ANIKA THERAPEUTICS INC
Form 10-K405
March 28, 2002

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# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-K

**(Mark One)**

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended December 31, 2001**

**or**

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.) |
| **236 West Cummings Park, Woburn, Massachusetts** (Address of Principal Executive Offices) | **01801** (Zip Code) |

Registrant's Telephone Number, Including Area Code: **(781) 932-6616**

Securities registered under Section 12 (b) of the Exchange Act: None

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý 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. ý

The aggregate market value of voting stock held by non-affiliates of the Registrant as of March 20, 2002 was $10,828,365 based on the closing price per share of Common Stock of $1.09 as of such date as reported on the NASDAQ National Market. At March 20, 2002, there were issued and outstanding 9,934,280 shares of Common Stock, par value $.01 per share.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required in response to Items 10, 11, 12 and 13 of Part III are hereby incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Stockholders to be held on June 6, 2002. 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.

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**FORM 10-K**
**ANIKA THERAPEUTICS, INC.**
**For Fiscal Year Ended December 31, 2001**

*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:*

*about the Company's future sales and product revenues, including possible retroactive price adjustments and expectations of increased unit volumes or other offsets to price reductions;*

*regarding the Company's efforts to increase sales of ophthalmic viscoelastic products;*

*concerning the Company's manufacturing capacity and commencement of manufacturing operations;*

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

*with respect to possible development of new products or the acquisition of new distribution and collaboration partners;*

*with respect to FDA or other regulatory approvals of new or potential products or the rates of patient enrollment in the Company's clinical trials and related costs;*

*regarding the Company's current strategy;*

*involving negotiations with potential and existing customers, including the Company's performance under any of its distribution or supply agreements or the Company's expectations with respect to sales pursuant to such agreements;*

*concerning the estimate of the time period for which the Company's cash and cash equivalents will be adequate to fund operations;*

*about the impact of the SEC investigation; and*

*identified by words such as "seek," "designed," "believe," "expect," "anticipate," "intend," "will," "develop," "would," future," "can," "may," "could," and other expressions, that are predictions of, or indicate future events and trends and which do not relate to historical matters.*

*You should not rely on forward-looking statements, because they involve known and unknown risks, uncertainties and other factors, some of which are beyond the control of the Company, including those factors described in the section titled "Risk Factors and Certain Factors Affecting Future Operating Results," in this Annual Report on Form 10-K. These risks, uncertainties and other factors may cause the Company's 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 were based upon the current assumptions of the Company's 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. The Company undertakes no obligation to publicly update or revise any forward-looking statement whether as a result of new information, future events or otherwise.*

## PART I

### ITEM 1. BUSINESS

Anika Therapeutics, Inc. ("Anika" or the "Company") develops, manufactures and commercializes therapeutic products and devices intended to promote the protection and healing of bone, cartilage and soft tissue. 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 marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans, and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC® is currently approved for sale and is being marketed in Canada, parts of Europe, Turkey, and Israel. In the United States, ORTHOVISC® is currently limited to investigational use. The Company manufactures AMVISC® and AMVISC® Plus for Bausch & Lomb, which are HA products used as viscoelastic supplements in ophthalmic surgery. STAARVISC®II, an injectable ophthalmic viscoelastic, is produced for STAAR Surgical Company, and ShellGel , also an injectable ophthalmic viscoelastic, is produced for Cytosol Ophthalmics, Inc.

The Company's current strategy is to:

seek to improve the financial performance of its core business,

successfully complete an ongoing Phase III clinical trial of ORTHOVISC® in order to secure FDA approval to market ORTHOVISC® in the U.S., and

focus research and development resources on evaluating potential product applications, including possible collaborations with other parties.

In 2001, approximately 65% of the Company's revenue was from the sale of ophthalmic viscoelastic products to Bausch & Lomb. The Company added three new distributors of ophthalmic viscoelastic products during 2001. While sales to such distributors in 2001 were not significant, the Company intends to continue efforts to increase business in this market in 2002. With respect to ORTHOVISC®, the Company is actively seeking distributors for international markets as well as considering U.S. marketing and distribution alternatives should the ongoing Phase III clinical trial be successful.

The following sections provide more specific information on the Company's products and related activities:

*ORTHOVISC®*

ORTHOVISC® is a high molecular weight, highly purified HA product designed to relieve pain and improve joint mobility in patients suffering from osteoarthritis of the knee. ORTHOVISC® is delivered by intra-articular injection to supplement and restore the body's natural HA found in the synovial fluid of joints.

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 analgesics, non-steroidal anti-inflammatory drugs and steroid injections.

In the United States, ORTHOVISC® is limited to investigational use. In October 1998, the Company was notified by the U.S. Food and Drug Administration (the "FDA") that its Pre-Market Approval Application ("PMA") was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC®. In late March 1999, the Company received an Investigational Device Exemption ("IDE") approval for ORTHOVISC® and initiated a second Phase III



clinical study. This trial completed patient enrollment, totaling 385 patients at 22 centers in the U.S. and Canada in August 1999. The final patient completed the six-month follow-up period on February 28, 2000. The statistical analysis of the clinical trial failed to show sufficient efficacy in this patient population to support the filing of a PMA application. In February 2001, the Company commenced its third Phase III clinical trial of ORTHOVISC®. The trial is expected to be conducted in up to 25 centers in the U.S. and Canada, with 360 patients expected to be enrolled, and with evaluation over a six-month period following treatment. There can be no assurances that (i) the results of this third Phase III clinical study will be adequate to demonstrate the effectiveness of ORTHOVISC® to obtain FDA approval, (ii) the Company will successfully complete the clinical study or (iii) that ORTHOVISC® will receive FDA approval in a timely manner, if at all.

On November 10, 2000, the Company entered into an agreement to terminate an ORTHOVISC® marketing and distribution agreement with Zimmer, Inc., ("Zimmer"), a subsidiary of Bristol-Myers Squibb Company. The Company has established interim relationships with third party logistics firms so that Anika can continue to supply ORTHOVISC® in Canada and the European countries previously covered under the distribution agreement with Zimmer. The Company recently entered into a three-year distribution agreement in the U.K., which is subject to earlier termination under certain circumstances. The Company is continuing to seek to establish long-term distribution relationships in those and other regions, but can make no assurances that it will be successful in doing so, "*Management's Discussion and Analysis of Financial Condition and Results of Operations Overview*", and *"Risk Factors and Certain Factors Affecting Future Operating Results."*

*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 Animal Health, Inc. in the United States.

*AMVISC PRODUCTS*

AMVISC® and AMVISC® Plus are 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 tissues such as the endothelium and maintain the space between them, thereby facilitating ophthalmic surgical procedures.

Anika manufactures the AMVISC® product line for Bausch & Lomb. The Company entered into a supply agreement (the "B&L Agreement") with Bausch & Lomb Surgical, a unit of Bausch & Lomb Incorporated, in July 2000. Bausch & Lomb Surgical was subsequently merged into Bausch & Lomb Incorporated. Under the terms of the B&L Agreement, effective January 1, 2001, the Company became Bausch & Lomb's exclusive provider of AMVISC® and AMVISC® Plus in the U.S. and international market. The B&L Agreement expires December 31, 2007 and superseded the prior supply agreement with Bausch & Lomb that was set to expire December 31, 2001. The B&L Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The B&L Agreement lifted certain contractual

restrictions on the Company's sales of certain ophthalmic products to other companies, subject to payment of royalties by Anika. In exchange, the Company agreed to a reduction in unit selling prices retroactively effective to April 1, 2000 and the elimination of minimum unit purchase obligations by Bausch & Lomb. See *"Risk Factors and Certain Factors Affecting Future Operating Results Dependence on Marketing Partners"* and *" Reliance on a Small Number of Customers."*



**RESEARCH AND DEVELOPMENT OF POTENTIAL PRODUCTS**

As discussed below in the section titled "*Risk Factors and Certain Factors Affecting Future Operating Results*," the Company has not obtained FDA approval for the sales and marketing in the U.S. of the potential products described below.

*INCERT*

In general, 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.

INCERT®-S is the Company's product designed to reduce post-surgical fibrosis following spinal surgery. The Company planned to commence clinical trials for the product in the first half of 2001. During 2001, the Company determined not to commence a clinical trial for this product and is evaluating various development options for this product and its underlying technology, including reconsideration of the Company's previous plans to launch a clinical trial. There can be no assurance that: (i) the Company will begin or successfully complete clinical trials of INCERT®-S; (ii) if completed, FDA approval for sales in the U.S. will be obtained; or (iii) if regulatory approvals are obtained, meaningful sales of INCERT®-S will be achieved.

Anika co-owns an issued United States patent covering the use of INCERT® for adhesion prevention (See *"Patent and Propriety Rights").*

*OSSIGEL®*

In June 1997, the Company executed a multi-year collaboration agreement with Orquest, Inc. to develop and manufacture OSSIGEL®, a formulation of basic fibroblast growth factor and HA. Orquest has indicated that it has focused its resources on other product development efforts and there can be no assurance that OSSIGEL® development will continue.

**MANUFACTURING OF HYALURONIC ACID**

The Company has been manufacturing HA since 1983 in its manufacturing facility located in Woburn, Massachusetts. This facility is approved by the FDA for the manufacture of medical devices and drugs. The Company has developed a proprietary HA manufacturing process for the extraction and purification of HA from rooster combs, a source of high molecular weight, highly purified HA.

The Company believes that a substantial supply of rooster combs is readily available and that all the other materials required for the manufacture of its HA products are also readily available from a number of sources. Although the Company obtains syringes used to deliver certain of its HA products from a single supplier, a sufficient supply of syringes is generally available or maintained in inventory to meet anticipated demand.

**PATENT AND PROPRIETARY RIGHTS**

The Company has a policy of seeking patent protection for patentable aspects of its proprietary technology. The Company's issued patents expire between 2007 and 2015. The Company co-owns certain United States 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. The Company also solely owns patents covering certain manufacturing processes. The Company also holds a license from Tufts University

to use technologies claimed in a United States patent for the anti-metastasis applications of HA oligosaccharides. The license expires upon expiration of the underlying patent. The Company intends to seek patent protection for products and processes developed in the course of its activities when it believes such protection is in its best interest and when the cost of seeking such protection is not inordinate relative to the potential benefits. See also "*Risk Factors and Certain Factors Affecting Future Operating Results We may be unable to adequately protect our intellectual property."*

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 the Company will not infringe the patent rights of others in the future. Any such infringement may have a material adverse effect on the Company's business, financial condition, and results of operations. In particular, in 1995, the Company received notice from the PTO that a third party may attempt to provoke a patent interference with respect to one of the Company's co-owned patents covering the use of INCERT® for post-surgical adhesion prevention. The existence of an interference proceeding may have a negative impact on the marketing of the INCERT® product, if such a product was approved by the FDA, and no assurance can be given that the Company would be successful in any such interference proceeding. If the interference proceeding were to be decided against the Company, involved claims of the Company's patent would be cancelled, the Company's potential sales, use, and marketing of the INCERT® product may be materially and adversely affected and the third party may enforce patent rights against the Company. See also "*Risk Factors and Certain Factors Affecting Future Operating Results We may be unable to adequately protect our intellectual property."*

The Company also relies upon trade secrets and proprietary know-how for certain non-patented aspects of its technology. To protect such information, the Company requires 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 will provide adequate protection. See also "*Risk Factors and Certain Factors Affecting Future Operating Results We may be unable to adequately protect our intellectual property."*

The Company has granted Bausch & Lomb a royalty-free, worldwide, exclusive license to the Company's manufacturing and product inventions which relate to the AMVISC® products, effective upon the earlier of (i) the termination date of the B&L Agreement or (ii) the loss of exclusivity there under.

**GOVERNMENT REGULATION**

Anika's research, development, manufacturing activities, and the future marketing of products by Anika are subject to regulation by numerous governmental authorities in the United States and other countries. In the United States, devices and drugs are subject to extensive and rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act governs the testing, safety, effectiveness, clearance, approval, manufacture, labeling, packaging, storage, record keeping, reporting, marketing, advertising, and promotion of Anika's products.

Product development and approval within the FDA regulatory framework takes a number of years and involves the expenditure of substantial resources to demonstrate safety and effectiveness. There can be no assurance that this regulatory framework will not change or that additional regulation will not arise at any stage of Anika's product development process, which may affect approval of, or delay an application, or require additional expenditures by Anika.

Furthermore, Anika or the FDA may suspend clinical trials at any time for a number of reasons, including, among other things, failure to comply with applicable requirements; or if there is reason to believe that the risks to subjects are not outweighed by the anticipated benefits to subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device, as used, is ineffective; or if an



unanticipated adverse device effect presents an unreasonable risk to subjects. If clinical studies are suspended, Anika may be unable to continue the development of the investigational products affected.

In addition to the FDA approval processes for products, manufacturing facilities for products that are subject to pre-market approval ("PMA") requirements, are subject to approval by the FDA. Among the conditions for such approval is the requirement that quality control and manufacturing procedures conform to the FDA's Good Manufacturing Practices/Quality System Regulations ("GMP/QSR"), which must be followed at all times. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. The FDA enforces compliance with these GMP/QSR through periodic inspections; and other federal, state, and local agencies may inspect manufacturing establishments as well.

In addition to regulations enforced by the FDA, Anika is 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 regulations of foreign governments. Federal, state and foreign regulations regarding the manufacture and sale of medical products are subject to change. Anika cannot predict what impact, if any, such changes might have on its business.

For marketing outside the United States, Anika will continue to be subject to FDA regulations regarding the export of products within its jurisdiction and to foreign regulatory requirements governing, among other things, human clinical trials and marketing approval for medical products and devices. The requirements relating to the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. The process of obtaining approvals from the FDA and foreign regulatory authorities can be costly, time consuming, and subject to unanticipated delays. There can be no assurance that approvals of Anika's products, processes or facilities will be granted or that Anika will obtain the financing needed to develop certain of such products. Any failure or delay in obtaining such approvals could adversely affect the ability of Anika to market its products in other countries.

Medical products regulated by the FDA are generally classified as drugs, biologics, and/or medical devices. AMVISC® is approved as a Class III device in the United States for ophthalmic surgical procedures in intraocular use 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. Anika believes that if FDA approval is obtained, its ORTHOVISC® and INCERT® products will have to meet the regulatory requirements of Class III devices.

*Devices*

The steps required to qualify a medical device for marketing in the United States are complex. Unless a medical device is exempted from pre-market submission and clearance, FDA approval or clearance is required before the products can be marketed in the U.S. Medical devices are classified as Class I, II, or III devices. In general, Class I devices require compliance with labeling GMP/QSR and record keeping regulations and are subject to other general controls. Class II devices may be subject to special controls, such as post market surveillance and are subject to general controls. Most Class I devices are exempt from pre-market notification and most Class II devices are subject to it. Class II devices also may be subject to clinical testing for purposes of pre-market notification to the FDA and clearance for marketing. Class III devices require clinical testing to assure safety and effectiveness prior to marketing and distribution. Most Class III devices also require PMA approval from the FDA.

At least 90 days prior to marketing, unless exempt, devices must be subject to a pre-market notification to the FDA to determine the product's classification and regulatory status. If a product is found to be "substantially equivalent" to a Class I or Class II device, or a Class III device not subject to a PMA requirement, it may be marketed without further FDA review. However, none of the Company's



products have been found to be "substantially equivalent" to a Class I or Class II device, nor have any of them been found to be a Class III device not subject to a PMA requirement. The FDA may require the submission of clinical data as a basis for determining whether a device is "substantially equivalent." If a device is found to be "not substantially equivalent," typically, the device manufacturer must file a PMA application with the FDA based on preclinical and clinical testing intended to demonstrate that the product is both safe and effective. HA-based products have in the past required, and will likely continue to require the approval of a PMA from the FDA prior to commercial sale.

The PMA approval process is lengthy, expensive, and typically requires, among other things, extensive data from pre-clinical testing and a well-controlled clinical trial or trials that demonstrate a reasonable assurance of safety and effectiveness. The performance of human clinical trials must be done under an IDE. Upon completion of required clinical trials, 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 staff then determines whether to accept the application for filing. If accepted for filing, the application is further reviewed by the FDA and then often reviewed by an FDA scientific advisory panel of people with expertise in the relevant field. The FDA will also conduct an inspection to determine whether an applicant conforms with the FDA's current GMP/QSR. If the FDA's evaluation is favorable, the FDA will subsequently publish an order granting the PMA for the device. Although the initial PMA review process is required to be completed within 180 days from the date when the PMA application is accepted for filing, the FDA in many cases raises additional issues which must be addressed prior to the approval of a PMA, which may significantly extend the review process. There is no assurance that review will 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.

*Drugs*

Medical devices may meet both the definition of a medical device and a drug or biologic. In these instances, the FDA may regulate these products as drugs or biologics or as both medical devices and drugs or biologics. The steps required before a drug or biologic may be marketed in the United States include (i) preclinical laboratory and animal tests; (ii) submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may commence; (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug; (iv) submission of a New Drug Application ("NDA") or Biologics License Application ("BLA") to the FDA; and (v) FDA approval of the NDA or BLA prior to any commercial sales or shipment of the drug. A clinical study program designed to demonstrate the safety and effectiveness of a drug usually proceeds in three phases:

Phase I involves testing the drug for, among other things, safety and tolerance in a small group of healthy patients or volunteers.

Phase II involves testing for efficacy and identifying possible side effects in a target patient group.

Phase III involves additional testing for efficacy and safety with an expanded patient group, preferably using a comparative control agent.

The results of the clinical testing, together with manufacturing information, are then submitted to the FDA in the form of an NDA or a BLA. Anika's HA products historically have not been classified as drugs or biologics. In the event that Anika's products are classified in the future as drugs or biologics, it may take five to ten years from discovery to approval, which typically would be substantially longer than the development process for devices and would be substantially more expensive. There is no assurance that



such a regulatory path would result in product approval, or that product approval, if achieved, would be timely.

*Foreign Regulation*

In addition to regulations enforced by the FDA, Anika and its 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 marketed in Canada, Europe, Turkey, and Israel. In Europe, ORTHOVISC® is sold under Communauté Européenne ("CE mark") authorization, a certification required under European Union ("EU") medical device regulations. The CE mark 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 October 1996, the Company received an EC Design Examination and an EC Quality System Certificate from a European Notified Body, which entitled the Company to affix a CE marking for ORTHOVISC® as a viscoelastic supplement or a replacement for synovial fluid in human joints. There can be no assurance that Anika will be able to achieve and/or maintain compliance required for CE marking or other foreign regulatory approvals for any or all of its 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**

The Company competes 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 the Company. The Company also competes with academic institutions, governmental agencies and other research organizations, which may be involved in research, development and commercialization of products. Many of the Company's competitors also compete against the Company in securing relationships with collaborators for their research and development and commercialization programs.

General competition in the Company's 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 the Company's ability to compete in its HA development and commercialization market include:

the quality and breadth of the Company's technology and technological advances;

the ability of the Company to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to its competitors.

the Company's ability to recruit and retain skilled employees; and

the availability of substantial capital resources to fund discovery, development and commercialization activities.

The Company is 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 United States or in certain foreign countries. There exists major competing products for the use of HA in ophthalmic surgery including Healon, manufactured by Pharmacia, and Provisc and Viscoat, distributed by Alcon. In addition, certain HA products for the treatment of osteoarthritis in the knee have received FDA approval and are being marketed in the United States and in select markets in Canada, Europe and other countries. There is a risk that the Company will be unable to compete effectively against its current or future competitors.



**RESEARCH AND DEVELOPMENT**

The Company's research and development efforts consist primarily of the development of new medical applications for its HA-based technology and 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. The Company's development of new products is accomplished primarily through in-house research and development personnel and resources as well as through collaboration with other companies and scientific researchers. For the years ended December 31, 2001, 2000, and 1999, research and development expenses were $4.3 million, $3.3 million, and $4.2 million, respectively. The Company anticipates that it will continue to commit substantial resources to research and development, including clinical trials, in the future. As of December 31, 2001, the Company had seven employees engaged primarily in research and development.

There is a risk that the Company's efforts will not be successful in (i) developing its existing product candidates, (ii) expanding the therapeutic applications of its existing products, or (iii) resulting in new applications for its HA technology. There is also a risk that the Company may choose not to pursue development of potential product candidates. The Company may not be able to obtain regulatory approval for any new applications it develops. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that the Company will achieve meaningful sales of such products or applications.

**EMPLOYEES**

As of December 31, 2001, the Company had approximately 67 full-time employees. The Company considers its relations with its employees to be good. No employees are represented by labor unions.

**ENVIRONMENTAL LAWS**

The Company believes that it is in compliance with all federal, state and local environmental regulations with respect to its manufacturing facilities and that the cost of ongoing compliance with such regulations does not have a material effect on the Company's operations. The Company's leased manufacturing facility is located within the Wells G&H Superfund site in Woburn, MA. The Company has not been named and is 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 there can be no assurance that substantial product liability claims will not be asserted against the Company. Although the Company has not received any material product liability claims to date and has coverage under its insurance policy of $5,000,000 per occurrence and $5,000,000 in aggregate, there can be no assurance that if material claims arise in the future, that the Company's 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 the Company's business, financial condition, and results of operation.

**RECENT DEVELOPMENTS**

On March 26, 2002, Anika announced certain management changes. Charles H. Sherwood, Ph.D., the current President and Chief Operating Officer, was named to succeed Douglas R. Potter as the Company's chief executive officer, effective April 2, 2002. Mr. Potter plans to leave the company to pursue entrepreneurial opportunities and personal interests. Mr. Potter will continue as the Company's Chief Financial Officer as the company seeks a new Chief Financial Officer and until the Company can effect an orderly transition. Anika also announced the appointment of Robert E. Tellis as Senior Vice President of Sales and Marketing.



**ITEM 2. PROPERTIES**

The Company leases 35,000 square feet of space at 236 West Cummings Park, Woburn, Massachusetts for its corporate headquarters and manufacturing facility. This facility has received all FDA and state regulatory approvals to operate as a sterile device and drug manufacturer. The lease for this facility terminates in February 2004. The Company also leases (i) approximately 10,000 square feet of administrative and research and development space in Woburn, Massachusetts and has agreed to lease this facility through October 2003; and (ii) approximately 9,000 square feet of warehouse space in Woburn, Massachusetts under a lease terminating in January 2004. For the year ended December 31, 2001, the Company had aggregate lease costs of approximately $703,482.

**ITEM 3. LEGAL PROCEEDINGS**

*Securities and Exchange Commission Investigation.* In May 2000, the Securities and Exchange Commission ("SEC") issued a formal order of investigation and has required the Company to provide information in connection with certain revenue recognition matters. The Company has been cooperating fully. These matters involve the Company's historical accounting for and disclosures concerning sales of ORTHOVISC® under a long-term supply and distribution agreement with Zimmer, as discussed in Note 16 to the financial statements included herein. The Company is not in a position to predict the probable outcome of the SEC's investigation or its potential impact on the Company's business or operations. See Note 15 to the financial statements included herein for a more detailed discussion of this investigation.

*Putative Class Action Complaints.* In 2000, three putative class action complaints were filed against the Company and its former chief executive officer, and former chief financial officer in the United States District Court for the District of Massachusetts (the "Court") on behalf of all purchasers of the Company's shares between April 15, 1998 and May 30, 2000 alleging violations of the federal securities laws by, *inter alia*, making material misrepresentations and omissions in certain public disclosures during the period between April 15, 1998 and May 30, 2000, as discussed in Note 15 to the financial statements included herein. The parties reached agreement on the terms of a potential settlement of the action. After preliminary approval of a Stipulation and Agreement of Settlement by the Court, the Company paid $1.25 million into a settlement fund. The Company's insurer paid the Company $400,000 in exchange for a release of the insurer's obligations under the policy, which policy's term was from December 1, 1999 to November 30, 2000 and which time period covers the allegations made in the securities class action litigation as well as the SEC investigation. The Company applied the $400,000 to the settlement amount in the shareholder class action lawsuit. See Note 15 to the financial statements included herein for a more detailed discussion of this matter.

**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 AND RELATED STOCKHOLDER MATTERS**

**COMMON STOCK INFORMATION**

The Company's common stock par value $0.01 per share (the "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 bid prices of the 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, 2000 | Bid Range High | Bid Range Low |
|---|---|---|
| First Quarter | $ 12.00 | $ 6.00 |
| Second Quarter | 9.97 | 1.38 |
| Third Quarter | 1.88 | 1.22 |
| Fourth Quarter | 1.81 | 0.69 |

| Year Ended December 31, 2001 | Bid Range High | Bid Range Low |
|---|---|---|
| First Quarter | $ 1.81 | $ 0.75 |
| Second Quarter | 1.69 | 0.98 |
| Third Quarter | 1.73 | 0.88 |
| Fourth Quarter | 1.15 | 0.84 |

At December 31, 2001, the closing price per share of Common Stock was $1.00 as reported on the Nasdaq National Market and there were approximately 308 holders of record of Common Stock.

The Company has never declared or paid any cash dividends on its Common Stock. The Company currently intends to retain earnings, if any, for use in its business and does not anticipate paying cash dividends on its Common Stock in the foreseeable future. Payment of future dividends, if any, on the Common Stock will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results, anticipated cash needs, and plans for expansion.



**ITEM 6. SELECTED FINANCIAL DATA**

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

| | Years ended December 31, 2001 | 2000 | 1999 | 1998 | 1997 |
|---|---|---|---|---|---|
| Product revenue | $ 11,299 | $ 12,935 | $ 13,426 | $ 11,430 | $ 9,255 |
| Licensing revenue | 13 | 3,400 | 400 | 1,500 | 2,700 |
| Total revenue | 11,312 | 16,335 | 13,826 | 12,930 | 11,955 |
| Cost of product revenue | 8,229 | 9,871 | 6,664 | 5,790 | 4,744 |
| Gross profit | 3,083 | 6,464 | 7,162 | 7,140 | 7,211 |
| Total operating expenses | 10,494 | 7,448 | 7,184 | 4,687 | 4,050 |
| (Loss) income before cumulative effect of change in accounting principle | (6,758) | 174 | 1,248 | 3,633 | 3,344 |
| Cumulative effect of change in accounting principle | | | (3,625) | | |
| Net (loss) income | $ (6,758) | $ 174 | $ (2,377) | $ 3,633 | $ 3,344 |
| Diluted (loss) income per common share: | | | | | |
| (Loss) income before cumulative effect of change in accounting principle | $ (0.68) | $ 0.02 | $ 0.12 | $ 0.33 | $ 0.44 |

| | Years ended December 31, | | | | |
|---|---|---|---|---|---|
| Cumulative effect of change in accounting principle | | | (0.35) | | |
| Net (loss) income | $ (0.68) | $ 0.02 | $ (0.23) | $ 0.33 | $ 0.44 |
| Diluted common shares outstanding | 9,934 | 10,042 | 10,221 | 11,006 | 7,587 |

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

| | December 31, | | | | |
|---|---|---|---|---|---|
| | **2001** | **2000** | **1999** | **1998** | **1997** |
| Cash and cash equivalents | $ 9,065 | $ 8,266 | $ 6,441 | $ 10,713 | $ 22,680 |
| Short term marketable securities | 3,994 | 10,040 | 13,743 | 12,008 | |
| Working capital | 16,756 | 23,083 | 18,973 | 26,361 | 25,329 |
| Total assets | 22,916 | 28,979 | 32,511 | 32,617 | 28,749 |
| Accumulated deficit | (11,357) | (4,599) | (4,773) | (2,277) | (6,029) |
| Treasury stock | (280) | (280) | (960) | (1,890) | |
| Stockholder's equity | 20,104 | 26,712 | 25,712 | 29,179 | 26,224 |



**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 the Company's 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 and Certain Factors Affecting Future Operating Results." 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.*

*Overview*

Anika develops, manufactures and commercializes therapeutic products and devices intended to promote the protection and healing of bone, cartilage and soft tissue. 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 marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans, and HYVISC®, which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC® is currently approved for sale and is being marketed in Canada, parts of Europe, Turkey, and Israel. In the U.S., ORTHOVISC® is currently limited to investigational use. The Company commenced a Phase III clinical trial of ORTHOVISC® in the U.S. and Canada in February 2001. The Company manufactures AMVISC® and AMVISC® Plus for Bausch & Lomb, which are HA products used as viscoelastic supplements in ophthalmic surgery. STAARVISC®II, an injectable ophthalmic viscoelastic, is produced for STAAR Surgical Company, and ShellGel , also an injectable ophthalmic viscoelastic, is produced for Cytosol Ophthalmics, Inc.

The Company receives a substantial portion of its revenue from the sale of AMVISC® and AMVISC®Plus to Bausch & Lomb. For the years ended December 31, 2001, 2000 and 1999, sales to Bausch & Lomb accounted for 65.2%, 54.1%, and 62.3% of product revenue, respectively. In July 2000, the Company entered into the B&L Agreement. Under the terms of the B&L Agreement, effective January 1, 2001, the Company became Bausch & Lomb's exclusive provider of AMVISC® and AMVISC® Plus, ophthalmic viscoelastic products, in the U.S. and international markets. The B&L Agreement expires December 31, 2007, and superceded the prior supply agreement with Bausch & Lomb that was set to expire December 31, 2001. The B&L Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The B&L Agreement lifts contractual restrictions on the Company's sales of certain ophthalmic products to other

companies, subject to payment of royalties to Bausch & Lomb by the Company. In exchange, the Company agreed to a reduction in unit selling prices effective April 1, 2000, and the elimination of minimum unit purchase obligations by Bausch & Lomb.



***Results of Operations***

*Year ended December 31, 2001 compared to year ended December 31, 2000*

**Statement of Operations Detail**

| | Years ended December 31, | |
|---|---|---|
| | **2001** | **2000** |
| Product revenue | $ 11,298,954 | $ 12,935,222 |
| Licensing revenue | 13,000 | 3,400,000 |
| Total revenue | 11,311,954 | 16,335,222 |
| Cost of product revenue | 8,228,751 | 9,870,559 |
| Gross profit | 3,083,203 | 6,464,663 |
| Operating expenses: | | |
| Research and development | 4,280,520 | 3,259,984 |
| Selling, general and administrative | 5,262,708 | 4,188,044 |
| Litigation settlement costs | 950,716 | |
| Total operating expenses | 10,493,944 | 7,448,028 |
| Loss from operations | (7,410,741) | (983,365) |
| Interest income, net | 662,192 | 1,172,859 |
| (Loss) income before provision for income taxes | (6,748,549) | 189,494 |
| Provision for Income taxes | 9,084 | 15,940 |
| Net (loss) income | $ (6,757,633) | $ 173,554 |

In November 1997, the Company entered into a marketing and distribution agreement with Zimmer that was subsequently amended in June 1998 and June 1999 (the "Zimmer Distribution Agreement".) The Zimmer Distribution Agreement provided Zimmer with exclusive marketing and distribution rights to ORTHOVISC® in the United States, Canada, Latin America, Asia and most of Europe. On November 10, 2000 the Company entered into an agreement with Zimmer to terminate the Zimmer Distribution Agreement. As a result of the termination of the Zimmer Distribution Agreement, Anika recognized an aggregate of $4,249,000 of revenue in the fourth quarter of 2000, comprised of $1,324,000 of product revenue and $2,925,000 of licensing revenue for amounts previously received from Zimmer, and a one-time payment received under the termination agreement. The termination agreement eliminated all obligations under the Zimmer Distribution Agreement with respect to milestone payments, minimum purchases, and unit pricing adjustments based on market prices, and provided for the disposal by January 31, 2001 of all units of ORTHOVISC® previously purchased by Zimmer, including units held in Anika's refrigerators at Zimmer's request.

*Product Revenue.* Product revenue for the year ended December 31, 2001 was $11,298,954, a decrease of $1,636,268 or 13%, compared with $12,935,222 recorded in the prior year. The decrease was primarily attributable to lower ORTHOVISC® sales due to the termination of the Zimmer Distribution Agreement, as well as reduced selling prices to another customer. In connection with the termination of the Zimmer Distribution Agreement referred to above, product revenue for the year ended December 31, 2000 included recognition of revenue of $1,149,000, which had previously been deferred. The Company has experienced volatility in its international sales of ORTHOVISC, particularly with respect to sales for the Turkish market. Ongoing economic issues in Turkey, and perhaps regional conflict and political uncertainties, may

contribute to sales volatility. A reduced selling price was negotiated to meet competitive market conditions in certain international markets and is not expected to result in increased volume sufficient to offset the price reduction in future periods. AMVISC® product sales increased $366,424 compared with 2000 as a result of higher unit volumes that partially offset lower unit prices under the B&L



Agreement, effective April 1, 2000. Under the terms of the agreement with Bausch & Lomb, the price for units sold in a calendar year is dependent on 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, 2001 were subject to possible retroactive price adjustments when the actual annual unit volume for 2001 became known. In accordance with the Company's revenue recognition policy, certain amounts of revenue are not recognized if the sale price is not fixed or determinable, and any amounts received in excess of revenue recognized is recorded as deferred revenue. In the fourth quarter of 2001, product revenue included the recognition of $401,475 of revenue related to sales of AMVISC® to Bausch & Lomb, which had been previously deferred during the first three quarters of fiscal 2001 until the actual annual unit volume for 2001 became fixed or determinable. The Company's sales of HYVISC® also increased by $77,920 during 2001 as compared with 2000 and is expected to continue to increase. The current agreement expires at the end of May 2002. The Company is currently in discussions to renew the agreement for an additional term, however, it cannot make any assurances that it will be successful in doing so, or that it will be able to enter into an agreement on terms as favorable as its current agreement.

*Licensing revenue.* The Company recognized licensing revenue of $13,000 for the year ended December 31, 2001 related to up-front payments on two new five year supply agreements with purchasers of the Company's ophthalmic products. Licensing revenue of $3,400,000 for the year ended December 31, 2000 includes: (i) $100,000 per quarter of amortization of milestone payments received in 1997 and 1998 under the Zimmer Distribution Agreement, in accordance with SAB 101; (ii) recognition of revenue, previously deferred, in the amount of $2,925,000 in the fourth quarter of 2000 as a result of the termination of the Zimmer Distribution Agreement; and (iii) a one-time payment in connection with the termination of the Zimmer Distribution Agreement.

*Gross Profit.* Gross profit for the year ended December 31, 2001 was $3,083,203, or 27% of revenue, compared with $6,464,663, or 40% of revenue, for the year ended December 31, 2000. Excluding the effects of the termination of the Zimmer Distribution Agreement, gross profit for 2000 was $2,765,000, or 23% of adjusted revenue. After learning of unfavorable results from a clinical trial of ORTHOVISC® announced on May 31, 2000, the Company suspended certain manufacturing activities in an effort to reduce work-in-process inventory of HA. As a result of the suspended manufacturing activities, work-in-process inventory has been reduced from $4.3 million at June 30, 2000 to $2.0 million at December 31, 2001. Late in the fourth quarter of 2001 the Company resumed the previously suspended manufacturing activities. During periods of reduced manufacturing activity, certain fixed costs of manufacturing were not fully absorbed into the cost of product manufactured and sold. Rather, such costs were charged to expense and amounted to approximately $2.1 million during the second half of 2000 and approximately $2.0 million during the full year of 2001. Gross profit also reflects lower prices for the Company's sales of ophthalmic products under the new Bausch & Lomb contract effective April 1, 2001 and lower prices to a foreign distributor of ORTHOVISC® in 2001, reflecting competitive market conditions.

*Research and Development.* Research and development expenses for the year ended December 31, 2001 increased by $1,020,536 or 31% to $4,280,520 from $3,259,984 recorded in the prior year. The increase in research and development during 2001 is primarily attributable to clinical trial costs for the ORTHOVISC® Phase III trial, which commenced in the first quarter of 2001. The Company expects that research and development expenses for 2002 will be comparable to 2001 as clinical trials for ORTHOVISC® proceed.

*Selling, General and Administrative.* Selling, general and administrative expenses for the year ended December 31, 2001 increased by $1,074,664 or 26% to $5,262,708 from $4,188,044 in the prior year. This increase is primarily attributable to several items. First, separation costs related to management changes implemented in June 2001 amounted to $545,000, including forgiveness of loans to former officers totaling $129,000. Second, accrued lease costs related to certain warehouse space was approximately $100,000.



Third, selling and marketing expenses related to ORTHOVISC® amounted to approximately $290,000. No such costs were incurred in 2000. Fourth, professional fees and public reporting costs were approximately $130,000 higher in 2001.

*Litigation settlement costs.* Litigation settlement costs for the year ended December 31, 2001 included a charge of $850,000, which is the portion of the $1.25 million settlement amount contributed by the Company, and $100,716 in professional fees related to the putative class action suit. The settlement received final court approval on October 22, 2001 (See Note 15 of the financial statements included in Item 8 herein.)

*Interest Income, Net.* The Company's net interest income decreased by $510,667, or 44%, to $662,192 for the year ended December 31, 2001 from $1,172,859 in the prior year. The decreases are attributable to reduced average cash balances and lower interest rates during 2001. Interest income in 2002 is also expected to be adversely affected by lower market interest rates as well as lower average cash and investment balances.

*Income Taxes.* The Company recorded income tax expense for the year ended December 31, 2001 of $9,084, and $15,940 for the year ended December 31, 2000. The tax provisions primarily represent state income taxes paid on investment income. For federal income tax purposes, the Company has had net operating losses available to offset otherwise taxable income. As of December 31, 2001, the Company has federal and state net operating loss carry-forwards of $10,208,949 and $5,389,235, respectively, which may be available to offset future taxable income, if any. As provided in Section 382 of the Internal Revenue Code ("IRC") the amount of net operating loss and credit carry-forwards that the Company may utilize in any one year may be restricted in the event of certain changes in ownership.



*Year ended December 31, 2000 compared to year ended December 31, 1999*

**Statement of Operations Detail**

| | Years ended December 31, | |
|---|---|---|
| | **2000** | **1999** |
| Product revenue | $ 12,935,222 | $ 13,425,642 |
| Licensing revenue | 3,400,000 | 400,000 |
| Total revenue | 16,335,222 | 13,825,642 |
| Cost of product revenue | 9,870,559 | 6,664,163 |
| Gross profit | 6,464,663 | 7,161,479 |
| Operating expenses: | | |
| Research and development | 3,259,984 | 4,154,479 |
| Selling, general and administrative | 4,188,044 | 3,029,394 |
| Litigation settlement costs | | |
| Total operating expenses | 7,448,028 | 7,183,873 |
| Loss from operations | (983,365) | (22,394) |
| Interest income, net | 1,172,859 | 1,068,430 |
| Gain on sale of securities | | 233,633 |
| Income before provision for income taxes | 189,494 | 1,279,669 |
| Provision for income taxes | 15,940 | 31,412 |
| Income before cumulative effect of change in accounting principle | 173,554 | 1,248,257 |
| Cumulative effect of change in accounting principle | | (3,625,000) |
| Net income (loss) | $ 173,554 | $ (2,376,743) |

*Product Revenue.* Product revenue for the year ended December 31, 2000 was $12,935,222, a decrease of $490,420 or 4%, compared with $13,425,642 recorded in the prior year. The decrease was partially attributable to reduced sales of AMVISC® products to Bausch & Lomb of $1,363,968 compared with the prior year, reflecting lower prices effective April 1, 2000 under the B&L Agreement. Product revenue associated with ORTHOVISC® increased by $600,504 compared to 1999 as a result of the recognition of approximately $1,324,000 million of revenue upon termination of the Zimmer Distribution Agreement as previously reported, and was partially offset by decreased sales to the

Company's Turkish distributor. The Company's sales of HYVISC® also increased by $304,680 during 2000 as compared with 1999.

*Licensing Revenue.* Licensing revenue of $3,400,000 for the year ended December 31, 2000 includes: (i) $100,000 per quarter of amortization of milestone payments received in 1997 and 1998 under the Zimmer Distribution Agreement, in accordance with SAB 101; (ii) deferred revenue recapture of $2,925,000 in the fourth quarter of 2000; and (iii) a one-time payment received as a result of the termination of the Zimmer Distribution Agreement referred to above.

*Gross Profit.* Gross profit for the year ended December 31, 2000 was $6,464,663, a decrease of $696,816 or 10% from $7,161,479 recorded in the prior year. Excluding the effects of the termination of the Zimmer Distribution Agreement (as referred to in the preceding paragraphs), gross profit for 2000 was $2,765,000, or 23% of adjusted revenue, compared with a gross profit of 52% in 1999. The decrease was primarily attributable to two factors. First, after learning of unfavorable results from a clinical trial of ORTHOVISC® announced on May 31, 2000, the Company suspended certain manufacturing activities in an effort to reduce work in process inventory