

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)

- 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

- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-21326

### Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

**04-3145961**  
(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  No

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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.

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

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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.

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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

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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

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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.

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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*

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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

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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.

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## **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.

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## 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.

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## 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	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
	Bid Range	
Year Ended December 31, 2001	High	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

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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

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**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
<b>Total revenue</b>	<b>11,311,954</b>	<b>16,335,222</b>
Cost of product revenue	8,228,751	9,870,559
<b>Gross profit</b>	<b>3,083,203</b>	<b>6,464,663</b>
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	
<b>Total operating expenses</b>	<b>10,493,944</b>	<b>7,448,028</b>
<b>Loss from operations</b>	<b>(7,410,741)</b>	<b>(983,365)</b>
Interest income, net	662,192	1,172,859
<b>(Loss) income before provision for income taxes</b>	<b>(6,748,549)</b>	<b>189,494</b>
Provision for Income taxes	9,084	15,940
<b>Net (loss) income</b>	<b>\$ (6,757,633)</b>	<b>\$ 173,554</b>

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.)

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*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.

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

*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

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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 of HA. Total inventory was reduced from \$7.2 million at

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June 30, 2000 to \$4.7 million at December 31, 2000. Cost of product revenue during the second half of 2000 included charges of approximately \$2.1 million to reflect this underutilization of manufacturing capacity. Second, the price reduction associated with the B&L Agreement, effective April 1, 2000, reduced gross margin by approximately \$2.2 million, as compared to the prior year.

*Research and Development.* Research and development expenses for the year ended December 31, 2000 decreased by \$894,495, or 22%, to \$3,259,984 from \$4,154,479 recorded in the prior year. The decrease in research and development during 2000 was primarily attributable to lower clinical trial costs as the prior ORTHOVISC® Phase III trial was completed during the first half of 2000. Costs of new trials during 2000 were minimal.

*Selling, General and Administrative.* Selling, general and administrative expenses for the year ended December 31, 2000 increased by \$1,158,650, or 44%, to \$4,188,044 from \$3,029,394 in the prior year. The increase was primarily due to increased professional fees associated with the SEC's investigation of certain revenue recognition matters, a shareholder class action suit, and contractual negotiations relating to various distribution agreements and other matters.

*Interest Income, Net, and Gain on Sale of Securities.* The Company's net interest income increased by \$104,429, or 10%, to \$1,172,859 for the year ended December 31, 2000 from \$1,068,430 in the prior year. The increase is attributable to higher market interest rates during 2000, but offset by lower average cash balances on hand in 2000 versus 1999. During the fourth quarter of 1999, the Company recorded a gain of approximately \$233,633, net of expenses, on the sale of equity securities purchased in the second quarter of 1999.

*Income Taxes.* The Company recorded tax expense for the year ended December 31, 2000 of \$15,940, and \$31,412 for the year ended December 31, 1999. The tax provisions primarily represent state income taxes 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, 2000, the Company has federal and state net operating loss carry-forwards of \$4,629,000 and \$1,403,000, respectively that 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.

### LIQUIDITY AND CAPITAL RESOURCES

The Company requires cash to fund its operating expenses and to make capital expenditures. The Company expects that its requirement for cash to fund these uses will increase as the scope of its operations expands. Historically the Company has funded its cash requirements from available cash and investments on hand.

At December 31, 2001, the Company had cash, cash equivalents and short-term investments in marketable securities of \$13.0 million versus cash, cash equivalents and short-term marketable securities of \$18.3 million at December 31, 2000, representing a decrease of 28%. During 2001, the Company's net loss adjusted for depreciation, and amortization used \$5.5 million of cash. During 2001, this use of cash was partially offset by cash provided by working capital items, primarily inventories, amounting to \$1.2 million. Accordingly, net cash used for operating activities was \$4.3 million. During 2001, the Company used \$908,000 for capital expenditures, primarily to construct certain manufacturing and laboratory facilities. Capital expenditures in 2002 are expected to include spending for small equipment, computers, and furniture and fixtures associated with normal operations. The Company anticipates that use of cash in 2002 will be significantly less than cash used in 2001.



The Company's future capital requirements and the adequacy of available funds will depend, on numerous factors, including:

- market acceptance of its existing and future products;
- the successful commercialization of products in development;
- progress in its 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 its products.

There can be no assurance that the Company will record profits in future periods. However, the Company believes that its cash and investments on hand will be sufficient to meet its requirements through at least the end of fiscal 2002. See "Risk Factors and Certain Other Factors Affecting Future Operating Results History of Losses; Uncertainty of Future Profitability."

The terms of any future equity financings may be dilutive to the Company's stockholders and the terms of any debt financings may contain restrictive covenants, which could limit the Company's ability to pursue certain courses of action. The ability of the Company to obtain financing is dependent on the status of the Company's 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 the Company or will be available on acceptable terms should such a need arise.

#### **Critical Accounting Policies**

In December 2001, the SEC requested that reporting companies discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one that is important to the portrayal of a company's financial condition and operating results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

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 this and other accounting policies, see Note 2 in the Notes to the Consolidated Financial Statements of this Annual Report on Form 10-K. The Company's preparation of this Annual Report on Form 10-K requires it to make estimates and assumptions that affect the reported amount of assets and liabilities, disclosure of contingent assets and liabilities at the date of its financial statements, and assurance that actual results will not differ from those estimates.

*Revenue Recognition.* Product revenue is recognized upon shipment to the customer as long as there is (i) persuasive evidence of an arrangement, (ii) the sales price is fixed or determinable and (iii) collection of the related receivable is probable. Amounts billed or collected

prior to recognition of revenue is classified as deferred revenue. Determination of criteria (ii) and (iii) are based on management's

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judgments regarding the fixed nature of the product fee and collectibility of those fees. Under the new agreement with Bausch and 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 interim quarters are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. In accordance with the Company's revenue recognition policy, the amount of revenue reasonably subject to the price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. ORTHOVISC® is 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. The Company recognizes non-refundable upfront or milestone payments received as part of supply, distribution, and marketing arrangements, ratably over the terms of the arrangements to which the payments apply. The Company has received up-front payments related to two five-year supply agreements for its ophthalmic products. In accordance with the Company's revenue recognition policy, the Company records these payments as deferred revenue at the time of receipt, and recognizes revenue over the period to which the payments relate.

*Reserve for Obsolete/Excess Inventory.* Inventories are stated at the lower of cost or market. We regularly review raw materials and work-in-process inventories and record a provision for excess and obsolete inventory if the inventory has not progressed through the manufacturing process for a period of time in excess of the typical inventory cycle period. The reserve is adjusted in subsequent periods to reflect the current movement of the inventory through the manufacturing process.

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## **RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS**

***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.

In order to sell ORTHOVISC® in the United States, it will have to meet regulatory requirements for a Class III device as determined by the FDA. Class III devices are those that generally must receive pre-market approval from the FDA (e.g. life-sustaining, life-supporting and implantable or new devices which have not been found to be substantially equivalent to legally marketed devices) and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. In order for us to commercially distribute ORTHOVISC® in the U.S., we must obtain a PMA. The PMA process can be expensive, uncertain and lengthy. A number of devices for which PMAs have been sought have never been approved for marketing. The review of an application often occurs over a protracted time period, potentially taking two years or more from the filing date to complete. We submitted a PMA application for ORTHOVISC® in December 1997. In October 1998, we were notified by the FDA that our PMA application for ORTHOVISC® was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC®. We submitted an IDE to the FDA in February 1999 and received approval in late March 1999 to commence a second Phase III clinical study. We received initial results from the Phase III clinical trial in late May 2000 that we determined did not show sufficient efficacy to support the filing of a PMA application. We have evaluated available information and announced its intention to pursue further clinical trials. In February 2001, we commenced another Phase III clinical trial of ORTHOVISC®. The trial is being 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 assurance that:

any additional clinical data will support the efficacy of ORTHOVISC®;

we will complete any additional clinical trials of ORTHOVISC®;

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we will be able to successfully complete the FDA approval process;

additional clinical trials will support a PMA application and/or FDA approval in a timely manner or at all.

There also can be no assurance that any delay in receiving FDA approvals will not continue to adversely affect our competitive position. (See "Competition" below) Furthermore, even if we were to receive a PMA approval:

the approval may include significant limitations on the indications and other claims sought for use for which the product may be marketed;

the approval may include other significant conditions to approval such as post-market testing, tracking, or surveillance requirements;

we may not be able to achieve meaningful sales of ORTHOVISC® in the U.S.

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Our HA product under development, INCERT®-S, has not obtained regulatory approval in the U.S. for commercial marketing and sale. We believe that INCERT®-S will be regulated as a Class III medical device and will require a PMA prior to marketing. We have received IDE approval from the FDA and are evaluating product development activities. There can be no assurance that:

we will begin or successfully complete clinical trials of INCERT®-S;

the clinical data will support the efficacy of INCERT®-S;

we will be able to successfully complete the FDA approval process;

additional clinical trials will support a PMA application and/or FDA approval in a timely manner or at all.

There also can be no assurance 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 product may be marketed;

the approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements;

meaningful sales of INCERT®-S may never be achieved.

Once obtained, marketing approval can be withdrawn by the FDA for a number of reasons, including, among other things, 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 that effect safety and effectiveness may be deemed approved after a 30-day notice unless the FDA requests a 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 Good Manufacturing Practices/Quality System Regulations (GMP/QSR). Ongoing compliance with GMP/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. There can be no assurance 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 there can be no assurance 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. There can be no assurance 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. There can be no assurance that approvals or clearances of our products will be granted or that we will have the necessary funds to develop certain of its products. Any failure to obtain, or delay in obtaining such approvals or clearances, could adversely affect our ability to market our products.

***We have historically incurred operating losses and we cannot make any assurances about our future profitability.***

From our inception through December 31, 1996 and in 1999, 2000, and 2001, we have incurred annual operating losses. As of December 31, 2001, we had an accumulated deficit of approximately \$11.4 million. The continued development of our products will require the commitment of substantial resources to conduct research and preclinical and clinical development programs, and to establish sales and marketing capabilities or distribution arrangements. Our ability of the Company to reach profitability is highly uncertain. To achieve profitability, we must, among other things, successfully complete development of certain of our products, obtain regulatory approvals and establish sales and marketing capabilities or distribution arrangements for certain of 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, 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, several of our competitors have already obtained FDA and foreign regulatory approvals for marketing HA products with applications similar to that of ORTHOVISC®. Thus, the successful commercialization of ORTHOVISC® will

depend in part on our ability to effectively market ORTHOVISC® against more established products with a longer sales history. 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 currently experiencing uncertainties in the Turkish market from economic, regional, political, and competitive factors. As a result, we are uncertain of the extent of our future sales in this market.

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***We are uncertain regarding the success of our clinical trials.***

Several of our products, including ORTHOVISC®, will require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. In late May 2000, our initial analysis of the results of our second Phase III clinical trial of ORTHOVISC® did not show sufficient efficacy to support the filing of a PMA application to obtain FDA approval. Although we have received (IDE) approval from the FDA for both ORTHOVISC® and INCERT®-S, there can be no assurance that:

any additional clinical data will support the efficacy of ORTHOVISC®,

we will begin or complete clinical trials of INCERT®-S or complete any additional clinical trials of ORTHOVISC®,

we will be able to successfully complete the FDA approval process for either ORTHOVISC® or INCERT®-S,

additional ORTHOVISC® or INCERT®-S clinical trials will support a PMA application and/or FDA approval in a timely manner, or at all.

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 B&L Agreement, effective January 1, 2001, we 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 an existing supply contract 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 our ability to sell certain ophthalmic products to other companies, subject to our payment of royalties. In exchange, we 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.

We have not achieved incremental sales of our ophthalmic products to Bausch & Lomb and/or other companies sufficient to offset the effects of the price reduction and royalties to Bausch & Lomb and there can be no assurances that we will be able to do so in the future. The reduction in unit prices resulted in a decrease in our revenue and gross profit from Bausch & Lomb. We expect revenue in 2002 to be consistent with 2001. 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, 2001 and 2000, sales of AMVISC® products to Bausch & Lomb accounted for 65.2% and 54.1% of product revenues, respectively. Although we intend to continue to seek new ophthalmic product customers, there can be no assurances that we will be successful in obtaining new customers or to achieve meaningful sales to such new customers.

The ORTHOVISC® distribution agreement with Zimmer 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, we reached an agreement with Zimmer for an early termination of its marketing and distribution agreement for ORTHOVISC®. The termination may continue to have a material adverse effect on our ability to market ORTHOVISC®, which is likely to have a material adverse effect on our future operating results. We have relationships with logistics agents (outsource order processing providers) to distribute ORTHOVISC® to customers in Canada and European countries previously served by Zimmer. We are seeking to establish long-term relationships with new distribution partners in those countries where Zimmer previously sold the product. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such partners. There can be no assurance that we will obtain European or other reimbursement approvals or, if such approvals are obtained, they will be obtained on a timely basis or at a satisfactory level of reimbursement.

We will need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners, such as Zimmer. Our current agreement for the distribution of HYVISC® in the United States with Boehringer Animal Health, Inc. expires at the end of May 2002. Although we are in negotiations to extend the agreement for an additional term, there can be no assurance that Boehringer will agree or that other partners will agree to market our products on acceptable terms. 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 will 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 PTO to determine priority of invention (see below), 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. Our issued patents and any patents, which arise from our licensed application, would provide competitive protection, if at all, only in the United States. We have not, to date, pursued foreign patents equivalent to those issued or applied for in the United States.

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. The existence of the interference proceeding may have a negative impact on the marketing of the INCERT® product, and 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 B&L Agreement, we have agreed to transfer to Bausch & Lomb, upon expiration of the term of the B&L agreement on December 31, 2007, or in connection with earlier termination in certain circumstances, our manufacturing process, know-how and technical information, which relate to AMVISC® products. Upon expiration of the 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. Furthermore, our manufacturing processes and research and development efforts involve animals and products derived from animals. 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.

***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 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. In addition, Congress and certain state legislatures have considered reforms that may

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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 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, cash equivalents and short-term marketable securities of approximately \$13.1 million as of December 31, 2001. 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 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.

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 who could have a material adverse effect on us. In June 2001, Mr. Engle, the former Chief Executive Officer and Chairman of the Board of Directors, and Mr. Slater, the former Vice President of Operations, ceased to be employees. As of April 2, 2002, Mr. Sherwood, the current President and Chief Operating Officer will succeed Mr. Potter as the Chief Executive Officer of the Company. Although Mr. Potter has agreed to remain the Chief Financial Officer while the Company seeks a new Chief Financial Officer in order to effect an orderly transition, we cannot make any assurances that an orderly transition will be achieved. In addition, we also appointed a new Senior Vice President of Sales and Marketing on March 25, 2002. There can be no assurances that such management changes will not adversely affect our business. In addition, 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.***

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During the years ended December 31, 2001 and 2000, approximately, 25.0% and 20.0%, respectively, of our product sales were sold 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. We sell our ORTHOVISC® product to a European sales and marketing company for supply of the Turkish market. The Turkish economic situation has been volatile and the impacts of this volatility on future sales of ORTHOVISC® are uncertain. 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. In particular, our stock price declined significantly in October 1998 following our announcement that the FDA had notified us that its PMA for ORTHOVISC® was not approvable and that additional

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clinical data would be required to demonstrate the effectiveness of ORTHOVISC®. The stock price declined again in May 2000 following our announcements that initial analysis of results from the Phase III clinical trial of ORTHOVISC® did not show sufficient efficacy to support the filing of a PMA application to obtain FDA approval, and that the SEC had issued a formal order of investigation and required us to provide information in connection with certain revenue recognition matters. 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.

***There is a risk that we may be unable to maintain our listing on the Nasdaq National Market.***

Our Common Stock is currently traded on the Nasdaq National Market. Under NASDAQ's listing maintenance standards, if the minimum bid price of our Common Stock is under \$1.00 per share for 30 consecutive trading days, NASDAQ may choose to notify us that it is delisting our Common Stock from NASDAQ. If the minimum bid price of our Common Stock does not thereafter regain compliance for a minimum of 10 consecutive trading days during the 90 days following notification by NASDAQ, our Common Stock may be delisted from trading on NASDAQ. There is a risk that our Common Stock will not meet NASDAQ's listing maintenance standards and fail to remain eligible for trading on the NASDAQ. If our Common Stock is delisted, the delisting would most likely have a material adverse effect on the price of our Common Stock and your ability to sell any of our Common Stock at all would be severely limited.

***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 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 its

Board of Directors.

*The SEC commenced an investigation concerning our revenue recognition matters.*

The SEC has issued a formal order of investigation and has required us to provide information in connection with certain revenue recognition matters. We have been cooperating fully. These matters, relating to our historical accounting for and disclosures concerning sales of ORTHOVISC® under a

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long-term supply and distribution agreement with Zimmer, were also the subject of our March 15, 2000 disclosure concerning an informal SEC inquiry and the restatement of results for 1998 and the first three quarters of 1999. On August 14, 2001, as a result of the SEC's ongoing investigation, we, in conjunction with our independent auditors, determined to again restate our financial results for the fourth quarter of 1998 and the first quarter of 1999 as discussed in Note 15 of the consolidated financial statements. We are not in a position to predict the probable outcome of the SEC investigation or its potential impact on our business or operations.

*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 who are significantly larger companies than us. For the year ended December 31, 2001, Bausch & Lomb accounted for 65.3% of product revenues and 83% of our accounts receivable balance and Pharmaren (an affiliate of Biomeks), our distributor in Turkey, accounted for 15.7% of product revenues and 0% of our accounts receivable balance. 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. On March 11, 2002, Bausch & Lomb's senior debt and short-term debt ratings were downgraded. Although Bausch & Lomb emphasized at that time it was not facing any issues with respect to liquidity, any such issues that impact their ability to pay their accounts with us could adversely impact future revenues. 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. Product revenue in the future may continue to be adversely impacted by economic uncertainties associated with the Turkish market.

The loss of any one of our major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay our recognition of revenues, harm our reputation in the industry, and reduce our ability to accurately predict cash flow, and, as a consequence, could seriously harm our business, financial condition, and results of operations.

We, through our distributors, distribute ORTHOVISC® in territories such as Spain, Portugal, Turkey, and Israel. Due to the result of the unfavorable results of the U.S. ORTHOVISC® Phase III clinical trial announced on May 31, 2000, marketing efforts in these countries have been and may continue to be negatively affected. There can be no assurance that past ORTHOVISC® sales levels will be maintained or that sales will occur at all in these countries.

**ITEM 7A. DERIVATIVE FINANCIAL INSTRUMENTS, OTHER FINANCIAL INSTRUMENTS, AND DERIVATIVE COMMODITY INSTRUMENTS**

As of December 31, 2001, the Company did not participate in any derivative financial instruments or other financial and commodity instruments for which fair value disclosure would be required under SFAS No. 107. All of the Company's investments consist of money market funds and commercial paper that are carried on the Company's books at amortized cost, which approximates fair market value. Accordingly, the Company has no quantitative information concerning the market risk of participating in such investments.

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*Primary Market Risk Exposures*

The Company's primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. The Company's investment portfolio of cash equivalent and short-term investments is subject to interest rate fluctuations, but the Company believes this risk is immaterial due to the short-term nature of these investments. The Company's exposure to currency exchange rate fluctuations is specific to certain sales to a foreign customer and to the extent that certain sales are effected through logistics agents in foreign currencies, and is expected to continue to be modest. The impact of currency exchange rate movements on sales to this foreign customer was immaterial for the year ended December 31, 2001. Currently, the Company does not engage in foreign currency hedging activities.

**Item 8. Financial Statements.**

**ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Consolidated Statements of Cash Flows for the Years Ended December 31, 2001, 2000 and 1999	39
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**Report of Independent Public Accountants**

The Board of Directors and Shareholders of  
Anika Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Anika Therapeutics, Inc. (the "Company") and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. 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 in accordance with auditing standards generally accepted in the 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Anika Therapeutics, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts  
February 12, 2002

**Anika Therapeutics, Inc. and Subsidiaries**  
**Consolidated Balance Sheets**

	December 31,	
	2001	2000
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 9,064,977	\$ 8,265,936
Short-term marketable securities	3,994,401	10,039,849
Accounts receivable, net of reserves of \$25,000 and \$124,000, at December 31, 2001 and 2000, respectively	2,240,929	1,692,457
Inventories	3,726,982	4,737,645
Prepaid expenses and other receivables	540,476	612,890
	19,567,765	25,348,777
Property and equipment, at cost	9,530,047	8,621,579
Less: accumulated depreciation	(6,583,175)	(5,498,455)
	2,946,872	3,123,124
Long-term deposits	148,160	124,600
Notes receivable from officers (Note 6)	253,000	382,000
	\$ 22,915,797	\$ 28,978,501
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 954,585	\$ 870,502
Accrued expenses	1,842,399	1,395,677
Deferred revenue	15,001	
	2,811,985	2,266,179
Commitments and contingencies (Notes 8 and 15)		
Stockholders' equity:		
Redeemable convertible preferred stock, \$.01 par value		
Authorized 750,000 shares, no shares issued and outstanding		
Undesignated preferred stock, \$.01 par value		
Authorized 1,250,000 shares, no shares issued and outstanding		
Common stock, \$.01 par value: Authorized 30,000,000 shares;		
Issued 9,991,943 shares in 2001 and 2000	99,919	99,919
Additional paid-in capital	31,640,234	31,735,660
Treasury stock (at cost, 57,663 shares in 2001 and 2000)	(279,756)	(279,756)
Deferred compensation		(244,549)
Accumulated deficit	(11,356,585)	(4,598,952)
	20,103,812	26,712,322
Total Liabilities and Stockholders' Equity	\$ 22,915,797	\$ 28,978,501

December 31,

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

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**Anika Therapeutics, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
**For the Years Ended December 31,**

	2001	2000	1999
Product revenue	\$ 11,298,954	\$ 12,935,222	\$ 13,425,642
Licensing revenue	13,000	3,400,000	400,000
<b>Total revenue</b>	<b>11,311,954</b>	<b>16,335,222</b>	<b>13,825,642</b>
Cost of product revenue	8,228,751	9,870,559	6,664,163
<b>Gross profit</b>	<b>3,083,203</b>	<b>6,464,663</b>	<b>7,161,479</b>
Operating expenses:			
Research & development	4,280,520	3,259,984	4,154,479
Selling, general & administrative	5,262,708	4,188,044	3,029,394
Litigation settlement costs (Note 15)	950,716		
<b>Total operating expenses</b>	<b>10,493,944</b>	<b>7,448,028</b>	<b>7,183,873</b>
Loss from operations	(7,410,741)	(983,365)	(22,394)
Interest income	662,192	1,172,859	1,068,430
Gain on sale of securities			233,633
(Loss) income before provision for income taxes	(6,748,549)	189,494	1,279,669
Provision for income taxes	9,084	15,940	31,412
(Loss) income before cumulative effect of change in accounting principle	(6,757,633)	173,554	1,248,257
Cumulative effect of change in accounting principle			(3,625,000)
<b>Net (loss) income</b>	<b>\$ (6,757,633)</b>	<b>\$ 173,554</b>	<b>\$ (2,376,743)</b>
Basic (loss) income per share:			
(Loss) income before cumulative effect of change in accounting principle	\$ (0.68)	\$ 0.02	\$ 0.13
Cumulative effect of change in accounting principle			(0.37)
<b>Net (loss) income</b>	<b>\$ (0.68)</b>	<b>\$ 0.02</b>	<b>\$ (0.24)</b>
Basic weighted average common shares outstanding	9,934,280	9,895,725	9,740,560
Diluted (loss) income per share:			
(Loss) income before cumulative effect of change in accounting principle	\$ (0.68)	\$ 0.02	\$ 0.12

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	2001	2000	1999
Cumulative effect of change in accounting principle			(0.35)
Net (loss) income	\$ (0.68)	\$ 0.02	\$ (0.23)
Diluted weighted average common shares and potential common shares outstanding	9,934,280	10,041,855	10,220,584

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

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**Anika Therapeutics, Inc. and Subsidiaries**  
**Consolidated Statements of Stockholders' Equity**

	Common Stock				Treasury Stock			Total Stockholders' Equity
	Number of Shares	\$.01 Par Value	Additional Paid-in Capital	Deferred Compensation	Number of Shares	Cost	Accumulated Deficit	
Balance, December 31, 1998	9,991,943	\$ 99,919	\$ 34,439,675	\$ (1,074,699)	344,500	\$ (1,889,793)	\$ (2,395,763)	\$ 29,179,339
Exercise of common stock options			(2,363,125)		(546,237)	2,878,913		515,788
Amortization of deferred compensation				342,464				342,464
Purchase of common stock					402,600	(1,948,989)		(1,948,989)
Reversal of deferred compensation			(117,234)	117,234				
Net loss							(2,376,743)	(2,376,743)
Balance, December 31, 1999	9,991,943	99,919	31,959,316	(615,001)	200,863	(959,869)	(4,772,506)	25,711,859
Exercise of common stock options			(140,181)		(143,200)	680,113		539,932
Amortization of deferred compensation				286,977				286,977
Reversal of deferred compensation			(83,475)	83,475				
Net income							173,554	173,554
Balance, December 31, 2000	9,991,943	99,919	31,735,660	(244,549)	57,663	(279,756)	(4,598,952)	26,712,322
Amortization of deferred compensation				149,123				149,123
Reversal of deferred compensation			(95,426)	95,426				
Net loss							(6,757,633)	(6,757,633)
Balance, December 31, 2001	9,991,943	\$ 99,919	\$ 31,640,234	\$	57,663	\$ (279,756)	\$ (11,356,585)	\$ 20,103,812

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

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

For the Years Ended December 31,

2001	2000	1999
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For the Years Ended December 31,

<b>Cash flows from operating activities:</b>			
Net (loss) income	\$ (6,757,633)	\$ 173,554	\$ (2,376,743)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,084,720	910,763	777,969
Amortization of deferred compensation	149,123	286,977	342,464
Forgiveness of note receivable from officer	129,000		
Provision for doubtful accounts		63,000	12,000
Advance rent payment			(50,215)
Changes in operating assets and liabilities:			
Accounts receivable	(548,472)	350,994	914,285
Inventories	1,010,663	756,056	(1,747,685)
Prepaid expenses	72,414	108,316	(471,183)
Accounts payable	84,083	241,423	(262,413)
Accrued expenses	446,722	(156,983)	196,075
Deferred revenue	15,001	(4,617,505)	3,478,157
Net cash (used in) provided by operating activities	(4,314,379)	(1,883,405)	812,711
<b>Cash flows from investing activities:</b>			
Proceeds of short-term marketable securities	19,423,688	49,914,742	38,902,548
Purchase of short-term marketable securities	(13,378,240)	(46,211,692)	(35,079,915)
Purchase of property and equipment	(908,468)	(505,346)	(1,740,410)
Notes receivable from officers		(29,000)	(160,000)
Deposits	(23,560)		(16,100)
Purchase of long-term marketable securities			(5,558,029)
Net cash provided by (used in) investing activities	5,113,420	3,168,704	(3,651,906)
<b>Cash flows from financing activities:</b>			
Purchase of treasury stock			(1,948,989)
Proceeds from exercise of stock options and warrants		539,932	516,369
Net cash provided by (used in) financing activities		539,932	(1,432,620)
Increase (decrease) in cash and cash equivalents	799,041	1,825,231	(4,271,815)
Cash and cash equivalents at beginning of year	8,265,936	6,440,705	10,712,520
Cash and cash equivalents at end of year	\$ 9,064,977	\$ 8,265,936	\$ 6,440,705
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for income taxes	\$ 4,956	\$	\$ 131,206

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



## ANIKA THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. NATURE OF 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 U.S., 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.

## 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 requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of Anika Therapeutics, Inc. and its wholly owned subsidiaries, Anika Securities, Inc. (a Massachusetts Securities Corporation) and Anika Therapeutics UK, Ltd. All intercompany balances and transactions have been eliminated in consolidation. There was no activity by the UK subsidiary during the year ended December 31, 2001.

*Cash and Cash Equivalents*

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

*Short-Term Marketable Securities*

The Company follows the provisions of Statement of Financial Accounting Standards ("SFAS") No. 115, *Accounting for Certain Investments in Debt and Equity Securities*. Short-term marketable securities consist of commercial paper with maturities within twelve months of the balance sheet date. The Company classifies these short-term marketable securities as held to maturity, and accordingly they are carried at

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amortized cost. Aggregate fair value, amortized cost and average maturity for short-term marketable securities held at December 31, 2001 and 2000 is as follows:

December 31, 2001		
Amortized Cost	Gross Unrealized Holding Gains	Fair Value
\$ 3,994,401	\$ 39,802	\$ 4,034,203

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December 31, 2001

Commercial Paper (weighted average maturity of 5.5 months)

December 31, 2000

	Amortized Cost	Gross Unrealized Holding Gains	Fair Value
Commercial Paper (weighted average maturity of 3.4 months)	\$ 10,039,849	\$ 82,384	\$ 10,122,233

During 2001, securities classified as held-to-maturity, with an amortized cost aggregating \$19,423,688, including interest and realized gains of \$477,198, matured.

*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, marketable securities, accounts receivable, notes receivable from officers and accounts payable. The estimated fair value of the Company's financial instruments approximate their carrying values.

*Revenue Recognition*

Product revenue is recognized upon shipment to the customer as long as there is persuasive evidence of an arrangement, the sales price is fixed or determinable and collection of the related receivable is probable. Amounts billed or collected prior to recognition of revenue are classified as deferred revenue. Under the new agreement with Bausch and 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 interim quarters are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. In accordance with the Company's revenue recognition policy, the amount of revenue reasonably subject to the price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. ORTHOVISC® is sold through several distribution arrangements as well as two 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. The Company recognizes non-refundable up-front or milestone payments received as part of supply, distribution, and marketing arrangements, ratably over the terms of the agreements to which the payments apply.

*Property and Equipment*

Property and equipment is stated at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, as follows:

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

*Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*

The Company follows the provisions of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*. This statement requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. As of December 31, 2001 and 2000, long-lived assets consisted of property and equipment, notes receivable from officers, and long-term deposits.

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During the years ended December 31, 2001, 2000, and 1999 the Company did not record losses on impairment.

### *Research and Development*

Research and development costs are expensed as incurred.

### *Earnings per Share*

The Company reports earnings per share in accordance with SFAS No. 128, *Earnings per Share*, which establishes standards for computing and presenting earnings (loss) per share. Basic earnings per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share are computed by dividing net income (loss) by the weighted average number of common shares and dilutive potential common shares outstanding during the period. Under the treasury stock method, unexercised 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. For periods where the Company has incurred a loss, dilutive net loss per share is equal to basic net loss per share. Accordingly, the dilutive effect of outstanding options totaling 1,439,722, 1,102,214, and 1,016,992 at December 31, 2001, 2000, and 1999, respectively, are excluded from the calculation of diluted weighted average shares outstanding because to include them would have been antidilutive for those periods presented.

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The following illustrates a reconciliation of the number of shares used in the calculation of basic and diluted net (loss) income per share for the years ended December 31, 2001, 2000, and 1999:

	Years ended December 31,		
	2001	2000	1999
Net (loss) income	\$ (6,757,633)	\$ 173,554	\$ (2,376,743)
Basic weighted average common shares outstanding	9,934,280	9,895,725	9,740,560
Dilutive effect of assumed exercise of stock options and warrants		146,130	480,024
Diluted weighted average common and potential common shares outstanding	9,934,280	10,041,855	10,220,584

### *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 bases of assets and liabilities.

### *Recently Issued Accounting Pronouncements*

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, *Business Combinations*. SFAS No. 141 requires all business combinations initiated after June 30, 2001 to be accounted for using the purchase method. The adoption of this statement did not have a material impact on the Company's consolidated financial statements.

In July 2001, the FASB issued SFAS No. 142, *Goodwill and Other Intangible Assets*. With the adoption of SFAS No. 142, goodwill and other intangible assets which have indefinite lives will no longer be subject to amortization over its estimated useful life, but instead these assets will be subject to at least an annual assessment for impairment by applying a fair-value-based test. The Company does not expect the adoption of this statement to have a material impact its consolidated financial statements.

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In August 2001, the FASB issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. This statement supersedes FASB Statement No. 121, and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. Under this statement, it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement will be effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company does not expect that the adoption of this statement will have a material impact on its consolidated financial statements.

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### *Stock-Based Compensation*

The Company has adopted SFAS No. 123, *Accounting for Stock-Based Compensation*, which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income disclosures for employee stock option grants as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of APB Opinion No. 25 for employee grants and provide the pro forma disclosure of SFAS No. 123 (see Note 9).

### *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.

Product revenue by significant customers is as follows:

	<b>Percent of Product Revenue Year ended December 31,</b>		
	<b>2001</b>	<b>2000</b>	<b>1999</b>
<b>AMVISC®:</b>			
Bausch & Lomb	65.3%	54.1%	62.3%
<b>ORTHOVISC®:</b>			
Zimmer	0.0%	16.4%	5.3%
Pharmaren/Biomeks	15.7%	17.7%	27.7%
	81.0%	88.2%	95.3%

As of December 31, 2001, one customer represented 83% of the Company's accounts receivable balance.

In the fourth quarter of 2000, product revenue included sales of ORTHOVISC® to Zimmer of \$1,324,000, which had been previously deferred. Prior to 2001, all of the licensing revenue recorded by the Company has been received under the terminated distribution agreement with Zimmer. Due to the termination of the Zimmer Distribution Agreement, a one-time payment from Zimmer was also recognized as licensing revenue in the fourth quarter of 2000. Additionally, as of December 31, 2000, three customers, two of whom are international customers, represented 39%, 35% and 22%, respectively, of the Company's accounts receivable balance.

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### 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, 2001, 2000, and 1999 and as a result, Comprehensive income (loss) is the same as reported net income (loss) 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 decision-making group consists of two individuals: the chief executive officer chief financial officer, and the president and chief operating 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.

Revenues by geographic location in total and as a percentage of total revenues are as follows for the years ended December 31, 2001, 2000, and 1999, respectively:

	Years ended December 31,					
	2001		2000		1999	
	Revenue	Percent of Revenue	Revenue	Percent of Revenue	Revenue	Percent of Revenue
<b>Geographic location:</b>						
United States	\$ 8,152,467	72.07%	\$ 13,041,791	79.84%	\$ 9,724,053	70.33%
Middle East	133,820	1.18%	2,445,821	14.97%	3,948,839	28.56%
Other/Europe	3,025,667	26.75%	847,610	5.19%	152,750	1.11%
<b>Total</b>	<b>\$ 11,311,954</b>	<b>100.00%</b>	<b>\$ 16,335,222</b>	<b>100.00%</b>	<b>\$ 13,825,642</b>	<b>100.00%</b>

Since early 2001, sales of product destined for the Turkish market have been made to a European-based entity and have accordingly been classified in the "Other/Europe" category since that time. During the years ended December 31, 2000 and 1999, sales of product for the Turkish market are included in the "Middle East" category.

### 3. ALLOWANCE FOR DOUBTFUL ACCOUNTS

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

	December 31,		
	2001	2000	1999
Balance, beginning of the year	\$ 124,000	\$ 61,000	\$ 57,000
Amounts provided		63,000	12,000
Amounts written off	(99,000)		(8,000)
<b>Balance, at the end of the year</b>	<b>\$ 25,000</b>	<b>\$ 124,000</b>	<b>\$ 61,000</b>

**4. INVENTORIES**

Inventories consist of the following:

	December 31,	
	2001	2000
Raw Materials	\$ 1,542,511	\$ 1,386,504
Work-in-process	1,971,067	3,169,358
Finished goods	213,404	181,783
<b>Total</b>	<b>\$ 3,726,982</b>	<b>\$ 4,737,645</b>

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.

**5. PROPERTY & EQUIPMENT**

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

	December 31,	
	2001	2000
Machinery and equipment	\$ 5,463,470	\$ 6,071,812
Furniture and fixtures	696,379	670,923
Leasehold improvements	3,370,198	1,878,844
	9,530,047	8,621,579
Less accumulated depreciation	(6,583,175)	(5,498,455)
<b>Total</b>	<b>\$ 2,946,872</b>	<b>\$ 3,123,124</b>

Costs of \$835,000 for a clean room under construction had previously been included in machinery and equipment. This amount was reclassified to leasehold improvements upon its completion in the first quarter of 2001.

**6. NOTES RECEIVABLE FROM OFFICERS**

Notes receivable from officers of \$253,000 consists of loans made to one officer and two former officers. The notes receivable from the officer and the former officers are secured by mortgages on their primary residences. Interest accrues at annual rates between 6.00% to 6.22%. In connection with the departure of two former officers in June 2001, notes totaling \$129,000 were forgiven. In addition, the maturity of a note in the amount of \$75,000 to the Company's former chief executive officer, which is secured by a mortgage on his primary residence, was extended to the earlier of the sale of such residence or March 31, 2002. The maturity of a note to another former officer, which is secured by a mortgage on his primary residence, is due on August 12, 2004.

**7. ACCRUED EXPENSES**

Accrued expenses consists of the following:

December 31,

	2001	2000
Accrued compensation	\$ 705,821	\$ 587,222
Accrued legal and professional fees	75,845	247,000
Clinical trials	568,724	30,001
Other	492,009	531,454
<b>Total</b>	<b>\$ 1,842,399</b>	<b>\$ 1,395,677</b>

## 8. LEASE OBLIGATIONS

The Company leases three facilities with one lease expiring in October 2001, another in January 2004 and the third lease in February 2004. These leases are accounted for as operating leases in the accompanying consolidated statements of operations. Net rental expense in connection with the leases, totaled \$703,482, \$647,348, and \$489,000 for the years ended December 31, 2001, 2000, and 1999, respectively. During 2001, the Company abandoned one of these facilities. As a result, the Company has accrued \$100,000 as of December 31, 2002 for the estimated loss, net of sublease income, it expects to incur over the remaining term of the lease. Future minimum lease payments under the operating leases for the years ending December 31<sup>st</sup> are as follows:

	Amount
2002	\$ 618,593
2003	619,793
2004	92,699
<b>Total</b>	<b>\$ 1,331,085</b>

## 9. STOCK OPTION PLAN

The Company has 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 "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 October 28, 1997, the Board of Directors granted to certain executive officers and

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employees of the Company options to acquire 269,000 shares of common stock at an exercise price of \$7.625 per share, vesting over a four-year period. Such grants received stockholder approval upon the amendment to the Plan on June 3, 1998. When the amendment was approved by the shareholders, the Company recorded deferred compensation of \$1,490,061, which represented the difference between the exercise price of the option and the fair market value of the common stock at the time of such approval. During 2001, 2000, and 1999, \$149,123, \$286,977, and \$342,464 were amortized to expense, respectively. At December 31, 2001, the deferred compensation had been completely amortized.

Combined stock option activity for both Plans is summarized as follows:

	Shares	Weighted Average Exercise Price per Share
Outstanding at December 31, 1998	2,173,904	\$ 4.02
Granted	223,500	5.60
Canceled	(256,116)	5.91
Exercised	(546,237)	2.08

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	Shares	Weighted Average Exercise Price per Share
Outstanding at December 31, 1999	1,595,051	4.99
Granted	682,776	4.49
Canceled	(413,505)	5.63
Exercised	(143,200)	3.46
Outstanding at December 31, 2000	1,721,122	4.77
Granted	489,800	1.12
Canceled	(771,200)	5.07
Outstanding at December 31, 2001	1,439,722	\$ 3.37
Exercisable, December 31, 2001	574,039	\$ 4.41
Exercisable, December 31, 2000	781,605	\$ 4.99
Exercisable, December 31, 1999	870,384	\$ 4.44

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 694,346 options available for future grant at December 31, 2001.

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The following table summarizes significant ranges of outstanding options under both Plans at December 31, 2001:

Ranges of Exercise Price	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.90 - 3.00	804,133	8.09	1.51	179,908	2.35
3.12 - 4.94	215,776	5.04	4.03	177,943	3.87
5.19 - 7.00	294,833	7.35	6.08	132,458	5.78
7.63 - 9.75	124,980	7.11	7.79	83,730	7.84
	1,439,722	7.20	3.37	574,039	4.41

The Company has determined that it will continue to account for stock-based compensation for employees under APB Opinion No. 25 as modified by FIN 44 and elect the disclosure-only alternative under SFAS No. 123 for stock-based compensation awarded in 2001, 2000, and 1999 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The underlying assumptions used are as follows:

December 31,		
2001	2000	1999



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	December 31,		
	2001	2000	1999
Risk-Free interest rate	5.13%	6.18%	5.56%
Expected dividend yield	0.00%	0.00%	0.00%
Expected lives	4	4	6
Expected volatility	71.40%	71.60%	65.10%
Weighted average grant date fair value of grants	\$ 1.96	\$ 2.16	\$ 3.21

Had compensation expense for employee stock options granted been determined based on the fair value at the date of grant as prescribed under SFAS No. 123, pro forma net income (loss) and net income (loss) per share would have been as follows:

	Years ended December 31,		
	2001	2000	1999 (as restated)
Net income (loss)			
As reported	\$ (6,757,633)	\$ 173,554	\$ (2,376,743)
Pro forma	\$ (7,267,014)	\$ (522,111)	\$ (3,046,048)
Net income (loss) per share, as reported			
Basic	\$ (0.68)	\$ 0.02	\$ (0.24)
Diluted	\$ (0.68)	\$ 0.02	\$ (0.23)
Net income (loss) per share, proforma			
Basic	\$ (0.73)	\$ (0.05)	\$ (0.31)
Diluted	\$ (0.73)	\$ (0.05)	\$ (0.30)

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## 10. SHAREHOLDER RIGHTS PLAN

On April 6, 1998, the Board of Directors adopted a shareholder rights agreement (the "Rights Plan"). 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: (i) a person becomes an "Acquiring Person" by acquiring 15% or more of the Company's Common Stock, (ii) a person commences a tender offer that would result in that person owning 15% or more of the Company's Common Stock, or (iii) 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 (i) the time at which any person becomes an "Acquiring Person" or an "Adverse Person", or (ii) 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, 2001, the Company had repurchased a total of 762,100 shares at a net cost of approximately \$3,872,807 and has reissued 704,437 shares upon exercise of employee stock options. No shares were purchased in 2001 or 2000.

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## 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, 2001, 2000, and 1999, the Company made matching contributions of \$186,863, \$184,049, and \$160,142, respectively.

## 13. LICENSING AND DISTRIBUTION AGREEMENTS

In July 2000, the Company entered into a seven-year supply agreement (the "B&L Agreement") with Bausch & Lomb Surgical, a unit of Bausch & Lomb. 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, ophthalmic viscoelastic products, in the U.S. and international markets. The B&L Agreement expires December 31, 2007, and supercedes an existing supply contract 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 ability to sell 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 B&L. Under the new agreement with Bausch and 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 interim quarters are subject to possible retroactive price adjustments when the actual annual unit volume for the year becomes known. In accordance with the Company's revenue recognition policy, the amount of revenue reasonably subject to the price adjustment is recorded as deferred revenue until the annual unit volume becomes known and the sales price becomes fixed. In accordance with the Company's revenue recognition policy, revenue is 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. During the years ended December 31, 2001, 2000, and 1999, the Company recognized revenues of \$7,389,342, \$7,021,779, and \$8,362,703, respectively, under this agreement and the prior Bausch & Lomb agreement. Additionally, during the years ended December 31, 2001, the Company paid royalties of \$12,852, to Bausch & Lomb under this agreement.

In April 2001, the Company entered into a five-year supply agreement with Cytosol Ophthalmics, Inc. Under the terms of the agreement, effective April 11, 2001, the Company became Cytosol Ophthalmic's exclusive provider of sterile sodium hyaluronate ophthalmic viscoelastic products, in the U.S. and international markets. Under the agreement, in lieu of an up-front payment, the Company is entitled to an increase in the price per unit of \$2 per unit for the initial 50,000 units purchased. As a result, the Company will recognize \$100,000 of revenue under this agreement ratably over the term of the agreement or as units are shipped, if longer. The agreement expires April 11, 2006. For the year ended December 31, 2001, the Company has recognized \$8,000 of the \$100,000 price adjustment associated with the first 4,000 units purchased as license revenue. The Company also recognized \$52,000 of product revenue from Cytosol Ophthalmics, Inc. during 2001.

In October 2001, the Company entered into a five-year supply agreement with A.M.A. Pharmaceuticals. Under the terms of the agreement, effective October 4, 2001, the Company

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became A.M.A. Pharmaceutical's exclusive provider of sterile sodium hyaluronate ophthalmic viscoelastic products, in the U.S. and international markets. The terms of the agreement provide for an annual up-front payment of \$20,000. The agreement expires October 4, 2006. The agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. For the year ended December 31, 2001, the Company has recognized \$5,000 of the annual up-front payment as license revenue.

### 14. INCOME TAXES

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by the enacted tax rates assumed to be in effect when these differences reverse.

As of December 31, 2001, the Company has net operating loss carry-forwards for federal and state tax purposes of approximately \$10,209,000, and \$5,389,000, respectively. These carry-forwards expire through 2021, and are subject to review and possible adjustment. The Internal Revenue Code (IRC) contains provisions that may limit the amount of net operating loss and tax credit carry-forwards that the Company may utilize in any one year in the event of certain cumulative changes in ownership over a three-year period. In the event that the Company has had a change of ownership, as defined in IRC Section 382, utilization of the carry forwards may be restricted.

The approximate income tax effect of each type of temporary difference and carry-forward is as follows:

	Years ended December 31,	
	2001	2000
Deferred tax assets:		
Depreciation	\$ 261,852	\$ 196,036
Accrued expenses and other	351,828	119,354
Inventory reserves	127,347	173,757
Nonqualified stock option amortization		112,627
Net operating loss carry-forwards	4,111,144	1,938,569
Credit carry-forwards	1,034,479	
	5,886,650	2,540,343
Gross deferred tax assets	5,886,650	2,540,343
Less: valuation allowance	(5,886,650)	(2,540,343)
	\$	\$
Net deferred tax asset		

Due to the uncertainty surrounding the timing of realization of the benefits of its favorable tax attributes in future tax returns, the Company has applied a full valuation allowance against its net deferred tax asset.

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Income tax expense was \$9,084, \$15,940, and \$31,412 for the years ended December 31, 2001, 2000, and 1999, respectively. The provision for income taxes 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,		
	2001	2000	1999
Computed expected tax (benefit) expense.	\$ (2,294,507)	\$ 64,562	\$ (837,867)
State tax expense (benefit) (net of federal benefit)	9,084	10,687	(147,859)
Nondeductible expenses	3,495	34,837	44,944
Research and development credits	(263,151)		
Other	(4,648)	(45,080)	30,133
Change in valuation allowance related to income tax benefit	2,558,811	(49,066)	942,061

Years ended December 31,

	Years ended December 31,		
Tax expense	\$ 9,084	\$ 15,940	\$ 31,412

## 15. LEGAL MATTERS

*Securities and Exchange Commission Investigation.* The SEC has 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, relating to the Company's historical accounting for and disclosures concerning sales of ORTHOVISC® under a long-term supply and distribution agreement with Zimmer, were also the subject of the Company's March 15, 2000 disclosure concerning an informal SEC inquiry and the restatement of results for 1998 and the first three quarters of 1999. On August 14, 2001, as a result of the SEC's on-going investigation, the Company, in conjunction with its independent auditors, determined to again restate its financial results for the fourth quarter of 1998 and the first quarter of 1999. 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.

*Putative Class Action Complaints.* Three putative class action complaints were filed against the Company, J. Melville Engle, the Company's former chief executive officer, and Sean Moran, the Company's 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 (the "Class"). The first, filed on or about June 8, 2000, is captioned *Casazza, et al. v. Anika Therapeutics, Inc., J. Melville Engle and Sean Moran*, Civil Action No. 00-11127-WGY. The second, filed on or about June 26, 2000, is captioned *Nemeth-Coslett, et al. v. Anika Therapeutics, Inc., J. Melville Engle and Sean Moran*, Civil Action No. 00-11257-WGY. The third, filed on or about August 2, 2000, is captioned *Rockefeller, et al. v. Anika Therapeutics, Inc., J. Melville Engle and Sean Moran*, Civil Action No. 00-11540-WGY. Each of these putative class action complaints encompasses the same class period and covers almost identical allegations. On or about August 7, 2000, David and Vivian West, alleged members of the Class, filed a motion to appoint themselves lead plaintiffs, and their law firm, lead counsel; as well as a motion for consolidation of the above cases. On or about September 13, 2000, the Court granted David and Vivian West's motions, consolidated the cases and recaptioned the case *In re Anika Therapeutics, Inc. Securities Litigation*, Civil Action No. 00-11127-WGY. On or about October 30, 2000, lead plaintiffs filed a consolidated amended complaint. The complaint alleges that the Company and the individual defendants

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violated 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. The alleged misrepresentations and omissions relate to the Company's historical revenue recognition policies and its restatement of revenues for 1998 and the first three quarters of 1999. The complaint seeks an unspecified amount of monetary damages, costs and expenses, and equitable and/or injunctive relief to restrict the defendants from disposing of various assets in order to assure adequate funds are available for the claimed damages. On December 14, 2000, the Company, Mr. Engle and Mr. Moran each filed motions to dismiss the consolidated amended complaint. On January 29, 2001, plaintiffs' counsel filed oppositions to defendants' motions to dismiss. The Defendants filed reply briefs on February 12, 2001.

Before the Court decided the motions to dismiss, the parties reached agreement on the terms of a potential settlement of the action. Accordingly, the parties negotiated and entered into a Memorandum of Understanding dated March 8, 2001 and the parties negotiated and entered into a Stipulation and Agreement of Settlement, Compromise and Release ("Stipulation") dated May 25, 2001, which contains the terms of a settlement of the action, subject to approval by the Court.

The Stipulation was submitted to the Court and, on May 31, 2001, the Court entered an Order of Preliminary Approval in connection with the settlement proceedings. After preliminary approval, plaintiff's counsel sent notice of the proposed settlement to the Class, and the Company paid \$1.25 million into a settlement fund that may, among other things, be used to pay authorized members of the Class. The Company entered into an agreement with its directors and officers liability insurer, under which the 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.

In the Stipulation, the parties requested that the Court have a Final Settlement Hearing at which, among other things, (i) the Court would certify, for purposes of settlement, the Class, and certify, for purposes of settlement, the Action as a class action; (ii) the Court would finally approve the settlement as provided for in the Stipulation, including the release of all claims by Class members against the Defendants; and (iii) the Court would enter final judgment dismissing with prejudice all claims of the plaintiffs and the Class against the Defendants. The Court

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originally scheduled the Final Settlement Hearing for August 8, 2001. Pursuant to the joint request of counsel for the plaintiffs and counsel for the Company, the hearing was extended because of the restatement of financial results for certain prior periods filed in the Annual Report on Form 10-K for the year ended December 31, 2000. The Final Settlement Hearing was held on October 22, 2001 and the Court approved the Settlement.

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**16. QUARTERLY FINANCIAL DATA (UNAUDITED)**

<b>Year 2001</b>	<b>Quarter ended March 31,</b>	<b>Quarter ended June 30,</b>	<b>Quarter ended September 30,</b>	<b>Quarter ended December 31,</b>
Total Revenue	\$ 2,178,618	\$ 2,919,034	\$ 3,053,779	\$ 3,160,523
Cost of Product Revenue	1,968,948	2,109,049	2,553,582	1,597,172
Gross Profit	209,670	809,985	500,197	1,563,351
Net Loss	\$ (2,318,433)	\$ (2,650,408)	\$ (1,332,037)	\$ (456,755)
Per common share information:				
Basic net loss per share	\$ (0.23)	\$ (0.27)	\$ (0.13)	\$ (0.05)
Basic common shares outstanding	9,934,280	9,934,280	9,934,280	9,934,280
Diluted net loss per share	\$ (0.23)	\$ (0.27)	\$ (0.13)	\$ (0.05)
Diluted common shares outstanding	9,934,280	9,934,280	9,934,280	9,934,280
<b>Year 2000</b>	<b>Quarter ended March 31,</b>	<b>Quarter ended June 30,</b>	<b>Quarter ended September 30,</b>	<b>Quarter ended December 31,</b>
Total Revenue	\$ 2,720,833	\$ 3,768,765	\$ 2,729,807	\$ 7,115,817
Cost of Product Revenue	1,232,968	2,422,617	2,804,285	3,410,689
Gross Profit (Loss)	1,487,865	1,346,148	(74,478)	3,705,128
Net (Loss) Income	\$ (564,087)	\$ (218,489)	\$ (1,382,824)	\$ 2,338,954
Per common share information:				
Basic net (loss) income per share	\$ (0.06)	\$ (0.02)	\$ (0.14)	\$ 0.24
Basic common shares outstanding	9,804,284	9,918,842	9,934,280	9,934,280
Diluted net (loss) income per share	\$ (0.06)	\$ (0.02)	\$ (0.14)	\$ 0.23
Diluted common shares outstanding	9,804,284	9,918,842	9,934,280	10,080,410

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

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 5, 2002 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 Compensation."

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

The information required by Item 12 is hereby incorporated by reference to the Proxy Statement under the heading "Beneficial Ownership of Common Stock."

**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."

**PART IV**

**ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

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

(1) Financial Statements

Report of Independent Public Accountant	35
Consolidated Balance Sheets	36
Consolidated Statements of Operations	37
Consolidated Statements of Stockholder's Equity	38
Consolidated Statements of Cash Flows	39
Notes to Consolidated Financial Statements	40-52

(2) Schedules

Schedules other than those listed above have been omitted since they are either not required or the information required is included in the consolidated financial statements or the notes thereto.

Arthur Andersen LLP's Report with respect to the above listed financial statements and financial statements schedules are included herein on Item 8 and Exhibit 23.1.

(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 at (c) below.

(b) Reports on Form 8-K

The Company did not file any Current Reports on Form 8-K during the last quarter of the period covered by this report.

Exhibit No.	Description
(3) 3.1	Articles of Incorporation and Bylaws: 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.

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Exhibit No.	Description
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.
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- 10.9 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.
- 10.10 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.
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- 10.13 Promissory Note for \$75,000 dated as of March 17, 1997 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.25 to the Company's Registration Statement on Form SB-2 (File no. 333-38993), filed with the Securities and Exchange Commission on October 29, 1997.

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- 10.14 Non-Disclosure and Non-Competition Agreement dated February 10, 1998 between the Company and Michael R. Slater, incorporated herein by reference to Exhibit 10.22 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.
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- 10.20 Non-Disclosure and Non-Competition Agreement dated April 3, 2000 by and between the Company and Douglas R. Potter, incorporated herein by reference to Exhibit 10.6 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.
- 10.21 Change in Control, Bonus and Severance Agreement dated April 26, 2000 by and between the Company and Douglas R. Potter, incorporated herein by reference to Exhibit 10.7 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.
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- 10.24 Separation Agreement dated June 15, 2001 by and between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.1 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.
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- 10.26 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.
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- (11) Statement Regarding the Computation of Per Share Earnings
- 11.1 See Note 2 to the Financial Statements included herewith.
- (21) Subsidiaries of the Registrant
- 21.1 List of Subsidiaries of the Registrant, incorporated herein by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.
- (23) Consent of Experts
- \*23.1 Consent of ARTHUR ANDERSEN LLP.
- (99) Additional Exhibits
- \*99.1 Letter pursuant to Temporary Note 3T to Article 3 of Regulation S-X

\*  
Filed 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 28, 2002.

ANIKA THERAPEUTICS, INC.

By:           /s/ DOUGLAS R. POTTER          

Douglas R. Potter  
*Chief Executive Officer and Chief Financial 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

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Signature	Title	Date
/s/ DOUGLAS R. POTTER <hr/>	Chief Executive Officer and Chief Financial Officer ( <i>Principal Executive Officer, Principal Financial Officer, and Principal Accounting Officer</i> )	March 28, 2002
Douglas R. Potter		
/s/ JOSEPH L. BOWER <hr/>	Director	March 28, 2002
Joseph L. Bower		
/s/ EUGENE A. DAVIDSON <hr/>	Director	March 28, 2002
Eugene A. Davidson		
/s/ SAMUEL F. MCKAY <hr/>	Director	March 28, 2002
Samuel F. McKay		
/s/ HARVEY S. SADOW <hr/>	Director	March 28, 2002
Harvey S. Sadow		
/s/ STEVEN E. WHEELER <hr/>	Director	March 28, 2002
Steven E. Wheeler		

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**EXHIBIT INDEX**

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.
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### QuickLinks

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Balance Sheet Data: (In thousands)

Statement of Operations Detail

Statement of Operations Detail

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Anika Therapeutics, Inc. and Subsidiaries Consolidated Balance Sheets

Anika Therapeutics, Inc. and Subsidiaries Consolidated Statements of Operations For the Years Ended December 31,

Anika Therapeutics, Inc. and Subsidiaries Consolidated Statements of Cash Flows

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PART IV

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