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)* | *(I.R.S. Employer Identification No.)* |

**160 New Boston Street, Woburn, Massachusetts 01801**
*(Address of Principal Executive Offices) (Zip Code)*
**(781) 932-6616**
*(Registrant s Telephone Number, Including Area Code)*

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yesx No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definitions of accelerated filer and large accelerated filer in Rule 12b-2 of the Securities Exchange Act

o Large accelerated filer x Accelerated filer o Non-accelerated filer

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

The aggregate market value of voting and non-voting stock held by non-affiliates of the Registrant as of June 30, 2005, the last day of the Registrant s most recently completed second fiscal quarter, was $120,445,000 based on the close price per share of Common Stock of $11.49 as of such date as reported on the NASDAQ National 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, 2006, there were issued and outstanding 10,529,330 shares of Common Stock, par value $.01 per share.

**Documents Incorporated By Reference**

Certain information required in response to Items 10, 11, 12, 13 and 14 of Part III are hereby incorporated by reference from the registrant s Proxy Statement for the Annual Meeting of Stockholders to be held on June 1, 2006. Such Proxy Statement shall not be deemed to be filed as part of this Annual Report on Form 10-K except for the parts therein which have been specifically incorporated by reference herein.

**ANIKA THERAPEUTICS, INC.**

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**ANIKA THERAPEUTICS, INC.**
**For Fiscal Year Ended December 31, 2005**

*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 efforts to increase sales of ophthalmic viscoelastic products and support of the distribution of ORTHOVISC® in the U.S. and internationally;

- our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;

- the timing of, scope of and rate of patient enrollment for clinical trials;

- development of possible new products, including plans to advance cosmetic tissue augmentation and post-surgical adhesion therapies into initial or additional human clinical trials;

- our ability to achieve or maintain compliance with laws and regulations;

- the timing of and/or receipt of FDA or other regulatory approvals and/or reimbursement approvals of new or potential products;

- our expectation with respect to reimbursements of ORTHOVISC products under J code;

- our intention to seek patent protection for our products and processes;

- negotiations with potential and existing partners, including our performance under any of our distribution or supply agreements or our expectations with respect to sales and milestones pursuant to such agreements;

- the level of our revenue or sales in particular geographic areas and/or for particular products;

- the market share for any of our products;

- our profitability and margin improvements resulting from a higher margin product mix;

- our expectations of the size of the U.S. and European markets for osteoarthritis of the knee;

- our intention to increase market share for ORTHOVISC in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee;

- our current strategy, including our corporate objectives and research and development and collaboration opportunities, including, without limitation, commencement, completion and evaluation of cosmetic tissue augmentation and INCERT® products;

- our search for a partner for our cosmetic tissue augmentation product and our efforts to continue development of the product;

- our and Bausch & Lomb s performance under the existing supply agreement for certain of our ophthalmic viscoelastic products;

- our ability to achieve performance and sales threshold milestones in our existing and future distribution and supply agreements;

- our expectations for ophthalmic products revenue;

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- our expectation for increases in operating expenses;
- our expectation for increases in capital expenditures;
- our ability to maintain a sufficient supply of HA to meet anticipated demands;
- our expected tax rate and taxable revenues;
- our ability and timing with respect to filling vacancies in management positions;
- the rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy of such cash; and
- possible negotiations or re-negotiations with existing or new distribution or collaboration partners, including a partner for REDEFYNE™.

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

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

**PART I**

**ITEM 1.** BUSINESS

**Overview**

Anika Therapeutics, Inc. ( Anika, the Company, we, us, or our ) develops, manufactures and commercializes therapeutic products for tissue protection and healing. 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; and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. In the U.S. ORTHOVISC is marketed by DePuy Mitek, a subsidiary of Johnson & Johnson (collectively, JNJ ), under the terms of a licensing, distribution, supply and marketing agreement. Outside the US, ORTHOVISC has been approved for sale since 1996 and is marketed by distributors in over 15 countries. HYVISC is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement.

Potential products in development include REDEFYNE™, an HA based dermal filler used for cosmetic tissue augmentation (CTA) applications, and INCERT®, an HA based anti-adhesive for surgical applications. In September 2005, we filed a Pre-Market Approval (PMA) application with the FDA seeking approval to market and sell REDEFYNE in the United States. We received *Conformité Européenne* marking (CE marking), a foreign regulatory approval for commercial marketing and sale, for INCERT in the third quarter of 2004. We received CE marking approval for CTA in the first quarter of 2006. In addition, we filed a pre-market approval application in September 2005 for our CTA product.

Our current strategy is to:

- support U.S. ORTHOVISC sales growth and to expand ORTHOVISC sales internationally;
- obtain PMA approval for REDEFYNE and sign a marketing agreement with a new partner;
- develop and implement a commercialization plan for INCERT®;
- initiate additional human clinical trials for new ORTHOVISC formulations;
- focus research and development resources on evaluating potential product applications, including possible collaborations with other parties; and
- increase gross margins by upgrading manufacturing processes and efficiencies.

In 2005, revenue from the sale of our products contributed 69% of our total revenue. Licensing, milestone and contract revenue contributed 31% of our total revenue in 2005. Revenue from the sale of ophthalmic viscoelastic products was 51% of product revenue. ORTHOVISC contributed 39% of our product revenue, and HYVISC contributed 10% of our product revenue in 2005.

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

*ORTHOVISC®*

In the U.S., ORTHOVISC is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics, such as acetaminophen. Outside the U.S., ORTHOVISC has been approved for use in all joints in Europe and certain other international markets. It is a sterile, non-pyrogenic, clear, viscoelastic solution of natural hyaluronan dissolved in physiological saline, and dispensed in a single-use syringe. A natural 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 the knee joint in a series of three intra-articular injections one week apart.

Osteoarthritis is a debilitating disease causing pain, inflammation 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.

ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is marketed by DePuy Mitek, Inc., a subsidiary of Johnson & Johnson, under the terms of a ten-year licensing, distribution, supply and marketing agreement (the JNJ Agreement ). The JNJ Agreement was originally entered into with Ortho Biotech Products, L.P., also a Johnson & Johnson company, and was assigned to DePuy Mitek in

mid-2005. Under the JNJ Agreement, DePuy Mitek performs sales, marketing and distribution functions. Additionally, DePuy Mitek has the right, under certain circumstances, to further develop and commercialize ORTHOVISC as well as other new products for the treatment of pain associated with osteoarthritis based on our 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. We received an initial payment of $2.0 million upon entering into the JNJ Agreement, a milestone payment of $20.0 million in February 2004, as a result of obtaining FDA approval of ORTHOVISC and a $5.0 million milestone payment in December 2004 for planned upgrades to our manufacturing operations for a total of $27.0 million. This amount was initially recorded as deferred revenue, and is being recognized as revenue ratably over the agreement s ten year life. Under the JNJ Agreement, we are the exclusive supplier of ORTHOVISC to Depuy Mitek. The JNJ Agreement provides for additional sales-based milestone payments to us contingent upon achieving specified sales targets, in addition to royalty and transfer fees. The JNJ Agreement is subject to early termination in certain circumstances and is otherwise renewable by DePuy Mitek for consecutive five-year terms.

We have a number of distribution relationships servicing international markets including Canada, European countries, Turkey, and parts of the Middle East. We will continue to seek to establish long-term distribution relationships in other regions. See the section captioned *Management s Discussion and Analysis of Financial Condition and Results of Operations Overview* and *Risk Factors.*

*HYVISC®*

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.

*OPHTHALMIC PRODUCTS*

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. The 2004 B&L Agreement applies to all products sold by us to Bausch & Lomb from the beginning of 2004, with a price increase that started in 2005. 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. Our former distributor for CoEase, Advanced Medical Optics ( AMO ), completed the acquisition of the surgical ophthalmology business of Pfizer, Inc., in September 2004, which included a competing line of viscoelastic products for use in ocular surgery. As a result, our agreement with AMO expired according to its terms in June 2005. See also the section captioned *Risk Factors.*

**Research and Development of Potential Products**

As discussed below in the section titled *Risk Factors,* we have not obtained FDA approval for the sales and marketing in the U.S. of the potential products described below.

*Cosmetic Tissue Augmentation*

REDEFYNE , our product for cosmetic tissue augmentation (CTA), is based on a family of chemically modified, cross-linked forms of HA designed for longer duration in the body. Cosmetic tissue augmentation is a therapy designed as a soft tissue filler for facial wrinkles, scar remediation and lip augmentation. This new class of tissue filler technology based on HA is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. In October 2005, we completed a pivotal U.S. clinical trial to evaluate CTA s effectiveness for correcting nasolabial folds. The trial was conducted by dermatologists and plastic surgeons at 10 centers throughout the U.S. The six month primary endpoint results of this trial were submitted to the U.S. Food and Drug Administration ( FDA ) in a Pre-Market Approval ( PMA ) application in September 2005. In the first quarter of 2006, we received CE mark approval to market REDEFYNE in the European Union.

In July 2004 we entered into an exclusive worldwide development and commercialization partnership (the OrthoNeutrogena Agreement) for our CTA products with the OrthoNeutrogena division of Ortho-McNeil Pharmaceuticals, Inc., an affiliate of Johnson & Johnson. Under the terms of the OrthoNeutrogena Agreement, we received an initial payment of $1.0 million. In addition, OrthoNeutrogena, subject to certain limitations, funded our pivotal clinical trial of our CTA product completed in October 2005. On September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement, and as noted above, we filed our PMA with the FDA seeking approval to market and sell our CTA product in the United States. The Company will continue the development effort on a go forward basis which will be self-funded. We are currently seeking a worldwide distribution partner for this product.

*INCERT®*

INCERT is a family of chemically modified, cross-linked forms of HA designed to prevent surgical adhesions. Surgical adhesions occur when fibrous bands of tissues form between adjacent tissue layers during the wound healing process. Although surgeons attempt to minimize the formation of adhesions, they nevertheless occur quite frequently after surgery. Adhesions in the abdominal and pelvic cavity can cause particularly serious problems such as intestinal blockage following abdominal surgery, and infertility following pelvic surgery. Fibrosis following spinal surgery can complicate re-operation and may cause pain. We received CE marking for INCERT in the third quarter of 2004.

INCERT-S is our product designed to reduce post-surgical fibrosis following spinal surgery. We completed a pilot human clinical trial in Europe in December 2005 involving patients undergoing spinal surgery, and demonstrated safety.

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

We have received CE marking for REDEFYNE and INCERT. We cannot assure you that: (1) we will successfully obtain regulatory approval for sales in the U.S. or internationally of our CTA or INCERT-S products; or (2) if regulatory approvals are obtained, meaningful sales of our CTA products or INCERT-S will be achieved.

**Manufacturing of Hyaluronic Acid**

We have been manufacturing HA since 1983 in our facility located in Woburn, Massachusetts. This facility is approved by the FDA for the manufacture of medical devices and drugs. We have developed a proprietary manufacturing process for the extraction and purification of HA from avian combs, a source of high molecular weight HA. We have taken steps to minimize risks associated with the availability of raw materials by obtaining regulatory approval to outsource certain key intermediates for our products. We believe that sufficient supplies of these materials are generally available, or maintained in inventory, to meet anticipated demand.

**Patent and Proprietary Rights**

We have a policy of seeking patent protection for patentable aspects of our proprietary technology. Our issued patents expire between 2009 and 2022. 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 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 Bausch & Lomb a royalty-free, worldwide, non-exclusive license to our manufacturing inventions which relate to the AMVISC products, effective upon the earlier of (1) the termination date of the 2004 B&L Agreement or (2) the loss of our rights of exclusivity thereunder.

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

AMVISC, ShellGel and STAARVISC are approved as Class III medical devices in the U.S. for 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. HYVISC is approved as an animal drug for intra-articular injection in horse joints to treat degenerative joint disease associated with synovitis. In the past, most HA products for human use have been regulated as medical devices. We believe that our products for CTA and INCERT will have to meet the regulatory requirements of Class III devices, including PMA.

Unless a new device is exempted from premarket notification, its manufacturer must obtain marketing clearance from the FDA through premarket notification (510(k)) or PMA before the device can be introduced into 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 for significant risk devices must be conducted under an 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 delay. 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) informed consent is inadequate; 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 an unanticipated adverse device effect presents 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 PMA applicant must submit other information relevant to the safety and effectiveness of the device, including, among other things, the results of non-clinical tests; 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 usually

also conducts an on-site inspection to determine whether an applicant conforms with the FDA s current Quality System Regulation (QSR), formerly known as Good Manufacturing Practices (GMP/QSR). FDA review of the PMA may not result in timely or any PMA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Product changes after approval where such change affects safety and effectiveness 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 manufacturing, quality control and quality assurance, maintenance of records and documentation, reporting of adverse events, and labeling and promotion. The FDC Act requires device manufacturers to comply with GMP/QSR. The FDA enforces these requirements through periodic inspections of device manufacturing facilities. In complying with standards 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 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.

*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 Europe, ORTHOVISC is sold under *Conformité Européene* (CE mark) authorization, a certification required under European Union (EU) 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. 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. 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.

**Competition**

We compete with many companies, including, among others, large pharmaceutical firms and specialized medical products companies. Many of these companies have substantially greater financial and other 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 market include:

- the quality and breadth of our technology and technological advances;

- our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors;

- our ability to recruit and retain skilled employees; and

- the availability of substantial capital resources to fund discovery, development and commercialization activities or the ability to defray such costs through securing relationships with collaborators for our research and development and commercialization programs.

We are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. There exists major worldwide competing HA based products for the use in ophthalmic surgery and orthopedics. In early 2004, the FDA approved two HA products for the treatment of facial wrinkles which has been marketed internationally since 1996. There is a risk that we will be unable to compete effectively against our current or future competitors.

**Research and Development**

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. These efforts are presently accomplished primarily through in-house research and development personnel and resources, as well as through collaboration with other companies and scientific researchers. As of December 31, 2005, we had ten employees engaged primarily in research and development and engineering, and three employees engaged in clinical and regulatory matters. For the years ended December 31, 2005, 2004, and 2003, these expenses were $4.7 million, $4.1 million, and $2.6 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

There is a risk that our efforts will not be successful in (1) developing our existing product candidates, (2) expanding the therapeutic applications of our existing products, or (3) resulting in new applications for our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We may not be able to obtain regulatory approval for any new applications we develop. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that we will achieve meaningful sales of such products or applications.

**Employees**

As of December 31, 2005, we had approximately 65 full-time 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, MA. We have not been named and are not a party to any such 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.

**Recent Developments**

In November 2005, the Centers for Medicare and Medicaid Services (CMS) announced they would not implement their previous decision to merge into a single J code all HA products designed for treatment of osteoarthritis, and that the same J codes used in 2005 would continue to be used in 2006. As a result, the Company expects physician reimbursement for OrthoVisc in 2006 to continue to be covered under a miscellaneous J code.

In January 2006, the Company announced Mr. Raymond J. Land s appointment to the board of directors as an independent director, and Mr. Samuel F. McKay s retirement from the board of directors. Mr. Land was also appointed chairman of the audit committee.

**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 Form 10-K.

**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 Form 10-K, and in the documents incorporated by reference into this 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, 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 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.

Our HA products under development, including a product for the cosmetic tissue augmentation market (CTA), and INCERT®, a product designed to prevent surgical adhesions, have not obtained U.S. regulatory approval for commercial marketing and sale. We received *Conformité Européenne* marking (CE marking), a foreign regulatory approval for commercial marketing and sale, for INCERT in the third quarter of 2004. We received CE marking approval for CTA in the first quarter of 2006. In addition, we filed a pre-market approval application in September 2005 for our CTA product. We cannot assure you that:

- we will begin or successfully complete U.S. clinical trials for these products;
- the clinical data will support the efficacy of these products;
- we will be able to successfully complete the FDA or foreign regulatory approval process, where required; or

- additional clinical trials will support a PMA application and/or FDA approval or other foreign regulatory approvals, where required, in a timely manner or at all.

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 standards, 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, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Changes in manufacturing procedures or methods of manufacturing that may affect safety and effectiveness may be deemed approved after a 30-day notice unless the FDA requests a 135-day supplement. 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. 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 us and our facilities from time to time to determine whether we are in compliance with regulations relating to medical device and manufacturing 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 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, withdrawal of approvals and criminal prosecution.

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, 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.

***Substantial competition could materially affect our financial performance.***

We compete with many companies, including, among others, large pharmaceutical companies and specialized medical products companies. Many of these companies have substantially greater financial and other resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations that may be involved in research, development and commercialization of products. Because a number of companies are developing or have developed HA products for similar applications and have received FDA approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to 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 for the treatment of osteoarthritis in the knee have received FDA approval before us and have been marketed in the U.S. since 1997, as well as select markets in Canada, Europe and other countries. In early 2004 the FDA approved two HA products for the treatment of facial wrinkles which has been marketed internationally since 1996. 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 will require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. We completed a pilot human clinical trial in Europe for INCERT-S in December 2005 and completed a pivotal clinical trial for our product for CTA in October 2005. There can be no assurance that we will be able to successfully complete the U.S. regulatory approval process for either INCERT-S or our CTA product. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate the clinical trials. In addition, we cannot make any assurance that such clinical trials, if completed, will ultimately demonstrate these products to be safe and efficacious.

***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 partners and the terms and conditions of our relationships with such marketing partners.

We cannot assure you that such marketing partners will not seek to renegotiate their current agreements on terms less favorable to us. Under the terms of the 2004 B&L Agreement, effective December 15, 2004, we will continue to be Bausch & Lomb s exclusive global supplier (other than with respect to Japan) of AMVISC and AMVISC Plus ophthalmic viscoelastic products. The B&L Agreement expires December 31, 2010, and superseded an existing supply contract with Bausch & Lomb that was set to expire December 31, 2007. The new contract 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. In addition, under certain circumstances, Bausch & Lomb has the right to terminate the agreement, and/or the agreement may revert to a non-exclusive basis; in each case, we cannot make any assurances that such circumstances will not occur. For the years ended December 31, 2005 and 2004, sales of AMVISC products to Bausch & Lomb accounted for 31% and 32% of total revenues, respectively.

Our distributor for CoEase, Advanced Medical Optics, completed its previously announced acquisition of the surgical ophthalmology business of Pfizer, Inc. in June 2004, which includes a competing line of viscoelastic products for use in ocular surgery. As a result, our agreement with Advanced Medical Optics was not renewed and terminated in June 2005 upon its expiration. Sales to Advanced Medical Optics were less than 1% of total revenue for 2005 compared to 8% of total revenue for 2004 or approximately $2.2 million. As a result, in the future we may not be able to sustain current product revenue levels in our ophthalmic business.

We have entered into various agreements for the distribution of ORTHOVISC internationally which are subject to termination under certain circumstances. 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.

In December 2003 we entered into a ten-year licensing and supply agreement with Ortho Biotech Products, L.P., a member of the Johnson & Johnson family of companies, to market ORTHOVISC in the U.S. and Mexico. This agreement was assigned to DePuy Mitek, Inc. in mid-2005. Under this Agreement, DePuy Mitek performs sales, marketing and distribution functions. Additionally, DePuy Mitek has the right under certain circumstances, to further develop and commercialize ORTHOVISC as well as other new products for the treatment of pain associated with osteoarthritis based on our viscosupplementation technology. We cannot assure you that Depuy Mitek will be able to market ORTHOVISC effectively or to establish sales levels to the extent that Anika and Depuy Mitek believe are possible in the timeframes expected, or at all, nor can we assure you that we will be able to achieve the performance- and sales- based milestones provided in the JNJ Agreement. For the year ended December 31, 2004, sales of ORTHOVISC to Depuy Mitek and royalties tied to end-user sales accounted for 18% of total revenue. Furthermore, we cannot predict whether the license granted to Depuy Mitek in the JNJ Agreement to further develop and commercialize ORTHOVISC products for the treatment of pain associated with osteoarthritis based on our viscosupplementation technology will result in any new products or indications for use.

On July 26, 2004, we announced the signing of an exclusive worldwide development and commercialization partnership with OrthoNeutrogena a division of Ortho-McNeil Pharmaceuticals, Inc., an affiliate of Johnson & Johnson, for our CTA therapy products. On September 1, 2005, the Company

announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement, and that we were seeking a new worldwide distribution partner. Also on September 1, 2005, we announced we had filed our PMA with the FDA seeking approval to market and sell our CTA product in the United States. There can be no assurance that we will successfully complete the FDA approval process. If we are able to successfully complete the FDA approval process for our CTA product, we cannot assure you that we will be able to successfully find a distribution partner and commercialize our CTA product effectively, or at all.

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, and third-party payers. Such acceptance may depend upon the extent to which the medical community perceives our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

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

Our 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. In particular, we received notice from the PTO in 1995 that a third party was attempting to provoke a patent interference with respect to one of our co-owned patents covering the use of INCERT for post-surgical adhesion prevention. It is unclear whether an interference will be declared. If an interference is declared it is not possible at this time to determine the merits of the interference or the effect, if any, the interference will have on our marketing of INCERT for this use. No assurance can be given that we would be successful in any such interference proceeding. If the third-party interference were to be decided adversely to us, involved claims of our patent would be cancelled, our marketing of the INCERT product may be materially and adversely affected and the third party may enforce patent rights against us which could prohibit the sale and use of INCERT products, which could have a material adverse effect on our future operating results.

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

Pursuant to the 2004 B&L Agreement, we have agreed to transfer to Bausch & Lomb, upon expiration of the term of the 2004 B&L agreement on December 31, 2010, or in connection with earlier termination in certain circumstances, our manufacturing process, know-how and technical information, which relate to only AMVISC products. Upon expiration of the 2004 B&L Agreement, there can be no assurance that Bausch & Lomb will continue to use us to manufacture AMVISC and AMVISC Plus. If Bausch & Lomb discontinues the use of us as a manufacturer after such time, our business, financial condition, and results of operations would likely be materially and adversely affected.

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

Our results of operations are dependent upon the continued operation of our manufacturing facility in Woburn, Massachusetts. 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 syringes 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 and in the future regulatory authorities could 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 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;
- 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 to the reimbursement status of newly approved health care products, and any failure or delay in obtaining reimbursement approvals can negatively impact sales or 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. Lack of adequate coverage and reimbursement provided by governments and other third party payers for our products and services, including continued classification by CMS of ORTHOVISC under a miscellaneous J-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 $44.7 million at December 31, 2005. 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 ORTHOVISC under the JNJ Agreement;
- the successful commercialization of products in development;
- progress in our product development efforts;
- the magnitude and scope of such product development efforts;
- 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 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; and
- the cost of maintaining adequate inventory levels to meet current and future product demands.

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

***We 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 scientific personnel.***

We are highly dependent on the members of our management and scientific staff, the loss of one or more of whom could have a material adverse effect on us. We experienced a number of management changes in 2004 and 2005. 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, scientific, 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 regulation and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.***

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

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

During the years ended December 31, 2005 and 2004, approximately, 43% and 30%, 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 adopted a Shareholders Rights Plan in April 1998. We are also subject to Chapter 110F of the Massachusetts General Laws which, subject to certain exceptions, prohibits a Massachusetts corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date that such stockholder became an interested stockholder. These provisions could discourage a third party from pursuing a takeover of us at a price considered attractive by many stockholders, since such provisions could have the effect of preventing or delaying a potential acquirer from acquiring control of us and our Board of Directors.

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

We have historically derived the majority of our revenues from a small number of customers, most of whom resell our products to end users and most of whom are significantly larger companies than us. For the year ended December 31, 2005, three customers accounted for 78% of product revenue. While it is expected that our ability to market ORTHOVISC in the U.S. will reduce our dependence on revenues from Bausch & Lomb, historically our largest customer, we will still 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, we may be subject to the perceived or actual leverage the customers may have given their relative size and importance to us in any future negotiations. 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.

***Additional costs for complying with recent and proposed future changes in Securities and Exchange Commission, Nasdaq Stock Market and accounting rules could adversely affect our profits.***

Recent and future changes in the Securities and Exchange Commission and Nasdaq rules, as well as changes in accounting rules, will cause us to incur additional costs including professional fees, as well as additional personnel costs, in order to keep informed of the changes and operate in a compliant manner. In addition, we have and continue to expect to incur general and administrative expense as we maintain compliance with Section 404 of the Sarbanes-Oxley Act of 2002, which requires management to report on, and our independent registered public accounting firm to attest to, our internal controls. These costs may be significant enough to cause our financial position and results of operations to be negatively impacted. In addition, compliance with these new rules could also result in continued diversion of management s time and attention, which could prove to be disruptive to our normal business operations. Failure to comply with any of the new laws and regulations could adversely impact market perception of our company, which could make it difficult to access the capital markets or otherwise finance our operations in the future.

***With new rules, including the Sarbanes-Oxley Act of 2002, we may have difficulty in retaining or attracting directors for the board and various sub-committees thereof or officers.***

The recent changes in SEC and Nasdaq rules, including those resulting from the Sarbanes-Oxley Act of 2002, may result in our being unable to attract and retain the necessary board directors and members of sub-committees thereof or officers, to effectively provide for our management. The perceived increased personal risk associated with these recent changes may deter qualified individuals from wanting to participate in these roles.

***We may have difficulty obtaining adequate directors and officers insurance and the cost for coverage may significantly increase.***

We may have difficulty in obtaining adequate directors and officers insurance to protect us and our directors and officers from claims made against them. Additionally, even if adequate coverage is available, the costs for such coverage may be significantly greater than current costs. This additional cost may have a significant effect on our profits and as a consequence our results of operations may be adversely affected.

## 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 2005 fiscal year and that remain unresolved.

## ITEM 2. PROPERTIES

Our corporate headquarters is located in Woburn, Massachusetts, where we lease approximately 10,000 square feet of administrative and research and development space. We extended our lease for this facility in 2004 for a term ending in December 2006. We also lease approximately 37,000 square feet of space at a separate location in Woburn, Massachusetts, for our manufacturing facility and warehouse. This facility has received all FDA and state regulatory approvals to operate as a sterile device and drug manufacturer. We extended our lease for this facility in 2003 for an additional five-year term ending in February 2009. For the year ended December 31, 2005, we had aggregate lease costs of approximately $724,000.

## ITEM 3. LEGAL PROCEEDINGS

None.

## 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.

**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 National 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 National Market. These prices represent prices between dealers and do not include retail mark-ups, markdowns, or commissions and may not necessarily represent actual transactions.

| Year Ended December 31, 2005 | High | Low |
|---|---|---|
| First Quarter | $13.49 | $8.05 |
| Second Quarter | 17.21 | 11.06 |
| Third Quarter | 14.49 | 10.13 |
| Fourth Quarter | 13.45 | 10.15 |

| Year Ended December 31, 2004 | High | Low |
|---|---|---|
| First Quarter | $ 11.87 | $ 6.48 |
| Second Quarter | 17.87 | 8.18 |
| Third Quarter | 17.45 | 10.01 |
| Fourth Quarter | 15.75 | 7.89 |

At December 31, 2005, the closing price per share of our common stock was $11.69 as reported on the Nasdaq National Market and there were approximately 253 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, 2005.

| | Equity Compensation Plan Information | | |
|---|---|---|---|
| Plan category | Number of securities to be issued upon exercise of outstanding options,warrants and rights (a) | Weighted Average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
| Equity compensation plans approved by security holders | 1,797,344 | $ 5.80 | 625,576 |
| Equity compensation plans not approved by security holders | | | |
| Total | 1,797,344 | $ 5.80 | 625,576 |

**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. The Balance Sheet Data at December 31, 2005 and 2004 and the Statement of Operations Data for each of the three years ended December 31, 2005 have been derived from the audited Consolidated Financial Statements for such years, included elsewhere in this Annual Report. The Balance Sheet Data at December 31, 2003, 2002 and 2001, and the Statement of Operations Data for each of the two years in the period ended December 31, 2002 have been derived from the audited Consolidated Financial Statements for such years, not included in this Annual Report.

The Consolidated Financial Statements for fiscal year 2001 were audited by Arthur Andersen LLP (Andersen) who has ceased operations.

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

| | Years ended December 31, | | | | |
|---|---|---|---|---|---|
| | **2005** | **2004** | **2003** | **2002** | **2001** |
| Product revenue | $ 20,534 | $ 22,286 | $ 15,330 | $ 13,129 | $ 11,299 |
| Licensing, milestone and contract revenue | 9,301 | 4,180 | 74 | 58 | 13 |
| Total revenue | 29,835 | 26,466 | 15,404 | 13,187 | 11,312 |
| Cost of product revenue | 11,144 | 9,949 | 8,005 | 8,109 | 8,229 |
| Product gross profit | 9,390 | 12,337 | 7,325 | 5,020 | 3,070 |
| Product gross margin | 46 % | 55 % | 48 % | 38 % | 27 % |
| Total operating expenses | 21,284 | 20,078 | 14,809 | 16,462 | 18,723 |
| Net income (loss) | $ 5,893 | $ 11,190 | $ 827 | $ (3,040 ) | $ (6,758 ) |
| Diluted net income (loss) per common share | $ 0.52 | $ 0.98 | $ 0.08 | $ (0.31 ) | $ (0.68 ) |
| Diluted common shares outstanding | 11,428 | 11,384 | 10,850 | 9,934 | 9,934 |

**Balance Sheet Data**
**(In thousands)**

| | December 31, | | | | |
|---|---|---|---|---|---|
| | **2005** | **2004** | **2003** | **2002** | **2001** |
| Cash and cash equivalents | $ 44,747 | $ 39,339 | $ 14,592 | $ 11,002 | $ 9,065 |
| Marketable securities | | | | 2,500 | 3,994 |
| Working capital | 46,584 | 42,135 | 18,450 | 14,921 | 16,756 |
| Total assets | 62,618 | 59,538 | 21,873 | 20,087 | 22,916 |
| Retained earnings (accumulated deficit) | 3,514 | (2,379 ) | (13,569 ) | (14,396 ) | (11,357 ) |
| Treasury stock | | | (27 ) | (280 ) | (280 ) |
| Stockholders equity | 37,892 | 30,363 | 17,984 | 17,064 | 20,104 |

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 termination payment of $3.1 million from ONI including $0.8 million for all outstanding clinical study costs incurred and committed to by the Company at the termination date. Given that there was 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.

We received an initial payment of $2.0 million in December 2003 upon entering into the JNJ Agreement. In February 2004 we received a milestone payment of $20.0 million as a result of obtaining FDA approval for ORTHOVISC, and in December 2004 we received a milestone payment of $5.0 million upon completion of certain manufacturing upgrades. We are recognizing these non-refundable payments as license revenue ratably over the expected term of the JNJ Agreement, which is currently 10 years, and as of December 31, 2005, we had recorded deferred revenue of $21.6 million related to the JNJ Agreement.

**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 the heading Business and 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 and healing. 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, STAARVISCs -II, and ShellGel , each an injectable ophthalmic viscoelastic HA product; and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. 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 US, ORTHOVISC has been approved for sale since 1996 and is marketed by distributors in over 15 countries. HYVISC is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement.

Products in development include REDEFYNE , an HA based dermal filler used for cosmetic tissue augmentation (CTA) applications, and INCERT®, an HA based anti-adhesive for surgical applications. In September 2005, we filed a Pre-Market Approval (PMA) application with the FDA seeking approval to market and sell REDEFYNE in the United States. We received *Conformité Européenne* marking (CE marking), a foreign regulatory approval for commercial marketing and sale, for INCERT in the third quarter of 2004. We received CE marking approval for CTA in the first quarter of 2006.

*Osteoarthritis Business*

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 31% of product revenue for the year ended December 31, 2005 and increased 56% compared to 2004. The increase was primarily due to increased market penetration in Turkey, Canada, Europe and the Middle East. We expect international sales to grow in 2006 compared to 2005 reflecting further increased market penetration in certain of our existing markets as well as anticipated expansion into new international markets. For these new opportunities we have assessed the world market and we are actively pursuing commercial partners.

As discussed in Part 1 above, ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is marketed by DePuy Mitek, Inc., a subsidiary of Johnson & Johnson, under the terms of a ten-year licensing, distribution, supply and marketing agreement (the JNJ Agreement ). The JNJ Agreement was

originally entered into with Ortho Biotech Products, L.P. (OBP), also a Johnson & Johnson company, and was assigned to DePuy Mitek in mid-2005. Sales of ORTHOVISC in the U.S. contributed 8% of our product revenue for the year ended December 31, 2005, considerably lower than 2004 due to initial overstocking of product by OBP in 2004. Consequently no units were sold to OBP/DePuy Mitek after March of 2005, however inventory levels have now been reduced to the point where a more regular order flow is expected for 2006.

Sales of ORTHOVISC to end-users grew slower than anticipated in 2004 and 2005 as a result of a number of factors. We believe that a primary contributing factor to this slower growth has been reimbursement and the lack of receiving assignment of a specific reimbursement code. The Healthcare Common Procedure Coding System (HCPCS) is a comprehensive and standardized coding system that describes classifications of like products that are medical in nature by category for the purpose of efficient claims processing. HCPCS codes are assigned by the Centers for Medicare and Medicaid Services (CMS). As is typical for a newly-introduced medical device, initial sales of ORTHOVISC were made without a unique reimbursement code and reimbursement submissions were made using a miscellaneous code with no specified reimbursement dollar value. We believe that using the miscellaneous reimbursement code without a specified reimbursement dollar value negatively impacted end-user sales of ORTHOVISC in 2004 and 2005. Ortho Biotech, with our help, submitted an application to secure a unique reimbursement code for ORTHOVISC in March 2004. In November 2004, Ortho Biotech received a decision on the application which assigned a unique reimbursement code to be used by hospitals in an outpatient setting (the C code) which specifies a reimbursement dollar value. Use of the C code was effective in January 2005. The CMS decision, however, did not assign a unique reimbursement code to be used in the physician office setting (the J code) as at the time we did not yet have six months of sales history required by CMS to make a decision. An updated application for a unique J code was submitted in January 2005. In late October 2005, CMS issued a new J code - J7318, which was to include all FDA approved HA based products for the treatment of osteoarthritis of the knee, for use starting on January 1, 2006. In early November 2005, CMS announced they wanted to further study the situation and therefore would not implement the October decision, and that the codes used in 2005 were to continue to be used in 2006. As a result, we expect reimbursement for ORTHOVISC in the physician office setting to continue to use a miscellaneous J code. The continued required use of a miscellaneous J code may result in physician reluctance to utilize ORTHOVISC as compared to if a unique J code had been assigned. There can be no assurance regarding the future course CMS will set for ORTHOVISC reimbursement. While the J code has no effect on product pricing, the Mitek team is taking significant steps to assist in the reimbursement process in physicians offices. At the end of the year, Mitek had a specialty sales force of about 13 professionals to support the sales representatives and provide hands-on assistance to the physicians offices. Mitek plans to significantly increase the number of specialists in 2006. Mitek also has developed a Web site for physicians office personnel as a resource for reimbursement issues.

Sales of HYVISC, our product for the treatment of equine osteoarthritis, contributed 10% to product revenue for the year ended December 31, 2005 and was essentially flat compared to 2004. We continue to look at other veterinary applications and opportunities to expand geographic territories.

*Ophthalmic Business*

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. For the year ended December 31, 2005, sales of ophthalmic products contributed 51% of our product revenue reflecting a decrease in sales of ophthalmic products of 9% compared to 2004. Sales to Bausch & Lomb accounted for 89% of ophthalmic sales for 2005 and contributed 46% of product revenue for the period.

Our former distributor for CoEase, Advanced Medical Optics ( AMO ), completed the acquisition of the surgical ophthalmology business of Pfizer, Inc., in September 2004, which included a competing line of viscoelastic products for use in ocular surgery. As a result, our agreement with AMO expired according to

its terms in June 2005. There were no sales to AMO in the second half of 2005. Sales to AMO decreased 89% for 2005 compared to last year. Sales to AMO contributed 19% of ophthalmic product revenue and 10% of total product revenue for the year ended December 31, 2004.

In December 2004, we entered into a multi-year supply agreement (the 2004 B&L Agreement) with Bausch & Lomb for viscoelastic products used in ophthalmic surgery. Under the new agreement, which extends through December 31, 2010, and superseded the existing supply contract that was set to expire December 31, 2007, 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. The 2004 B&L Agreement applies to all products sold by us to Bausch & Lomb from the beginning of 2004, with a price increase starting in 2005. 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.

*Research and Development*

REDEFYNE , our product for cosmetic tissue augmentation (CTA), is based on a family of chemically modified, cross-linked forms of HA designed for longer duration in the body. Cosmetic tissue augmentation is a therapy designed as a soft tissue filler for facial wrinkles, scar remediation and lip augmentation. This new class of tissue filler technology based on HA is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. In October 2005, we completed a pivotal U.S. clinical trial to evaluate CTA s effectiveness for correcting nasolabial folds. The trial was conducted by dermatologists and plastic surgeons at 10 centers throughout the U.S. The six month primary endpoint results of this trial were submitted to the U.S. Food and Drug Administration ( FDA ) in a Pre-Market Approval ( PMA ) application in September 2005. In the first quarter of 2006, we received CE mark approval to market REDEFYNE in the European Union.

In July 2004 we entered into an exclusive worldwide development and commercialization partnership (the OrthoNeutrogena Agreement) for our CTA products with the OrthoNeutrogena division of Ortho-McNeil Pharmaceuticals, Inc., an affiliate of Johnson & Johnson. Under the terms of the OrthoNeutrogena Agreement, we received an initial payment of $1,000,000. In addition, OrthoNeutrogena, subject to certain limitations, funded our pivotal clinical trial of our CTA product completed in October 2005. On September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement, and as noted above, we filed our PMA with the FDA seeking approval to market and sell our CTA product in the United States. The Company will continue the development effort on a go-forward basis which will be self-funded. We are currently seeking a worldwide distribution partner for this product.

INCERT-S is our product designed to reduce post-surgical fibrosis following spinal surgery. We completed a pilot human clinical trial in Europe in December 2005 involving patients undergoing spinal surgery, and demonstrated safety.

**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, 2005.

*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*.

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. ORTHOVISC has been sold through several distribution arrangements as well as outsource order-processing arrangements (logistic agents). Sales of product through third party logistics agents in certain markets are recognized as revenue upon shipment by the logistics agent to the customer.

Under the 2000 B&L Agreement, the price for units sold in a calendar year was dependent on total unit volume of sales to Bausch & Lomb and other customers of certain ophthalmic products during the year. Prices fluctuated based on sales levels, and interim quarters were subject to possible retroactive price adjustments when the actual annual unit volume for the year became known. Given the pricing in this arrangement was not fixed and was determined based on qualifying sales to multiple customers, we determined that we could not reliably estimate the rebate, and accordingly, we deferred the maximum rebate that could be due until the annual sales volume was known in the fourth quarter. Under the 2004 B&L Agreement, the pricing is based solely on ophthalmic products sold to Bausch & Lomb. While the unit prices will be discounted for those units in excess of cumulative quarterly minimum sales levels, no additional amounts will be rebated. Starting in the 2005 first quarter, the applicable discount has been measured quarterly, subject to adjustment based on cumulative annual thresholds.

In July 2004 the Company entered into an exclusive worldwide development and commercialization agreement (the OrthoNeutrogena Agreement) for our CTA products with the OrthoNeutrogena, a division of Ortho-McNeil Pharmaceuticals, Inc., an affiliate of Johnson & Johnson. This arrangement included up front payments, specified funding of ongoing development activities, milestones upon achievement of predefined goals, and payments for supply of CTA products and royalties on sales. Under the EITF 00-21 framework, 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. While this arrangement included several elements, we believed that two separate units of accounting existed (a combined license and development unit and a manufacturing unit) under the EITF 00-21 model. We accounted for the combined license and development unit using the performance

based revenue recognition model. Pursuant to this model, we estimated both the total revenues we expected to earn and the expenses we expected to incur related to the license and development unit. We recognized revenue based on the proportion of effort expended to total estimated effort, limited to the amount of non-refundable cash received or receivable. Quarterly, we reviewed our estimates of total revenue and expenses related to the license and development unit. Actual revenue earned and/or expenses incurred may differ from our estimates and may have a material effect upon our results of operations.

Under the OrthoNeutrogena Agreement, we received non-refundable upfront fees of $1,000,000 and reimbursement for approximately $1,305,000 of costs which we incurred prior to the inception date of this agreement. We have treated both these amounts as upfront fees that we recognized over the expected term of the license and development unit. In addition to the upfront fees, we received reimbursement of pre-approved development costs. For 2004, we recognized $1,392,000 as contract revenue under this arrangement pursuant to the performance-based model. For the six months ended June 30, 2005 we recognized an additional $3,167,000 as contract revenue under this arrangement pursuant to the performance-based model. On September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement. The Company received a payment of $3,115,000 from ONI including a $2,300,000 contract termination fee. 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 during the third quarter of 2005, including $251,000 of previously deferred revenue under the performance-based model. Total contract revenue recognized during 2005 related to the agreements with OrthoNeutrogena was $6,537,000.

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. We 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, we have deferred non refundable payments received of $27,000,000 which we are recognizing ratably over the expected 10 year term of the JNJ Agreement. Under the JNJ Agreement, we are the exclusive supplier of ORTHOVISC to Depuy Mitek, Inc. a subsidiary of Johnson& Johnson. The JNJ Agreement provides for additional sales-based milestone payments to us contingent upon achieving specified sales targets, in addition to royalty and transfer fees. The JNJ Agreement is subject to early termination in certain circumstances and is otherwise renewable by DePuy Mitek for consecutive five-year terms.

*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.

*Deferred tax assets.* 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.

In 2004, we achieved milestones under the JNJ Agreement and received payments totaling $25,000,000 which we recognized as taxable income in 2004. As a result, we utilized all of our net operating loss and credit carry-forwards in our 2004 tax return to offset part of our taxable income. In accordance with our revenue recognition policy, for financial statement purposes, the milestone payments totaling $25,000,000 were deferred and are being recognized ratably over the expected ten-year term of the JNJ Agreement. In 2004, based on management s expectations regarding future profitability, we released the valuation allowance previously established against our deferred tax assets and recorded a one-time income tax benefit of $7,039,000.

**Results of Operations**

***Year ended December 31, 2005 compared to year ended December 31, 2004***

*Statement of Operations Detail*

| | Year Ended December 31, | |
|---|---|---|
| | **2005** | **2004** |
| Product revenue | $ 20,534,000 | $ 22,286,000 |
| Licensing, milestone and contract revenue | 9,301,000 | 4,180,000 |
| Total revenue | 29,835,000 | 26,466,000 |
| Operating Expenses: | | |
| Cost of product revenue | 11,144,000 | 9,949,000 |
| Research and development | 4,731,000 | 4,087,000 |
| Selling, general and administrative | 5,409,000 | 6,042,000 |
| Total operating expenses | 21,284,000 | 20,078,000 |
| Income from operations | 8,551,000 | 6,388,000 |
| Interest income | 1,241,000 | 389,000 |
| Income before income taxes | 9,792,000 | 6,777,000 |
| Provision for income taxes | 3,899,000 | 2,626,000 |
| Benefit from release of valuation allowance | | (7,039,000) |
| Net income | $ 5,893,000 | $ 11,190,000 |
| Product gross profit | $ 9,390,000 | $ 12,337,000 |
| Product gross margin | 46% | 55% |

*Net and operating income.* For the year ended December 31, 2005 income from operations was $8,551,000 compared to $6,388,000 for 2004. The primary driver for the improved operating performance was $6,537,000 of contract and termination revenue recorded in the third quarter of 2005, which is discussed in more detail hereunder. Net income for 2005 was $5,893,000 or $.52 per diluted share compared to $11,190,000 or $.98 per diluted share for the same period last year. The 2004 net income benefited from the release of valuation allowance in the amount of $7,039,000 or $.62 per diluted share.

*Revenue* Total revenue for the year ended December 31, 2005 increased $3,369,000 to $29,835,000 compared to $26,466,000 for 2004 primarily due to the receipt of $2,300,000 in connection with the termination of the OrthoNeutrogena agreement. However, product revenue for 2005 decreased $1,752,000 to $20,534,000 for two primary reasons. Sales of ORTHOVISC to DePuy Mitek in 2005 were significantly lower than in 2004 due to overstocking of inventory by JNJ in 2004, and Advanced Medical Optics did not renew their contract with us as they

acquired a competing line of viscoelastic products for use in ocular surgery. See below for further details.

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*Product revenue by product line.* Product revenue for the year ended December 31, 2005 was $20,534,000, a decrease of $1,752,000, or 8%, compared with $22,286,000 for the year ended December 31, 2004.

| | Year Ended December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Ophthalmic Products | $ 10,522,000 | $ 11,533,000 |
| ORTHOVISC | 7,938,000 | 8,699,000 |
| HYVISC | 2,074,000 | 2,054,000 |
| | $ 20,534,000 | $ 22,286,000 |

Ophthalmic products sales decreased $1,011,000, or 9%, to $10,522,000. The decrease was primarily attributable to the loss of business from Advanced Medical Optics. Sales to Advanced Medical Optics decreased to $249,000 from $2,195,000, or 89%, in 2005 compared to last year, and contributed only 2% of ophthalmic product revenue for 2005 versus 19% in 2004. The decrease in sales to Advanced Medical Optics was attributable to Advanced Medical Optics acquisition of a competing line of viscoelastic products for use in ocular surgery. Our agreement with Advanced Medical Optics expired according to its terms in June 2005. This decrease was partially offset by increased sales to Bausch & Lomb and, to a lesser extent, to increased sales to each of our other ophthalmic customers.

Our sales of ORTHOVISC decreased $761,000, or 9%, to $7,938,000 in 2005 as compared with $8,699,000 in 2004. The decrease in ORTHOVISC sales for 2005 was primarily due to overstocking of inventory by JNJ in 2004. This resulted in substantially lower purchases of ORTHOVISC by JNJ from the Company in 2005. This domestic decrease was partially offset by continued robust international sales. U.S. sales of ORTHOVISC were $1,643,000, or 8% of product sales, in 2005 compared to $4,669,000, or 21% of product sales, in 2004. The impact of the decrease in unit sales was partially offset by a 32% increase in royalty fees tied to end-user sales, and increased international sales. International sales of ORTHOVISC increased to $6,296,000 from $4,030,000, or 56% in 2005 compared to the same periods last year. The increase in international sales was primarily attributable to increased market penetration by our distributors in Turkey, Canada, Western Europe and Middle East countries. We expect both U.S. and international sales to increase in 2006 compared to 2005 reflecting increased market penetration in certain of our existing markets as well as expansion into new international markets.

Sales of HYVISC were essentially flat in 2005 as compared to 2004 and represented 10% and 9%, respectively, of product sales. Sales of HYVISC are made to a single customer under an exclusive agreement which expires in May 2006. We expect this agreement to be renewed.

*Licensing, milestone and contract revenue.* Licensing, milestone and contract revenue for the year ended December 31, 2005 was $9,301,000, compared to $4,180,000 for 2004. 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 $675,000 per quarter. Contract revenue was $6,537,000 for 2005, compared to $1,296,000 in 2004. Revenue in 2005 consisted of $4,237,000 for reimbursement of clinical and development costs due under the OrthoNeutrogena contract, and a $2,300,000 termination fee to exit the contract. As previously discussed, on September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement. All amounts due and contractual obligations by both parties have been satisfied.

*Product gross profit.* Product gross profit for the year ended December 31, 2005 was $9,390,000, or 46% of product revenue, compared with $12,337,000, or 55% of product revenue, for the year ended December 31, 2004. The decrease in product gross margin was mainly due to three factors: the cost impact of a midyear product recall totaling $370,000, a lower margin product mix, and volume based

inefficiencies in our manufacturing process. We expect product gross margin to improve in 2006 compared to 2005 reflecting improved product mix and higher manufacturing volume, partially offset by the impact of the implementation of stock option expensing in 2006 under SFAS 123R.

*Research and development.* Research and development expenses for the year ended December 31, 2005 increased by $644,000, or 16%, to $4,731,000 from $4,087,000 for the prior year. Research and development expenses include those costs associated with our in-house research and development efforts for the development of new medical applications for our HA-based technology, the management and cost of clinical trials, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. The increase in research and development expenses during 2005 was primarily attributable to expenditures associated with the pivotal clinical trial for our CTA product initiated in 2004 and completed in late 2005, as well as engineering and scale-up activities in preparation for the manufacture of our CTA product. The Company filed a PMA application with the FDA based on the results of this clinical trial. We expect research and development expenses will increase in the future related to follow on CTA clinical trials, next generation ORTHOVISC products, and other research and development programs in the pipeline, as well as from the impact of the implementation of stock option expensing in 2006 under SFAS 123R.

*Selling, general and administrative.* Selling, general and administrative expenses for the year ended December 31, 2005 decreased by $633,000 or 10%, to $5,409,000 from $6,042,000 in the prior year. The decrease was primarily due to lower business development expenses and professional fees related to Sarbanes Oxley, which were partially offset by higher fees related to recruiting. The Company expects that selling, general and administrative expenses will increase in the future related to headcount increases, recruiting costs, strategic planning efforts, and infrastructure expansion, as well as from the impact of implementation of stock option expensing in 2006 under SFAS 123R.

*Interest income.* Interest income increased $852,000, or 219%, to $1,241,000 for the year ended December 31, 2005, from $389,000 in 2004. The increase was primarily attributable to higher average available cash and invested balances during 2005 as well as increasing interest rates. Interest income in 2006 is expected to increase as a result of higher average cash and investment balances.

*Income taxes.* Income tax provision for 2005 is $3,899,000 versus a net tax benefit of $4,413,000 recorded for 2004. The 2004 net benefit was comprised of a provision for income taxes of $2,626,000 offset by a $7,039,000 benefit resulting from the release of the valuation allowance. As a result of the receipt of the $25,000,000 in milestone payments in 2004 from Ortho Biotech, our recent operating results, and forecasted future income, together supported an assertion that ultimate realization of our deferred tax assets was more likely than not at December 31, 2004. Accordingly, the Company fully released the valuation allowance during 2004 and correspondingly recorded a one-time tax benefit of $7,039,000 or $.62 per fully diluted share.

***Year ended December 31, 2004 compared to year ended December 31, 2003***

***Statement of Operations Detail***

| | Year Ended December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Product revenue | $ 22,286,000 | $ 15,330,000 |
| Licensing, milestone and contract revenue | 4,180,000 | 74,000 |
| Total revenue | 26,466,000 | 15,404,000 |
| Operating Expenses: | | |
| Cost of product revenue | 9,949,000 | 8,005,000 |
| Research and development | 4,087,000 | 2,595,000 |
| Selling, general and administrative | 6,042,000 | 4,209,000 |
| Total operating expenses | 20,078,000 | 14,809,000 |
| Income from operations | 6,388,000 | 595,000 |
| Interest income | 389,000 | 144,000 |
| Income before income taxes | 6,777,000 | 739,000 |
| Provision for income taxes | 2,626,000 | (88,000) |
| Benefit from release of valuation allowance | (7,039,000) | |
| Net income | $ 11,190,000 | $ 827,000 |
| Product gross profit | $ 12,337,000 | $ 7,325,000 |
| Product gross margin | 55% | 48% |

*Product revenue.* Product revenue for the year ended December 31, 2004 was $22,286,000, an increase of $6,956,000, or 45%, compared with $15,330,000 for the year ended December 31, 2003.

| | Year Ended December 31, | |
|---|---|---|
| | 2004 | 2003 |
| Ophthalmic Products | $ 11,533,000 | $ 10,512,000 |
| ORTHOVISC | 8,699,000 | 3,073,000 |
| HYVISC | 2,054,000 | 1,745,000 |
| | $ 22,286,000 | $ 15,330,000 |

Ophthalmic products sales increased $1,021,000, or 10%, to $11,533,000 compared with sales of $10,512,000 in 2003. The increase was primarily attributable to increased sales to Bausch & Lomb and, to a lesser extent, to increased sales to each of our other ophthalmic customers. In December 2004, the company entered into the 2004 B&L Agreement which, among other things, established reduced unit pricing to Bausch & Lomb for units purchased in 2004 in excess of a specified volume. Under the terms of the 2000 B&L Agreement, which was replaced by the 2004 B&L Agreement in December 2004, the price for all units sold for a calendar year was dependent on the total unit volume of sales of certain ophthalmic products during the year. Accordingly, unit prices for sales occurring in the nine months ended September 30, 2004 and 2003 were subject to possible retroactive price adjustments when the actual annual unit volume became known. In accordance with our revenue recognition policy, the amount of revenue reasonably subject to the price adjustment was recorded as deferred revenue until the annual unit volume became known and the sales price becomes fixed. In the fourth quarter 2004, as a result of entering into the 2004 B&L Agreement, we applied the terms of the 2004 B&L Agreement retroactively to the beginning of 2004 and included in product revenue $761,000 of revenue related to sales of AMVISC to Bausch & Lomb which had been previously deferred during the first three quarters of 2004 and rebated $252,000 to Bausch & Lomb. Under the 2000 B&L Agreement, during the fourth quarter of 2003 the actual annual unit volume, and therefore the final sales price, became known and determinable and

product revenue included the recognition of $846,000 of revenue related to sales of AMVISC to Bausch & Lomb previously deferred during the first three quarters of 2003. Our agreement with Advanced Medical Optics was not renewed as a result of their acquisition of a competing line of viscoelastic products for ophthalmic surgery and expired according to its terms in June 2005. Sales to Advanced Medical Optics contributed 19% of ophthalmic product revenue and 10% of total product revenue for the year ended December 31, 2004.

Our sales of ORTHOVISC increased $5,626,000, or 183%, to $8,699,000 in 2004 as compared with $3,073,000 in 2003. The increase was primarily due to sales to our U.S. distributor, Ortho Biotech, and royalty fees tied to end-user sales. U. S. sales of ORTHOVISC were 21% of product sales for 2004. International sales of ORTHOVISC increased 31% for 2004 to $4,030,000 from $3,073,000 for 2003. The increase was primarily due to increased sales to our Turkey distributor combined with increased sales in Canada and Greece.

Sales of HYVISC increased $309,000, or 18%, to $2,054,000 for 2004 as compared with $1,745,000 for 2003. Sales of HYVISC were made to a single customer under an exclusive agreement which expires in May 2006. We expect this agreement to be renewed. Sales of HYVISC in 2003 included distributor inventory replenishment for certain units shipped without regulatory approval in the third quarter of 2002.

*Licensing, milestone and contract revenue.* Licensing, milestone and contract revenue for the year ended December 31, 2004 was $4,180,000, compared to $74,000 for 2003. Licensing and milestone revenue included the ratable recognition of the $2,000,000 up-front payment and $25,000,000 in milestone payments from Ortho Biotech. These amounts were being recognized in income ratably over the ten-year expected life of the agreement, or $675,000 per quarter. Contract revenue was $1,392,000 for the year ended December 31, 2004. Contract revenue consisted of reimbursement of clinical and development costs from OrthoNeutrogena as well as development-related fees and milestones under the OrthoNeutrogena agreement recorded utilizing a performance-based method for revenue recognition.

*Product Gross profit.* Product gross profit for the year ended December 31, 2004 was $12,337,000, or 55% of revenue, compared with $7,325,000, or 48% of revenue, for the year ended December 31, 2003. The increase in product gross profit on product revenue was mainly due to a higher margin product mix combined with efficiency gains in our manufacturing process. We introduced outsourced intermediates in our manufacturing process for most of our products in 2004 and completed the remaining in early 2005.

*Research and development.* Research and development expenses for the year ended December 31, 2004 increased by $1,492,000, or 57%, to $4,087,000 from $2,595,000 for the prior year. Research and development expenses included those costs associated with our in-house research and development efforts for the development of new medical applications for our HA-based technology, the management and cost of clinical trials, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. The increase in research and development expenses during 2004 was primarily attributable to expenditures associated with the pilot study for INCERT-S initiated in April 2004 and the pivotal clinical trial for our product for cosmetic tissue augmentation initiated in May 2004, including costs associated with the start-up of the clinical trials incurred in the first quarter of 2004. The comparative increase in 2004 was partially offset by the elimination of costs primarily incurred in the first half of 2003 associated with the completion of our pivotal clinical trial for ORTHOVISC.

In 2004, our efforts were primarily related to INCERT, a product designed to prevent surgical adhesions and our products for the CTA market. Our research and development efforts included seeking new applications for the HA molecule as well as our proprietary chemically modified HA and other therapeutics applications of our ORTHOVISC formulation that target osteoarthritis-related ailments.

*Selling, general and administrative.* Selling, general and administrative expenses for the year ended December 31, 2004 increased by $1,833,000 or 44%, to $6,042,000 from $4,209,000 in the prior year. The

increase in selling, general and administrative expenses during 2004 was primarily due to an increase in professional and outside services fees of $1,393,000 combined with an increase in personnel related costs of $403,000 compared with 2003. The increase in professional and outside services fees included an increase in audit and tax fees and consulting fees of $773,000 primarily relating to costs for the implementation and compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

*Interest income.* Interest income increased $245,000, or 170%, to $389,000 for the year ended December 31, 2004, from $144,000 in 2003. The increase was primarily attributable to a higher average cash and investment balances during 2004.

*Income taxes.* A net tax benefit of $4,413,000 was recorded for the year ended December 31, 2004, comprising a provision for income taxes of $2,626,000 offset by a $7,039,000 benefit resulting from the release of the valuation allowance. As a result of the receipt of the $20,000,000 milestone payment in February 2004 and the $5,000,000 milestone payment received in December 2004 from Ortho Biotech, our recent operating results and forecasted future income support an assertion that ultimate realization of our deferred tax assets was more likely than not at December 31, 2004. Accordingly, the Company fully released the valuation allowance during 2004 and correspondingly recorded a one-time tax benefit of $7,039,000.

We recorded a provision for income taxes of $66,000 and an income tax benefit of $154,000 for year ended December 31, 2003. In 2002 federal tax law changed to allow for a five year carryback period and a suspension of certain limitations on the use of alternative minimum tax losses. We filed an income tax carryback claim to carry our 2001 tax loss back to prior tax years. As a result of the carryback claim, in the first quarter of 2003, we received a refund of approximately $154,000 of taxes paid in prior years.

**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 a combination of cash provided by operations, and available cash and investments on hand. 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, 2005, cash and cash equivalents totaled $44.7 million compared to $39.3 million at December 31, 2004, and $14.6 million at December 31, 2003.

We received an initial payment of $2.0 million in December 2003 upon entering into the JNJ Agreement. In February 2004, we received a milestone payment of $20.0 million as a result of obtaining FDA approval for ORTHOVISC and in December 2004 we received a milestone payment of $5.0 million to use for manufacturing upgrades. In July 2004 we received an initial payment of $1.0 million upon entering into the OrthoNeutrogena Agreement. And in September 2005, we received a fee of $2.3 million in connection with the termination of the OrthoNeutrogena Agreement.

Cash provided by operating activities was $6,452,000, $23,824,000 and $2,012,000 for 2005, 2004, and 2003 respectively. Cash provided by operating activities decreased by $17,372,000 from 2004 primarily due to receipts of milestone payments under the JNJ agreement in 2004. Cash provided by operating activities in 2005 resulted primarily from net income of $5,893,000, a decrease in deferred tax assets of $1,911,000, a decrease in inventory of $826,000, tax benefit of $1,080,000 related to exercise of stock options, and net cash of $896,000 from other working capital assets and liabilities. This increase was partially offset by a decrease in deferred revenue of $4,613,000 as a result of milestone payment revenue recognized for the year. Cash provided by operating activities in 2004 resulted primarily from net income of $11,190,000 which includes a one-time non-cash income tax benefit of $7,039,000 from the release of the previously established valuation allowance against our deferred tax assets and an increase in deferred revenue of $24,165,000. The increase in cash provided by operating activities was partially offset by a net increase in

other current assets and liabilities of $1,663,000. The increase in deferred revenue was primarily due to the $25.0 million in milestone payments received in 2004 from Ortho Biotech.

Cash used in investing activities was $1,600,000 in 2005. Cash provided by investing activities was $344,000 and $1,485,000 for 2004 and 2003, respectively. Cash used for investing activities in 2005 was primarily the result of deposits for manufacturing equipment and construction costs to build a new manufacturing suite in connection with our new CTA product currently in development. Net cash flows from investing activities for 2004 includes the release of restricted cash of $818,000 which was partially offset by capital expenditures of $474,000, primarily for manufacturing and computer equipment. In connection with the issuance of an irrevocable letter of credit to one of our vendors we had deposited $818,000 with our bank to collateralize the letter of credit which amount is recorded in restricted cash at December 31, 2003. These funds were restricted from our use during the term of the letter of credit which expired in April 2004. We expect to increase our capital expenditures in 2006 primarily to complete upgrading and expanding our manufacturing and packaging equipment. Total costs related to manufacturing facility upgrades and manufacturing equipment for the CTA product is expected to be approximately $3,500,000, $1,300,000 of which was included in the cash used in investing activities in 2005. The remaining balance is expected to be spent in the first half of 2006.

Cash provided by financing activities of $556,000, $579,000 and $93,000 for 2005, 2004 and 2003, respectively, reflects the proceeds from the exercise of stock options.

*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 November 2004, the FASB issued SFAS 151, Inventory Costs which amends the guidance in Accounting Research Bulletin No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). In addition, SFAS 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS 151 are effective for the first annual reporting period beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the Company s Consolidated Financial Statements.

In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard No. 123R, Share-Based Payment ( SFAS 123R ). This statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based at their fair values. The provisions of this statement were effective for the Company on January 1, 2006. The Company has evaluated the provisions of this statement and determined it will have a material negative effect on consolidated net income. We currently estimate that adoption of the statement will increase 2006 operating expenses by approximately $1,500,000 on a pre-tax basis, for options granted through February 28, 2006, without forfeiture assumptions. We expect additional grants for the remainder of 2006 will result in an additional $200,000 in operating expenses. The amount will change based upon the number and value of actual stock option grants and forfeiture rates.

*Contractual Obligations and Other Commercial Commitments*

We have no material commitments for purchases of inventories. We expect to incur additional investments in our operations related to capital expenditures in 2006 for CTA manufacturing scale-up and to meet anticipated higher volume requirements and for computers and software and furniture and fixtures associated with normal operations. 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. 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.

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 ORTHOVISC under the JNJ Agreement;
- the successful commercialization of products in development;
- progress in our product development efforts;
- the magnitude and scope of such efforts;
- 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; and
- the cost of maintaining adequate inventory levels to meet current and future product demands.

We cannot assure you that we will record profits in future periods. 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 2006. See the section captioned *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 contractual obligations of non-cancelable operating leases at December 31, 2005:

| | **Payments due by period** | | | | |
|---|---|---|---|---|---|
| | **Total** | **Less than 1 year** | **1-3 years** | **3-5 years** | **More than 5 years** |
| Operating leases | $ 2,185,000 | $ 762,000 | $ 1,314,000 | $ 109,000 | $ |

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

As of December 31, 2005, 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. All of our investments consist of money market funds, commercial paper 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. Our investment portfolio of cash equivalent is subject to interest rate fluctuations, but we believe this risk is immaterial due to the short-term nature of these investments. We currently do not hedge interest rate exposure.

**ITEM 8.** FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

**ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

**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, 2005. 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, 2005.

Our management s assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

**Report of Independent Registered Public Accounting Firm**

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

We have completed integrated audits of Anika Therapeutics, Inc. s 2005 and 2004 consolidated financial statements and of its internal control over financial reporting as of December 31, 2005 and an audit of its 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

*Consolidated financial statements*

In our opinion, the consolidated financial statements in the accompanying index present fairly, in all material respects, the financial position of Anika Therapeutics, Inc. and its subsidiaries at December 31, 2005 and 2004, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements includes 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. We believe that our audits provide a reasonable basis for our opinion.

*Internal control over financial reporting*

Also, in our opinion, management s assessment, included in Management s Report on Internal Control Over Financial Reporting appearing under this Item 8, that the Company maintained effective internal control over financial reporting as of December 31, 2005 based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in *Internal Control - Integrated Framework* issued by the COSO. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management s assessment and on the effectiveness of the Company s internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides 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, 2006

**Anika Therapeutics, Inc. and Subsidiary**

**Consolidated Balance Sheets**

| | December 31, 2005 | 2004 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 44,747,000 | $ 39,339,000 |
| Accounts receivable, net of reserves of $23,000 at December 31, 2005 and 2004 | 2,066,000 | 2,354,000 |
| Inventories | 3,271,000 | 4,227,000 |
| Current portion deferred income taxes | 1,301,000 | 1,824,000 |
| Prepaid expenses | 1,025,000 | 1,339,000 |
| Total current assets | 52,410,000 | 49,083,000 |
| Property and equipment, at cost | 11,949,000 | 10,349,000 |
| Less: accumulated depreciation | (9,853,000) | (9,394,000) |
| | 2,096,000 | 955,000 |
| Long-term deposits | 143,000 | 143,000 |
| Deferred income taxes | 7,969,000 | 9,357,000 |
| Total Assets | $ 62,618,000 | $ 59,538,000 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,277,000 | $ 791,000 |
| Accrued expenses | 1,719,000 | 2,041,000 |
| Deferred revenue | 2,830,000 | 4,116,000 |
| Total current liabilities | 5,826,000 | 6,948,000 |
| Long-term deferred revenue | 18,900,000 | 22,227,000 |
| Commitments and contingencies (Note 8) | | |
| Stockholders equity | | |
| Preferred stock, $.01 par value; 1,250,000 shares authorized, no shares issued and outstanding at December 31, 2005 and 2004 | | |
| Common stock, $.01 par value; 30,000,000 shares authorized, 10,500,393 shares issued and outstanding at December 31, 2005, 10,257,472 shares issued and outstanding at December 31, 2004 | 105,000 | 103,000 |
| Additional paid-in-capital | 34,273,000 | 32,639,000 |
| Retained earnings (accumulated deficit) | 3,514,000 | (2,379,000) |
| Total stockholders equity | 37,892,000 | 30,363,000 |
| Total Liabilities and Stockholders Equity | $ 62,618,000 | $ 59,538,000 |

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

**Anika Therapeutics, Inc. and Subsidiary**

**Consolidated Statements of Operations**

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| Product revenue | $ 20,534,000 | $ 22,286,000 | $ 15,330,000 |
| Licensing, milestone and contract revenue | 9,301,000 | 4,180,000 | 74,000 |
| Total revenue | 29,835,000 | 26,466,000 | 15,404,000 |
| Operating expenses: | | | |
| Cost of product revenue | 11,144,000 | 9,949,000 | 8,005,000 |
| Research & development | 4,731,000 | 4,087,000 | 2,595,000 |
| Selling, general & administrative | 5,409,000 | 6,042,000 | 4,209,000 |
| Total operating expenses | 21,284,000 | 20,078,000 | 14,809,000 |
| Income from operations | 8,551,000 | 6,388,000 | 595,000 |
| Interest income | 1,241,000 | 389,000 | 144,000 |
| Income before income taxes | 9,792,000 | 6,777,000 | 739,000 |
| Income tax expense (benefit) | | | |
| Provision (benefit) for income taxes | 3,899,000 | 2,626,000 | (88,000) |
| Benefit from release of valuation allowance | | (7,039,000) | |
| Net income | $ 5,893,000 | $ 11,190,000 | $ 827,000 |
| Basic net income per share: | | | |
| Net income | $ 0.57 | $ 1.11 | $ 0.08 |
| Basic weighted average common shares outstanding | 10,410,920 | 10,103,835 | 9,953,733 |
| Diluted net income per share: | | | |
| Net income | $ 0.52 | $ 0.98 | $ 0.08 |
| Diluted weighted average common shares outstanding | 11,428,201 | 11,384,155 | 10,849,610 |

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

**Anika Therapeutics, Inc. and Subsidiary**

**Consolidated Statements of Stockholders Equity**

| | Common Stock | | | Treasury Stock | | Retained Earnings (Accumulated Deficit) | Total Stockholders Equity |
|---|---|---|---|---|---|---|---|
| | Number of Shares | $.01 Par Value | Additional Paid-in Capital | Number of Shares | Cost | | |
| Balance, December 31, 2002 | 9,991,943 | $ 100,000 | $ 31,640,000 | 57,663 | $ (280,000 ) | $ (14,396,000 ) | $ 17,064,000 |
| Exercise of common stock options | | | (160,000 ) | (52,125 ) | 253,000 | | 93,000 |
| Net income | | | | | | 827,000 | 827,000 |
| Balance, December 31, 2003 | 9,991,943 | 100,000 | 31,480,000 | 5,538 | (27,000 ) | (13,569,000 ) | 17,984,000 |
| Exercise of common stock options | 265,529 | 3,000 | 549,000 | (5,538 ) | 27,000 | | 579,000 |
| Tax benefit related to stock options | | | 610,000 | | | | 610,000 |
| Net income | | | | | | 11,190,000 | 11,190,000 |
| Balance, December 31, 2004 | 10,257,472 | 103,000 | 32,639,000 | | | (2,379,000 ) | 30,363,000 |
| Exercise of common stock options | 242,921 | 2,000 | 554,000 | | | | 556,000 |
| Tax benefit related to stock options | | | 1,080,000 | | | | 1,080,000 |
| Net income | | | | | | 5,893,000 | 5,893,000 |
| Balance, December 31, 2005 | 10,500,393 | $ 105,000 | $ 34,273,000 | | $ | $ 3,514,000 | $ 37,892,000 |

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

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

| | For the Years Ended December 31, | | |
|---|---|---|---|
| | **2005** | **2004** | **2003** |
| Cash flows from operating activities: | | | |
| Net income | $ 5,893,000 | $ 11,190,000 | $ 827,000 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Depreciation | 459,000 | 710,000 | 1,006,000 |
| Deferred income taxes | 1,911,000 | (11,181,000) | |
| Provision for and writedown of inventory | 130,000 | 42,000 | |
| Tax benefit related to stock options | 1,080,000 | 610,000 | |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 288,000 | (933,000) | (223,000) |
| Inventories | 826,000 | (642,000) | (703,000) |
| Prepaid expenses | 314,000 | (1,258,000) | 239,000 |
| Accounts payable | 486,000 | 442,000 | (497,000) |
| Customer deposit | | | (327,000) |
| Accrued expenses | (322,000) | 744,000 | (406,000) |
| Deferred revenue | (4,613,000) | 24,165,000 | 2,031,000 |
| Income taxes payable | | (65,000) | 65,000 |
| Net cash provided by operating activities | 6,452,000 | 23,824,000 | 2,012,000 |
| Cash flows from investing activities: | | | |
| Proceeds from the redemption of marketable securities | | | 2,500,000 |
| Restricted cash | | 818,000 | (818,000) |
| Purchase of property and equipment | (1,600,000) | (474,000) | (256,000) |
| Proceeds from repayment of notes receivable from officers | | | 59,000 |
| Net cash (used in) provided by investing activities | (1,600,000) | 344,000 | 1,485,000 |
| Cash flows from financing activities: | | | |
| Proceeds from exercise of stock options | 556,000 | 579,000 | 93,000 |
| Net cash provided by financing activities | 556,000 | 579,000 | 93,000 |
| Increase in cash and cash equivalents | 5,408,000 | 24,747,000 | 3,590,000 |
| Cash and cash equivalents at beginning of year | 39,339,000 | 14,592,000 | 11,002,000 |
| Cash and cash equivalents at end of year | $ 44,747,000 | $ 39,339,000 | $ 14,592,000 |
| Supplemental disclosure of cash flow information: | | | |
| Cash paid for income taxes | $ 637,000 | $ 7,156,000 | $ 3,000 |

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

**Anika Therapeutics, Inc. and Subsidiary**
**Notes to Consolidated Financial Statements**

**1. Nature of Business**

Anika Therapeutics, Inc. ( Anika or the Company ) develops, manufactures and commercializes therapeutic products for tissue protection and healing. 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; and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. 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 US, ORTHOVISC has been approved for sale since 1996 and is marketed by distributors in over 15 countries. HYVISC is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. Potential products in development include REDEFYNE™, an HA based dermal filler used for cosmetic tissue augmentation (CTA) applications, and INCERT®, an HA based anti-adhesive for surgical applications.

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.

**Cash and Cash Equivalents**

Cash and cash equivalents consists of cash and highly liquid investments with original maturities of 90 days or less.

**Financial Instruments**

SFAS No. 107, Disclosures About Fair Value of Financial Instruments , requires disclosure about fair value of financial instruments. Financial instruments consist of cash equivalents, accounts receivable,

and accounts payable. The estimated fair values of the Company s financial instruments approximate their carrying values.

**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*.

***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.

In December 2004, the Company entered into the 2004 B&L Agreement, a supply agreement with Bausch & Lomb through December 31, 2010 for viscoelastic products used in ophthalmic surgery. This agreement superseded the 2000 B&L Agreement that was set to expire on December 31, 2007. The Company continues 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 the Company 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 the Company. Under the 2000 B&L Agreement, the price for units sold in a calendar year was dependent on total unit volume of sales to Bausch & Lomb and other customers of certain ophthalmic products during the year. Prices fluctuated based on sales levels, and interim quarters were subject to possible retroactive price adjustments when the actual annual unit volume for the year became known. Given the pricing in this arrangement was not fixed and was determined based on qualifying sales to multiple customers, the Company determined that it could not reliably estimate the rebate, and accordingly, deferred the maximum rebate that could be due until the annual sales volume was known in the fourth quarter. Under the 2004 B&L Agreement, the pricing is based solely on ophthalmic products sold to Bausch & Lomb. While the unit prices will be discounted for those units in excess of cumulative minimum sales levels, no additional amounts will be rebated. Starting in the 2005 first quarter, the applicable discount has been measured quarterly, subject to adjustment based on cumulative annual thresholds.

***License, Milestone and Contract Revenue***

In July 2004, the Company entered into an exclusive worldwide development and commercialization agreement (the OrthoNeutrogena Agreement) for the Company s CTA products with the OrthoNeutrogena, a division of Ortho-McNeil Pharmaceuticals, Inc., an affiliate of Johnson & Johnson. This arrangement included up front payments, specified funding of ongoing development activities, milestones upon achievement of predefined goals, and payments for supply of CTA products and royalties on sales. Under the EITF 00-21 framework, 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. While this arrangement included several elements, the Company believed that two separate units of accounting exist (a combined license and development unit and a

manufacturing unit) under the EITF 00-21 model. The Company accounted for the combined license and development unit using the performance based revenue recognition model. Pursuant to this model, the Company estimated both the total revenues it expected to earn and the expenses it expected to incur related to the license and development unit. The Company recognized revenue based on the proportion of effort expended to total estimated effort, limited to the amount of non-refundable cash received or receivable. Quarterly, the Company reviewed its estimates of total revenue and expenses related to the license and development unit.

Under the OrthoNeutrogena Agreement, the Company received non-refundable upfront fees of $1,000,000 and reimbursement for approximately $1,305,000 of costs which it incurred prior to the inception date of this agreement. The Company treated both these amounts as upfront fees that would be recognized over the expected term of the license and development unit. In addition to the upfront fees, the Company received reimbursement of pre-approved development costs. For 2004, the Company recognized $1,392,000 as contract revenue under this arrangement pursuant to the performance-based model. For the six months ended June 30, 2005, the Company recognized an additional $3,167,000 as contract revenue under this arrangement pursuant to the performance-based model. On September 1, 2005, the Company announced that it had mutually agreed with OrthoNeutrogena to terminate its development and commercialization agreement. The Company received a termination payment of $3,115,000 from ONI including $815,000 for all outstanding clinical study costs incurred and committed to by the Company at the termination date. Given there is no continuing performance obligations with respect to the development and commercialization agreement or the related termination agreement, all amounts were recognized during the third quarter of 2005, including $251,000 of previously deferred revenue under the performance-based model. Total contract revenue recognized during 2005 related to the agreements with OrthoNeutrogena was $6,537,000.

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 have deferred non refundable payments received of $27,000,000 which we are recognizing ratably over the expected 10 year term of the JNJ Agreement. Under the JNJ Agreement, we are the exclusive supplier of ORTHOVISC to Johnson& Johnson. The JNJ Agreement provides for additional sales-based milestone payments to us contingent upon achieving specified sales targets, in addition to royalty and transfer fees. The JNJ Agreement is subject to early termination in certain circumstances and is otherwise renewable by DePuy Mitek for consecutive five-year terms.

**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 historical write-off experience by industry and regional economic data. The Company reviews its allowance for doubtful

accounts monthly. 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. The Company does not have any off-balance-sheet credit exposure related to its customers.

**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.

**Property and Equipment**

Property and equipment are carried at cost less accumulated depreciation. Costs of major additions and betterments 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 as follows:

| | |
|---|---|
| Machinery and equipment | 3-7 years |
| Furniture and fixtures | 3-5 years |
| Leasehold improvements | Shorter of lease term or estimated useful life |

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, 2005 and 2004, long-lived assets consisted of machinery, equipment and leasehold improvements.

During the years ended December 31, 2005, 2004, and 2003 the Company did not record losses on impairment.

**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.

**Stock-Based Compensation**

Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation, as amended by SFAS No. 148, requires that companies either recognize compensation expense for grants of stock options and other equity instruments based on fair value, or provide pro forma disclosure of net income (loss) and net income (loss) per share in the notes to the financial statements. At December 31, 2005, the Company has stock options outstanding under three stock-based compensation plans, which are described more fully in Note 9. The Company accounts for those plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Accordingly, no compensation cost has been recognized under SFAS 123 for the Company s employee stock option plans. Had compensation cost for the awards under those plans been determined based on the grant date fair values, consistent with the method required under SFAS 123, the Company s net income and net income per share would have been reduced to the pro forma amounts indicated below:

| | December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| Net income | | | |
| As reported | $ 5,893,000 | $ 11,190,000 | $ 827,000 |
| Add: Stock-based employee compensation expense included in reported net income | | | |
| Deduct: Total stock-based employee compensation under the fair-value-based method for all awards, net of tax | (697,000) | (481,000) | (439,000) |
| Pro forma net income | $ 5,196,000 | $ 10,709,000 | $ 388,000 |
| Basic net income per share | | | |
| As reported | $ 0.57 | $ 1.11 | $ 0.08 |
| Proforma | $ 0.50 | $ 1.06 | $ 0.04 |
| Diluted net income per share | | | |
| As reported | $ 0.52 | $ 0.98 | $ 0.08 |
| Proforma | $ 0.45 | $ 0.94 | $ 0.04 |

The fair value of each stock option granted is estimated on the grant date using the fair value method with the following weighted average assumptions:

| | December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| Risk-free interest rate | 3.84 % | 3.27 % | 2.69 % |
| Expected dividend yield | 0.00 % | 0.00 % | 0.00 % |
| Expected lives | 4 | 4 | 4 |
| Expected volatility | 69.51 % | 77.68 % | 101.66 % |

**Concentration of Credit Risk and Significant Customers**

SFAS No. 105, Disclosure of Information About Financial Instruments with Off-Balance-Sheet-Risk and Financial Instruments with Concentrations of Credit Risk requires disclosure of any significant off-balance-sheet-risk, or concentrations of credit risk. The Company has no significant off-balance sheet or concentrations of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements. The Company, by policy, limits the amount of credit exposure to any one financial institution, and 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, 2005, Bausch & Lomb, Boehringer Ingelheim Vetmedica, Pharmaren, JNJ, Staar Surgical and Ferrer Grupo combined, represented 91% of the Company s accounts receivable balance. As of December 31, 2004, Bausch & Lomb, JNJ, OrthoNeutrogena, and Boehringer Ingelheim Vetmedica, combined, represented 90% of the Company s accounts receivable balance.

**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, 2005, 2004, and 2003 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. Substantially all of the operations and assets of the Company have been derived from and are located in the United States.

**Recent Accounting Pronouncements**

In November 2004, the FASB issued SFAS 151, Inventory Costs which amends the guidance in Accounting Research Bulletin No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). In addition, SFAS 151 requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of SFAS 151 are effective for the first annual reporting period beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the Company s Consolidated Financial Statements.

In December, 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard No. 123R, Share-Based Payment ( SFAS 123R ). This statement is a revision of SFAS No. 123, Accounting for Stock-Based Compensation , and supersedes APB opinion No. 25, Accounting for Stock Issued to Employees. SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based at their fair values. The provisions of this statement were effective for the Company on January 1, 2006. The Company has evaluated the provisions of this statement and determined it will have a material negative effect on

consolidated net income. The Company currently estimates that adoption of the statement will increase 2006 operating expenses by approximately $1,500,000 on a pre-tax basis, for options granted through February 28, 2006, without forfeiture assumptions. The amount will change based upon the number and value of actual stock option grants and forfeiture rates.

**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.

Shares used in calculating basic and diluted earnings per share for each of the years ended December 31, 2005, 2004 and 2003, are as follows:

| | 2005 | 2004 | 2003 |
|---|---|---|---|
| Net income | $ 5,893,000 | $ 11,190,000 | $ 827,000 |
| Basic weighted average common shares outstanding | 10,410,920 | 10,103,835 | 9,953,733 |
| Dilutive effect of assumed exercise of stock options and warrants | 1,017,281 | 1,280,320 | 895,877 |
| Diluted weighted average common and potential common shares outstanding | 11,428,201 | 11,384,155 | 10,849,610 |

Options to purchase approximately 85,000, 14,000, and 728,000 shares were outstanding at December 31, 2005, 2004, and 2003, 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.

**4. Allowance for Doubtful Accounts**

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

| | December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| Balance, beginning of the year | $ 23,000 | $ 29,000 | $ 35,000 |
| Amounts written off | | (6,000) | (6,000) |
| Balance, end of the year | $ 23,000 | $ 23,000 | $ 29,000 |

**5. Inventories**

Inventories consist of the following:

| | December 31, 2005 | 2004 |
|---|---|---|
| Raw Materials | $ 1,594,000 | $ 1,842,000 |
| Work-in-Process | 1,507,000 | 1,589,000 |
| Finished Goods | 170,000 | 796,000 |
| Total | $ 3,271,000 | $ 4,227,000 |

**6. Property & Equipment**

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

| | December 31, 2005 | 2004 |
|---|---|---|
| Machinery and equipment | $ 7,270,000 | $ 6,237,000 |
| Furniture and fixtures | 737,000 | 725,000 |
| Leasehold improvements | 3,942,000 | 3,387,000 |
| | 11,949,000 | 10,349,000 |
| Less accumulated depreciation | (9,853,000) | (9,394,000) |
| Total | $ 2,096,000 | $ 955,000 |

Depreciation expense was $459,000, $710,000, and $1,006,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

**7. Accrued Expenses**

Accrued expenses consist of the following:

| | December 31, 2005 | 2004 |
|---|---|---|
| Payroll and benefits | $ 1,007,000 | $ 933,000 |
| Professional fees | 347,000 | 637,000 |
| Clinical trial | 151,000 | 265,000 |
| Other | 214,000 | 206,000 |
| Total | $ 1,719,000 | $ 2,041,000 |

**8. Commitments and Contingencies**

*Operating Leases.* The Company s corporate headquarters is located in Woburn, Massachusetts, where it leases approximately 10,000 square feet of administrative and research and development space. The lease on this facility terminates in December 2006. The Company also leases approximately 37,000 square feet of space at a separate location in Woburn, Massachusetts, for its manufacturing facility and warehouse. The lease for this facility terminates in February 2009. Rental expense in connection with the leases, totaled $724,000, $700,000, and $685,000, for the years ended December 31, 2005, 2004, and 2003, respectively.

Future minimum lease payments under noncancelable operating leases at December 31, 2005 are as follows:

| | Amount |
|---|---|
| 2006 | $ 762,000 |
| 2007 | 658,000 |
| 2008 | 656,000 |
| 2009 | 109,000 |
| 2010 | |
| Thereafter | |
| Total | $ 2,185,000 |

*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.

**9. Stock Option Plan**

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 stock options to employees, directors, consultants and advisors under the 2003 Plan, which was approved by stockholders on June 4, 2003.

Combined stock option activity under the three plans is summarized as follows:

| | 2005 | | 2004 | | 2003 | |
|---|---|---|---|---|---|---|
| | 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 | 1,707,305 | $ 4.16 | 2,072,297 | $ 3.51 | 1,352,647 | $ 2.49 |
| Granted | 409,525 | $ 10.46 | 207,000 | $ 12.60 | 811,400 | $ 4.99 |
| Canceled | (76,565) | $ 5.31 | (275,925) | $ 7.73 | (39,625) | $ 1.34 |
| Expired | | | (25,000) | $ 2.63 | | |
| Exercised | (242,921) | $ 2.29 | (271,067) | $ 2.13 | (52,125) | $ 1.78 |
| Outstanding at end of year | 1,797,344 | $ 5.80 | 1,707,305 | $ 4.16 | 2,072,297 | $ 3.51 |
| Options exercisable at end of year | 1,030,507 | $ 3.90 | 1,015,055 | $ 3.32 | 974,472 | $ 2.92 |
| Weighted average fair value of options granted at fair value | | $ 5.76 | | $ 7.45 | | $ 3.53 |

Generally, options vest in equal, annual installments up to four years after the date of grant and have an expiration date no later than ten years after the date of grant. There are 625,576 options available for future grant at December 31, 2005.

The following table summarizes significant ranges of outstanding options under the three plans at December 31, 2005:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Number Outstanding | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
| $0.90 - $1.05 | 352,826 | 6.52 | $ 1.02 | 253,826 | $ 1.00 |
| 1.06 - 1.17 | 278,125 | 5.22 | $ 1.17 | 257,938 | $ 1.17 |
| 1.18 - 4.75 | 125,924 | 5.04 | $ 2.48 | 93,549 | $ 2.60 |
| 4.76 - 9.21 | 420,400 | 5.63 | $ 7.21 | 239,500 | $ 6.07 |
| 9.22 - 10.69 | 384,194 | 8.12 | $ 9.33 | 175,819 | $ 9.29 |
| $9.22 - $15.45 | 235,875 | 9.57 | $ 11.94 | 9,875 | $ 13.73 |
| | 1,797,344 | | | 1,030,507 | |

**10. Shareholder Rights Plan**

On April 6, 1998, the Board of Directors adopted a shareholder rights agreement (the Rights Plan ) which was subsequently amended as of November 5, 2002. In connection with the adoption of the Rights Plan, the Board of Directors declared a dividend distribution of one preferred stock purchase right (a Right ) for each outstanding share of common stock to stockholders of record as of the close of business on April 23, 1998. Currently, these Rights are not exercisable and trade with the shares of the Company s Common Stock.

Under the 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, (2) a person commences a tender offer that would result in that person owning 15% or more of the Company s Common Stock, or (3) the Board of Directors deems a person to be an Adverse Person, as defined under the Rights Plan. In the event that a person becomes an Acquiring Person, or an Adverse Person, each holder of a Right (other than the Acquiring Person or Adverse Person) would be entitled to acquire such number of units 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 $45.00.

The Rights will expire at the close of business on April 6, 2008 (the Expiration Date ), unless previously redeemed or exchanged by the Company as described below. 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 an Adverse Person , or (2) the Expiration Date. At any time after any person becomes an Acquiring Person or an Adverse 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.

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.

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 150,000 shares of preferred stock for issuance upon exercise of the Rights.

**11. Stock Repurchase Plan**

In October 1998, the Board of Directors approved a stock repurchase plan under which the Company is authorized to purchase up to $4,000,000 of the Company s Common Stock, with the total number of shares repurchased not to exceed 9.9% of the total number of shares issued and outstanding. Under the plan, shares may be repurchased from time to time and in such amounts as market conditions warrant, subject to regulatory considerations. As of December 31, 2005 and 2004, the Company had repurchased a total of 762,100 shares at a net cost of approximately $3,873,000 and has reissued all shares upon exercise of employee stock options. No shares were purchased in 2005 or 2004.

**12. 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, 2005, 2004, and 2003, the Company made matching contributions of $202,000 $177,000, and $157,000 respectively.

**13. Revenue by Product Group, by Significant Customer and by Geographic Region**

Product revenue by product group is as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Ophthalmic Products | $ 10,522,000 | $ 11,533,000 | $ 10,512,000 |
| ORTHOVISC | 7,938,000 | 8,699,000 | 3,073,000 |
| HYVISC | 2,074,000 | 2,054,000 | 1,745,000 |
| | $ 20,534,000 | $ 22,286,000 | $ 15,330,000 |

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

| | Percent of Product Revenue Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Bausch & Lomb Incorporated | 45.6 % | 38.3 % | 50.6 % |
| Pharmaren AG/Biomeks | 23.2 % | 13.6 % | 14.3 % |
| Boehringer Ingelheim Vetmedica | 10.1 % | 9.2 % | 11.3 % |
| Depuy Mitek / Ortho Biotech | 8.0 % | 21.0 % | |
| Advanced Medical Optics | 1.2 % | 9.9 % | 13.4 % |
| | 88.1 % | 92.0 % | 89.6 % |

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

| | Years Ended December 31, 2005 | | 2004 | | 2003 | |
|---|---|---|---|---|---|---|
| | Revenue | Percent of Revenue | Revenue | Percent of Revenue | Revenue | Percent of Revenue |
| **Geographic location:** | | | | | | |
| United States | $ 21,090,000 | 70.7 % | $ 19,768,000 | 74.7 % | $ 9,918,000 | 64.4 % |
| Europe | 3,167,000 | 10.6 % | 3,115,000 | 11.8 % | 2,848,000 | 18.5 % |
| Turkey | 4,764,000 | 16.0 % | 3,024,000 | 11.4 % | 2,208,000 | 14.3 % |
| Other | 814,000 | 2.7 % | 559,000 | 2.1 % | 430,000 | 2.8 % |
| Total | $ 29,835,000 | 100.00 % | $ 26,466,000 | 100.00 % | $ 15,404,000 | 100.00 % |

All licensing, milestone and contract revenue was derived in the United States for 2005, 2004 and 2003.

**14. Income Taxes**

Income tax expense (benefit) was $3,899,000, ($4,413,000), and ($88,000) for the years ended December 31, 2005, 2004, and 2003, respectively. Prepaid taxes of $663,000 and $933,000 were included in the prepaid expenses and other receivables at December 31, 2005 and 2004, respectively.

The components of the provision for income taxes and benefit from release of valuation allowance are as follows:

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Current: | | | |
| Federal | $ 1,787,000 | $ 5,846,000 | $ (90,000) |
| State | 201,000 | 922,000 | 2,000 |
| | 1,988,000 | 6,768,000 | (88,000) |
| Deferred: | | | |
| Federal | 1,298,000 | (3,680,000) | |
| State | 613,000 | (462,000) | |
| | 1,911,000 | (4,142,000) | |
| Provision for income taxes | 3,899,000 | 2,626,000 | (88,000) |
| Benefit from release of valuation allowance: | | | |
| Federal | | (5,760,000) | |
| State | | (1,279,000) | |
| | | (7,039,000) | |
| Tax expense (benefit) | $ 3,899,000 | $ (4,413,000) | $ (88,000) |

The Company receives a tax deduction upon the exercise of nonqualified stock options and disqualifying dispositions by employees for the difference between the exercise price and the market price of the underlying common stock on the date of exercise. The benefit of the related tax deduction in the amounts of $1,080,000 and $610,000 were not recorded through the tax provision, rather they were credited directly to additional paid in capital in 2005 and 2004, respectively.

In 2004, the Company achieved milestones under the JNJ Agreement and received payments totaling $27,000,000 which the Company recognized as taxable income in 2004. As a result, the Company has determined that it will be able to utilize all of its net operating loss and credit carry-forwards in 2004 to offset part of its taxable income. In accordance with the Company s revenue recognition policy, for financial statement purposes, the milestone payments totaling $27,000,000 were deferred and are being recognized ratably over the expected ten-year term of the JNJ Agreement. The Company recorded a deferred tax asset of approximately $9,800,000 representing the approximate income tax effect of the timing difference of revenue recognition for financial statement purposes and for tax purposes related to these milestone payments as of December 31, 2004. As of December 31, 2004, based on management s expectations regarding future profitability, the Company released the valuation allowance previously established against its deferred tax assets and recorded a one-time income tax benefit of $7,039,000.

The income tax expense (benefit) differs from the amounts computed by applying the U.S. Federal income tax rate to pretax income as a result of the following:

| | Years ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Computed expected tax expense | $ 3,329,000 | $ 2,304,000 | $ 251,000 |
| State tax expense (net of federal benefit) | 418,000 | 190,000 | 48,000 |
| State deferred tax assets rate change | 436,000 | | |
| Permanent items, including nondeductible expenses | (83,000) | 58,000 | 4,000 |
| Federal and state research and development, and other credits | (137,000) | (121,000) | (64,000) |
| Alternative minimum tax benefit from carryback | | | (154,000) |
| Alternative minimum tax liability | | | 64,000 |
| Other | (64,000) | | (34,000) |
| Federal rate difference | | 195,000 | |
| Change in valuation allowance related to income tax benefit | | (7,039,000) | (203,000) |
| Tax (benefit) expense | $ 3,899,000 | $ (4,413,000) | $ (88,000) |

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. The approximate income tax effect of each type of temporary difference and carryforward is as follows:

| | Years ended December 31, | |
|---|---|---|
| | 2005 | 2004 |
| Deferred tax assets: | | |
| Depreciation | $ 654,000 | $ 525,000 |
| Accrued expenses and other | 144,000 | 366,000 |
| Inventory reserves | 84,000 | 68,000 |
| Deferred revenue | 8,388,000 | 10,222,000 |
| Deferred tax asset | $ 9,270,000 | $ 11,181,000 |

As of December 31, 2005, 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.

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

| Year 2005 | Quarter ended December 31, | Quarter ended September 30, | Quarter ended June 30, | Quarter ended March 31, |
|---|---|---|---|---|
| Product revenue | $ 4,774,000 | $ 5,999,000 | $ 4,084,000 | $ 5,677,000 |
| Total revenue | 5,466,000 | 10,058,000 | 7,020,000 | 7,291,000 |
| Cost of product revenue | 2,266,000 | 3,767,000 | 2,117,000 | 2,994,000 |
| Gross profit on product revenue | 2,508,000 | 2,232,000 | 1,967,000 | 2,683,000 |
| Net income | $ 823,000 | $ 2,531,000 | $ 1,337,000 | $ 1,202,000 |
| Per common share information | | | | |
| Basic net income per share | $ 0.08 | $ 0.24 | $ 0.13 | $ 0.12 |
| Basic common shares outstanding | 10,496,453 | 10,482,850 | 10,391,538 | 10,269,389 |
| Diluted net income per share | $ 0.07 | $ 0.22 | $ 0.12 | $ 0.11 |
| Diluted common shares outstanding | 11,412,632 | 11,480,570 | 11,537,538 | 11,264,595 |

| Year 2004 | Quarter ended December 31, | Quarter ended September 30, | Quarter ended June 30, | Quarter ended March 31, |
|---|---|---|---|---|
| Product revenue | $ 5,473,000 | $ 5,554,000 | $ 5,690,000 | $ 5,569,000 |
| Total revenue | 7,656,000 | 6,407,000 | 6,262,000 | 6,141,000 |
| Cost of product revenue | 2,335,000 | 2,451,000 | 2,442,000 | 2,721,000 |
| Gross profit on product revenue | 3,138,000 | 3,103,000 | 3,248,000 | 2,848,000 |
| Net income | $ 1,755,000 | $ 884,000 | $ 765,000 | $ 7,786,000 |
| Per common share information | | | | |
| Basic net income per share | $ 0.17 | $ 0.09 | $ 0.08 | $ 0.78 |
| Basic common shares outstanding | 10,224,407 | 10,140,925 | 10,060,866 | 9,987,410 |
| Diluted net income per share | $ 0.15 | $ 0.08 | $ 0.07 | $ 0.69 |
| Diluted common shares outstanding | 11,329,592 | 11,506,999 | 11,396,116 | 11,257,264 |

During the second quarter of 2005, the Company s ophthalmic sales were significantly impacted as a result of a voluntary product recall instigated by our discovery of defective vendor-supplied finished goods packaged with our HA viscoelastic product. This voluntary recall resulted in a decrease of $1,359,000 in sales of ophthalmic product for the three months ended June 30, 2005 and a corresponding similar increase in third quarter sales as we completed restocking of our customers, with very little impact on revenue from the recall for the nine and twelve months ended September 30 and December 31, 2005, respectively.

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 termination payment of $3,115,000 from ONI including $815,000 for all outstanding clinical study costs incurred and committed to by the Company at the termination date. Given there is 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 under the performance-based model. See Notes 2.

In the first quarter of 2004, based on its expectations regarding future profitability, the Company released the previously established valuation allowance against its deferred tax assets and recorded a one-time income tax benefit of $7,039,000. See Note 14.

**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 the 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 reasonably effective to ensure that material information relating to us 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. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures. 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 2005 that have materially affected, or that are reasonably likely to materially affect, our internal controls over financial reporting.

**ITEM 9B.** OTHER INFORMATION

None.

**PART III**

**ITEM 10.** DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 is hereby incorporated by reference to the Registrant s Proxy Statement (the Proxy Statement) for the Annual Meeting of Stockholders to be held on June 1, 2006 under the heading Election of Directors.

**ITEM 11.** EXECUTIVE COMPENSATION

The information required by Item 11 is hereby incorporated by reference to the Proxy Statement under the heading Executive Co-mpensation.

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

The information required by Item 12 is hereby incorporated by reference to the Proxy Statement under the heading Beneficial Ownership of Common Stock and from Item 5 of this Annual Report on Form 10-K under the heading Equity Compensation Plan Information.

**ITEM 13.** CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is hereby incorporated by reference to the Proxy Statement under the headings Agreements with Named Executive Officers and Certain Relationships and Related Transactions.

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

The information required by Item 14 is hereby incorporated by reference to the Proxy Statement under the headings Principal Accounting Fees and Services.

**PART IV**

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

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

(1) Financial Statements



(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 | The Amended and 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 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 Amended and 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 period ended November 30, 1996, (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997. |
| 3.4 | Certificate of Vote of Directors Establishing a Series of a Class of Stock, incorporated herein by reference to Exhibit 3.1 of the Company s Registration Statement on Form 8-AB12 (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998. |
| 3.5 | Amendment to the Amended and 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 ending June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002. |
| 3.6 | The 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. 000-21326), 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 6, 1998 between the Company and Firstar 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, 1998. |
| 4.2 | Amendment to Shareholder Rights Agreement dated as of November 5, 2002 between the Company and American Stock Transfer and Trust Company, as successor to Firstar Trust Company incorporated herein by reference to Exhibit 4.2 to the Company s quarterly report on Form 10-Q for the quarterly period ended September 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on November 13, 2002. |
| (10) Material Contracts | |
| 10.1 | Supply Agreement dated as of July 25, 2000 by and between the Company and Bausch & Lomb, Inc., 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, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2000. Confidential treatment was granted to certain portions of this Exhibit. |
| 10.2 | 1993 Stock Option Plan, as amended, incorporated herein by reference to Annex A of the Company s Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 28, 2000. |
| 10.3 | Lease dated March 10, 1995 between the Company and Cummings Properties, 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 Exchange Commission on April 2, 2001. |
| 10.4 | First Amendment to Lease dated December 11, 1997 between the Company and Cummings Properties, 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 Exchange Commission on April 2, 2001. |

| | |
|---|---|
| 10.5 | Extension of Lease dated November 23, 1999 between the Company and Cummings Properties, 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 Exchange Commission on April 2, 2001. |
| 10.6 | Second Amendment to Lease dated November 23, 1998 between the Company and Cummings Properties, 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 Exchange Commission on April 2, 2001. |
| 10.7 | Lease dated September 23, 1999 between the Company and Cummings Properties, 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 Exchange Commission on April 2, 2001. |
| 10.8 | Letter Agreement dated April 15, 1998 between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.3 to the Company s quarterly report on Form 10-Q for the quarterly period ended June 30, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2000. |
| 10.9 | Non-Disclosure and Non-Competition Agreement dated May 5, 1998 between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.26 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 Exchange Commission on April 2, 2001. |
| 10.10 | 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. |
| 10.11 | Amendment to Lease #3 dated November 1, 2001 by and between the Company and Cummings Properties, 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. |
| 10.12 | Sublease effective as of November 2001, between MedChem Products, Inc. and the Company, 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, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on May 14, 2002. |
| 10.13 | Amended and Restated Change in Control, Bonus and Severance Agreement dated July 8, 2002 by and between the Company and Charles H. Sherwood incorporated herein by reference to Exhibit 10.4 to the Company s quarterly report on Form 10-Q for the quarterly period ended June 30, 2002 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2002. |
| 10.14 | Change in Control, Bonus and Severance Agreement dated June 9, 2003 by and between the Company and Francesco J. Luppino, incorporated herein by reference to Exhibit 10.35 to the Company s quarterly report on Form 10-Q for the quarterly period ended June 30, 2003 (File no. 000-21326), filed with the Securities and Exchange Commission on August 14, 2003. |

| | |
|---|---|
| 10.15 | Lease Extension dated October 8, 2003 by and 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. 000-21326), filed with the Securities and Exchange Commission on November 14, 2003. |
| 10.16 | Lease Amendment dated October 8, 2003 by and between the Company and MedChem Products, Inc., 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. 000-21326), filed with the Securities and Exchange Commission on November 14, 2003. |
| 10.17 | 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 year ended December 31, 2003 (File no. 000-21326), filed with the Securities and Exchange Commission on March 29, 2004. |
| 10.18 | License Agreement dated as of July 23, 2004 by and between the Company and Ortho-McNeil Pharmaceutical, Inc., acting through its OrthoNeutrogena Division., incorporated herein by reference to Exhibit 10.39 to the Company s quarterly report on Form 10-Q for the quarterly period ended June 30, 2004 (File no. 000-21326), filed with the Securities and Exchange Commission on August 16, 2004. Confidential treatment was granted to certain portions of this Exhibit. |
| 10.19 | Letter Agreement dated October 6, 2004 by and between the Company and Carol A. Toth, Ph.D., incorporated herein by reference to the Company s current report on Form 8-K (File no. 000-21326), filed with the Securities and Exchange Commission on November 19, 2004. |
| 10.20 | Change of Control, Bonus and Severance Agreement dated October 6, 2004 by and between the Company and Carol A. Toth, Ph.D., incorporated herein by reference to the Company s current report on Form 8-K (File no. 000-21326), filed with the Securities and Exchange Commission on November 19, 2004. |
| **10.21 | Supply Agreement dated as of December 15, 2004 by and between the Company and Bausch & Lomb, Incorporated. |
| 10.22 | Lease Amendment dated October 13, 2004 by and between the Company and MedChem Products, Inc., incorporated herein by reference to the Company s annual report on Form 10-K for the period ended December 31, 2004 (File no. 001-14027), filed with the Securities and Exchange Commission on March 16, 2005. |
| 10.23 | Letter Agreement dated June 30, 2005, as amended, by and between the Company and Kevin W. Quinlan, incorporated herein by reference to the Company s current report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on July 12, 2005. |
| 10.24 | Change in Control, Bonus and Severance Agreement, dated as of July 11, 2005, by and between the Company and Kevin W. Quinlan, incorporated herein by reference to the Company s current report on Form 8-K (File no. 001-14027), filed with the Securities and Exchange Commission on July 12, 2005. |

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| 10.25 | Letter Agreement, dated as of August 31, 2005, regarding the termination of the License Agreement, dated as of July 23, 2004, between the Company and OrthoNeutrogena Division, OrthoMcNeil Pharmaceutical, Inc., 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, 2005 (File no. 001-14027), filed with the Securities and Exchange Commission on November 7, 2005. |
| 10.26 | 2003 Stock Option and Incentive Plan, as amended, incorporated herein by reference to Exhibit A of the Company s Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 30, 2003. |
| 10.27 | First Amendment to the Company s 2003 Stock Option and Incentive Plan incorporated herein by reference to Exhibit 4.9 of the Company s Form S-8 (File no. 333-110326), filed with the Securities and Exchange Commission on November 7, 2003. |
| 10.28 | 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. |
| 10.29 | 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. |
| (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. |
| *31.1 | Certification of Charles H. Sherwood, Ph.D. pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| *31.2 | Certification of Kevin W. Quinlan pursuant to Rules 13a-15(e) and 15d-15(e), 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. |
| (99) | Additional Exhibits<br>None |

* 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.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized in Woburn, Massachusetts on March 9, 2006.

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| | | ANIKA THERAPEUTICS, INC. |
| Date: March 9, 2006 | By: | /s/ CHARLES H. SHERWOOD, PH.D. |
| | | Charles H. Sherwood, Ph.D. |
| | | *Chief Executive Officer* |

**SIGNATURES**

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

| Signature | Title | Date |
|---|---|---|
| /s/ CHARLES H. SHERWOOD, PH.D. | Chief Executive Officer and Director | March 9, 2006 |
| Charles H. Sherwood, Ph.D. | *(Principal Executive Officer)* | |
| /s/ KEVIN W. QUINLAN | Chief Financial Officer | |
| Kevin W. Quinlan | *(Principal Accounting Officer)* | March 9, 2006 |
| /s/ JOSEPH L. BOWER | | |
| Joseph L. Bower | Director | March 9, 2006 |
| /s/ EUGENE A. DAVIDSON, PH.D. | | |
| Eugene A. Davidson, Ph.D. | Director | March 9, 2006 |
| /s/ RAYMOND J. LAND | | |
| Raymond J. Land | Director | March 9, 2006 |
| /s/ HARVEY S. SADOW, PH.D. | | |
| Harvey S. Sadow, Ph.D. | Director | March 9, 2006 |
| /s/ STEVEN E. WHEELER | | |
| Steven E. Wheeler | Director | March 9, 2006 |