ANIKA THERAPEUTICS INC
Form 10-K/A
September 05, 2001

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A

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

FOR FISCAL YEAR ENDED DECEMBER 31, 2000

|_| 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 001-14027

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 last 90 days. Yes |X| No |_|

Indicate by check mark if disclosure of delinquent filers in response 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/A or any amendment to this Form 10-K/A. |_|

The aggregate market value of voting stock held by non-affiliates of the Registrant as of March 20, 2001 was $11,176,065 based on the closing price per share of Common Stock of $1.125 as of such date as reported by the NASDAQ National Market. At March 20, 2001 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 held on June 6, 2001. Such Proxy Statement shall not be deemed to be "filed" as part of this Annual Report on Form 10-K/A except for the parts therein which have been specifically incorporated by reference herein.

FORM 10-K/A
ANIKA THERAPEUTICS, INC.
FOR FISCAL YEAR ENDED DECEMBER 31, 2000

INTRODUCTORY NOTE

This amendment on Form 10-K/A amends and supercedes the Registrant's Annual Report on Form 10-K for the year ended December 31, 2000, as filed by the Registrant on April 2, 2001, and is being filed to reflect the restatement of the Registrant's consolidated financial statements for the years ended December 31, 1998 and 1999 announced on August 14, 2001. The items amended in this Form 10-K/A are Items 6, 7, 8 and 14. Information regarding the restatement and the effect of the restatement on the Registrant's results of operations is included in Note 2 to the consolidated financial statements included in Item 8.

THIS ANNUAL REPORT ON FORM 10-K/A 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. THE WORDS "BELIEVE," "EXPECT", "SEEK", "PLAN", "DEVELOP", "ANTICIPATE," "INTEND," "ESTIMATE," "WILL" AND OTHER EXPRESSIONS, WHICH ARE PREDICTIONS OF OR INDICATE FUTURE EVENTS AND TRENDS AND WHICH DO NOT RELATE TO HISTORICAL MATTERS IDENTIFY FORWARD-LOOKING STATEMENTS. FORWARD-LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER FACTORS, INCLUDING BUT NOT LIMITED TO STATEMENTS REGARDING: FUTURE SALES, POSSIBLE DEVELOPMENT OF NEW PRODUCTS, CLINICAL TRIALS, POSSIBLE REGULATORY APPROVAL OF ORTHOVISC(R) AND INCERT(R)-S, AND NEW OR POTENTIAL PRODUCTS, CAPACITY OF MANUFACTURING FACILITIES AND PERFORMANCE UNDER SUPPLY AGREEMENTS. THERE CAN BE NO ASSURANCES THAT THE COMPANY WILL CONTINUE TO ACHIEVE INCREASED SALES OF ITS OPHTHALMIC PRODUCTS TO BAUSCH & LOMB AND/OR OTHER COMPANIES SUFFICIENT TO OFFSET THE EFFECTS OF THE PRICE REDUCTION TO BAUSCH & LOMB. IN ADDITION, THERE CAN BE NO ASSURANCE THAT (I) THE TERMINATION OF THE DISTRIBUTION AGREEMENT WITH ZIMMER WILL NOT HAVE A MATERIAL ADVERSE IMPACT ON SALES OR DISTRIBUTION OF ORTHOVISC(R) OR EFFECTIVELY TRANSITION THE DISTRIBUTION OF ORTHOVISC(R) TO SUCH DISTRIBUTORS, ONCE ENGAGED. FURTHERMORE, THE COMPANY MAY NOT BE ABLE TO IDENTIFY OR ENGAGE APPROPRIATE DISTRIBUTION OR COLLABORATION PARTNERS FOR SALES OF ORTHOVISC(R) OR INCERT(R)-S. THE COMPANY CANNOT MAKE ANY ASSURANCES THAT (I) THE INVESTMENT OF ITS SPANISH DISTRIBUTOR IN AN ADDITIONAL HUMAN CLINICAL TRIAL FOR ORTHOVISC(R) WILL RENDER POSITIVE RESULTS; (II) IT WILL SUBMIT AN APPLICATION FOR, OR SUCCESSFULLY OBTAIN CE MARK REGISTRATION APPROVAL FOR INCERT(R)-S ON A TIMELY BASIS, OR AT ALL; (III) INVENTORY MANAGEMENT OR OTHER EFFORTS WILL RESULT IN IMPROVED GROSS MARGINS BY MID-2001 OR EVER; OR (IV) THE CURRENT LEVELS OF SELLING, GENERAL AND ADMINISTRATIVE EXPENSES WILL NOT CONTINUE. MOREOVER, THERE CAN BE NO ASSURANCES THAT THE COMPANY'S INVESTMENTS OR

ITS INCREASED EMPHASIS IN CLINICAL RESEARCH AND PRODUCT DEVELOPMENT, SUCH AS ITS SCREENING PROCESS OF POTENTIAL OPPORTUNITIES AND ESTABLISHMENT OF A PILOT PRODUCTION LABORATORY, AS WELL AS ITS CURRENTLY CONTEMPLATED CLINICAL TRIALS OF ORTHOVISC(R) AND INCERT(R), WILL LEAD TO VIABLE PRODUCTS OR REVENUE GROWTH. THE COMPANY'S ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENT COULD DIFFER MATERIALLY FROM ANTICIPATED RESULTS, PERFORMANCE OR ACHIEVEMENT, EXPRESSED OR IMPLIED IN SUCH FORWARD-LOOKING STATEMENTS. CERTAIN FACTORS THAT MIGHT CAUSE SUCH A DIFFERENCE ARE DISCUSSED THROUGHOUT THIS ANNUAL REPORT ON FORM 10-K INCLUDING SECTIONS TITLED "BUSINESS" BEGINNING ON PAGE 2, "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS" BEGINNING ON PAGE 19, "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" BEGINNING ON PAGE 13 AND ELSEWHERE IN THIS ANNUAL REPORT ON FORM 10-K/A. 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 repair, 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(R), which is an HA product used in the treatment of somE forms of osteoarthritis in humans and HYVISC(R), which is an HA product used in the treatment of equinE osteoarthritis. ORTHOVISC(R) is currently approved for sale and marketed in Canada, Europe, Turkey, and Israel. IN the U.S. ORTHOVISC(R) is currently limited to investigational use and the Company commenced a Phase III clinicaL trial in the U.S. and Canada in late February 2001. The Company manufactures AMVISC(R) and AMVISC(R)Plus, which ARE HA products used as viscoelastic supplements in ophthalmic surgery, for Bausch & Lomb Surgical. The Company is currently developing INCERT(R), which is a family of HA-based products designed for use in the prevention oF post-surgical adhesions. In collaboration with Orquest, Inc., Anika also has exclusive rights to produce OSSIGEL(R)1, an injectable formulation of basic fibroblast growth factor combined with HA designed to accelerate thE healing of bone fractures.

AMVISC PRODUCTS

AMVISC(R) and AMVISC(R) 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(R) product line for Bausch & Lomb. The Company entered into a new supplY agreement (the "BLS Agreement") with Bausch & Lomb Surgical, a unit of Bausch & Lomb Incorporated, in July 2000. Under the terms of the BLS Agreement, effective January 1, 2001, the Company became Bausch & Lomb Surgical's exclusive provider of AMVISC(R) and AMVISC(R) Plus in the U.S.

and international market. The BLS Agreement expiRES December 31, 2007, superseding an existing supply contract with Bausch & Lomb Surgical that was set to expire December 31, 2001. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS 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 BLS. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - DEPENDENCE ON MARKETING PARTNERS" AND "--RELIANCE ON A SMALL NUMBER OF CUSTOMERS."

ORTHOVISC(R)

ORTHOVISC(R) 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(R) 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.

ORTHOVISC(R) is approved for sale and marketed in Canada, Europe, Turkey, and Israel. In Europe ORTHOVISC(R) is sold under Communaute Europeenne ("CE mark") authorization. The CE mark, a certification required under European Union ("EU") medical device regulation, allows ORTHOVISC(R) to be marketed without further approvals iN most of the EU nations as well as other countries that recognize EU device regulation.

In the U.S., ORTHOVISC(R) 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

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(1) OSSIGEL(R) is a registered trademark of Orquest, Inc.

and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC(R). The PMA was submitted to the FDA in December 1997 and contained clinical data collected from a 226 patient, randomized double blind clinical study completed in June 1997. In late March 1999, the Company received an Investigational Device Exemption ("IDE") approval and initiated a second Phase III clinical study. This trial completed patient enrollment, totaling 385 patients at 22 centers in the U.S. and Canada in August 1999. The final patient completed the six-month follow-up period on February 28, 2000. The statistical analysis of the clinical trial failed to show sufficient efficacy in this patient population to support the filing of a PMA application. In February

2001, the Company commenced its third Phase III clinical trial of ORTHOVISC(R). The trial is expected to be conducted in up to 20 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 the results of this third Phase III clinical study will be adequate to demonstrate the effectiveness of ORTHOVISC(R) to obtain FDA approval.

On November 10, 2000, the Company entered into an agreement to terminate the ORTHOVISC(R) marketing and distribution agreement with Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company. Under the terms of the termination agreement, Zimmer had the right to continue to distribute from its existing inventory through December 31, 2000 in the countries in which it had previously sold ORTHOVISC(R). The Company has established interim relationships with third party logistics firms so that Anika can continue to supply ORTHOVISC(R) in Canada and the European countries previously covered under the Zimmer Distribution Agreement. The Company will 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. The Company has licensed ORTHOVISC(R) marketing and distribution rights to Grupo Ferrer, Internacional for Spain and Portugal, and to RAFA Laboratories Ltd. in Israel. See "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OVERVIEW" beginning on page 13.

HYVISC(R)

HYVISC(R) 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(R) has viscoelastic properties that lubricate and protect the tissues in horse joints. HYVISC(R) is distributed by Boehringer Ingelheim Animal Health, Inc. in the United States under an agreement terminating May 2002.

RESEARCH AND DEVELOPMENT OF POTENTIAL PRODUCTS

As discussed below in the section titled "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - COMPREHENSIVE GOVERNMENT REGULATION; NO ASSURANCE OF FDA APPROVAL" beginning on page 19, the Company has not obtained FDA approval for the sales and marketing in the U.S. of the potential products described below.

INCERT

INCERT(R) 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, nevertheless they 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. The Company has tested INCERT(R) in pre-clinical animal studies.

INCERT(R)-S is the Company's product designed to reduce post-surgical fibrosis following spinal surgery. The Company has received an IDE approval from the FDA and plans to commence clinical trials for the product in the first half of 2001. The planned trial is expected to initially include up to 100 patients in up to 20 centers in the U.S. and, if results from these patients support further development, to expand patient recruitment to up to 380 patients. There can be no assurance that: (i) the Company will begin or successfully complete clinical trials of INCERT(R)-S; (ii) if completed, FDA approval for sales in the U.S. will be received; or (iii) if regulatory approvals are obtained, meaningful

sales of INCERT(R) will be achieved.

Anika co-owns an issued United States patent covering the use of INCERT(R) for adhesion prevention.

OSSIGEL

In June 1997, the Company executed a multi-year collaboration agreement with Orquest, Inc. to develop and manufacture OSSIGEL(R), a formulation of basic fibroblast growth factor and HA. OSSIGEL(R) has been shown iN pre-clinical animal models to accelerate the healing of bone fractures. Orquest commenced human clinical testing of OSSIGEL(R) in Europe and the United States during 1998. Orquest has filed a patent application with the U.S. Patent and Trademark Office for the use of OSSIGEL(R) in accelerating fracture healing.

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 that yield 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. The Company obtains syringes used to deliver certain of its HA products from a single supplier; however, it keeps sufficient syringes in its inventory to meet anticipated demand for at least six months.

PATENT AND PROPRIETARY RIGHTS

The Company has a policy of seeking patent protection for patentable aspects of its proprietary technology. The Company co-owns certain United States patents and a patent application which claim certain adhesion prevention uses and certain drug delivery uses of HA, and the Company solely owns patents covering certain manufacturing processes. The Company also holds an exclusive license from Tufts University to use technologies claimed in a United States patent which relates to the anti-metastasis applications of HA oligosaccharides. The Company's issued patents expire between 2007 and 2015 and the license expires upon expiration of all related patents. The Company intends to seek patent protection with respect to 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. 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 or licensed patents will provide the Company 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 the Company's patents. The Company's issued patents and any patents which arise from the Company's licensed application would provide competitive protection, if at all, only 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 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(R) for post-surgical adhesion prevention. The existence of an interference proceeding may have a negative impact on the marketing of the INCERT(R) product, and no assurance can be given that the Company would be successful in any such interference proceeding. If the third party interference were to be decided adversely to the Company, involved claims of the Company's patent would be cancelled, the Company's sales, use, and marketing of the INCERT(R) product may be materially and adversely affected and the third party may enforce patent rights against the Company which could prohibit the sale and use of the INCERT(R) products, which could have a material adverse effect on the Company's future operating results.

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 provide meaningful protection or that they will not be breached; that the Company would have adequate remedies for any such breach; or that the Company's trade secrets, proprietary know-how, and technological advances will

not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by the Company, others have not and will not obtain access to the Company's proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

The Company has granted Bausch & Lomb Surgical a royalty-free, worldwide, exclusive license to the Company's manufacturing and product inventions which relate to the AMVISC(R) products, effective upon the earlier of (i) the termination date of the BLS 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 rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act governs the testing, safety, effectiveness, clearance, approval, manufacture, labeling, packaging, storage, record keeping, reporting, 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 outweighted by the anticipated benefits to subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device, as used, is ineffective; or if an unanticipated adverse device effect presents an unreasonable risk to subjects. If clinical studies are suspended, Anika may be unable to continue the development of the investigational products affected.

In addition to the FDA approval processes for products, manufacturing facilities for drugs, biologics, and devices, subject to 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, monies and effort in the area of production and quality control to ensure full technical compliance. The FDA enforces compliance with these GMP/QSR through periodic inspections; and other federal, state, and local agencies may inspect manufacturing establishments as well.

In addition to regulations enforced by the FDA, Anika is subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other existing and potential 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(R) is approved as a Class III device in the United States for ophthalmic surgical procedures in intraocular use in humans. HYVISC(R) 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(R) and INCERT(R) 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 premarket 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 premarket notification and most Class II devices are subject to it. Class II devices also may be subject to clinical testing for purposes of premarket 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 premarket 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, and will likely continue to require the approval of a PMA from the FDA prior to commercial sale.

The PMA approval process is lengthy, expensive, and typically requires, among other things, extensive data from pre-clinical testing and a well-controlled clinical trial or trials that demonstrate a reasonable assurance of safety and effectiveness. The performance of human clinical trials must be done under an IDE. Upon completion of required clinical trials, results are presented to the FDA in a PMA application. In addition to the results of clinical investigations, the PMA applicant must submit other information relevant to the safety and effectiveness of the device, including, among other things, the results of non-clinical tests; a full description of the device and its components; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA staff then determines whether to accept the application for filing. If accepted for filing, the application is further reviewed by the FDA and then often reviewed by an FDA scientific advisory panel of people with expertise in the relevant field. The FDA will also conduct an inspection to determine whether an applicant conforms with the FDA's current GMP/QSR. If the FDA's evaluation is favorable, the FDA will subsequently publish an order granting the PMA for the device. Although the initial PMA review process is required to be completed within 180 days from the date when the PMA application is accepted for filing, the FDA in many cases raises additional issues which must be addressed prior to the approval of a PMA, which may significantly extend the review process. There is no assurance that review will result in timely or any PMA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

DRUGS

Medical devices may meet both the definition of a medical device and a drug or biologic. In these instances, the FDA may regulate these products as drugs or biologics or as both medical devices and drugs or biologics. The steps required before a drug or biologic may be marketed in the United States include (i) preclinical laboratory and animal tests; (ii) submission to the FDA of an Investigational New Drug application ("IND"), which must become effective before human clinical trials may commence; (iii) adequate and well-controlled human

clinical trials to establish the safety and efficacy of the drug; (iv) submission of a New Drug Application ("NDA") or Biologics License Application ("BLA") to the FDA; and (v) FDA approval of the NDA or BLA prior to any commercial sales or shipment of the drug. A clinical study program designed to demonstrate the safety and effectiveness of a drug usually proceeds in three phases:

- Phase I involves testing the drug for, among other things, safety and tolerance in a small group of healthy patients or volunteers.
- Phase II involves testing for efficacy and identifying possible side effects in a target patient group.
- Phase III involves additional testing for efficacy and safety with an expanded patient group, preferably using a comparative control agent.

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

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. Because a number of companies are developing HA products for similar applications, the successful commercialization of a particular product will depend in part upon the ability of the Company to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to its competitors. There can be no assurance that the Company will be able to compete against current or future competitors or that competition will not have a material adverse effect on the Company's business, financial condition, and results of operations.

The Company is aware of several companies, including Pharmacia, Alcon, Genzyme Biosurgery (successor to Biomatrix, Inc.), Hyal Pharmaceutical Corp., Q-Med AB, Fidia s.p.a., LifeCore Biomedical, Inc., Smith & Nephew plc and Seikagaku Corporation, that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the United States or in certain foreign countries. Major competing products for the use of HA in ophthalmic surgery include Healon (manufactured by Pharmacia) and Provisc and Viscoat (distributed by Alcon). Three HA products for the treatment of osteoarthritis in the knee, Hyalgan, Synvisc and Supartz have received FDA approval and are being marketed in the U.S. Hyalgan is manufactured by Fidia s.p.a. and is distributed by Sanofi Pharmaceuticals. In addition, Fidia s.p.a. is selling the product in select

markets in Europe. Synvisc is manufactured by Genzyme Biosurgery and is distributed in the United States by Wyeth-Ayerst Laboratories, a division of American Home Products Corp. Synvisc is also marketed in Canada, Europe, Latin America, Australia and other countries utilizing various other distribution partners. Supartz is manufactured by Seikagaku Corporation and is distributed in Japan, Spain, Sweden, the U.S. and other countries. Genzyme has received marketing approvals in Europe and the U.S. for a chemically modified HA for the prevention of post-surgical adhesions under the brand name of Seprafilm. LifeCore Biomedical has completed a Phase III human clinical trial on its HA product INTERGEL(TM) to prevent surgical adhesions and has filed a PMA with the FDA. Smith & Nephew has licensed Supartz from Seikagaku Corporation for distribution in the U.S., Europe, and other countries.

RESEARCH AND DEVELOPMENT

The Company intends to continue development of its existing product candidates, to expand the therapeutic applications of its existing products, and to develop new therapeutic applications for its HA-based technology.

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 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 with collaboration with other companies and scientific researchers. For the years ended December 31, 2000, 1999 and 1998, research and development expenses were $3.3 million, $4.2 million, and $2.0 million, respectively. The Company anticipates that it will continue to commit substantial resources to research and development in the future. As of December 31, 2000, the Company

had ten employees engaged primarily in research and development. Given its current plans for commencing two clinical trials in 2001, the Company expects its investments in research and development in 2001 to be roughly twice the level of such spending in 2000.

There can be no assurances that the Company's efforts will be successful in developing its existing product candidates, expanding the therapeutic applications of its existing products, or result in new applications for its HA technology, or that the Company will 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, 2000, the Company had approximately 64 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.

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 9,000 square feet of administrative and research and development space in Woburn, Massachusetts under a lease terminating in October 2001 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, 2000 the Company had aggregate lease costs of approximately $647,000.

ITEM 3. LEGAL PROCEEDINGS

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. These matters, relating to the Company's historical accounting for sales of its product under a long-term supply and distribution agreement with Zimmer, Inc., 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. The Company has been cooperating fully. However, the Company is not in a position to predict the probable outcome of this matter or its potential impact on the Company's business or operations.

PUTATIVE CLASS ACTION COMPLAINTS. Three putative class action complaints have been filed against the Company, J. Melville Engle, 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 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. The Company is vigorously defending the lawsuit. The Company is not able to predict the probable outcome of this matter or its potential impact on the Company's business or operations.

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

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

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

COMMON STOCK INFORMATION

The Company's common stock par value $0.01 per share (the "Common Stock") has traded on the Nasdaq National Market since November 25, 1997 under the symbol "ANIK". The following table sets forth, for the periods indicated, the high and low bid prices of the Common Stock on the Nasdaq National Market. These prices represent prices between dealers and do not include retail mark-ups, markdowns, or commissions and may not represent actual transactions.

YEAR ENDED DECEMBER 31, 1999

First Quarter..... $
Second Quarter.....
Third Quarter.....
Fourth Quarter.....

YEAR ENDED DECEMBER 31, 2000

First Quarter	$1
Second Quarter	
Third Quarter	
Fourth Quarter	

At December 31, 2000, there were 309 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,				F T P D
	2000	1999	1998	1997	
		(AS RESTATED)	(AS RESTATED)		
Product revenue	$12,935	$13,426	$11,430	$9,255	
Licensing revenue	3,400	400	1,500	2,700	
Total revenue	16,335	13,826	12,930	11,955	
Cost of product revenue	9,871	6,664	5,790	4,744	
Gross profit (loss)	6,464	7,162	7,140	7,211	
Total operating expenses	7,448	7,184	4,687	4,050	
Income (loss) before cumulative effect of change in accounting principle	174	1,248	3,633	3,344	
Cumulative effect of change in accounting principle	-	(3,625)	-	-	
Net income (loss)	$174	$(2,377)	$3,633	$3,344	

Diluted income (loss) per common share:				
Income (loss) before cumulative effect of change in accounting principle	$0.02	$0.12	$0.33	$0.44
Cumulative effect of change in accounting principle	-	(0.35)	-	-
Net income (loss)	$0.02	$(0.23)	$0.33	$0.44
Diluted common shares outstanding	10,042	10,221	11,006	7,587

BALANCE SHEET DATA:
(IN THOUSANDS)

	DECEMBER 31,				A
	2000	1999	1998 (AS RESTATED)	1997	1996
Cash and cash equivalents	$8,266	$6,441	$10,713	$22,680	$2,705
Investments in Marketable Securities	10,040	13,743	12,008	-	-
Working capital	23,083	18,973	26,361	25,329	4,226
Total assets	28,979	32,511	32,617	28,749	6,920
Redeemable convertible preferred stock	-	-	-	-	2,603
Accumulated deficit	(4,599)	(4,773)	(2,277)	(6,029)	(9,374)
Treasury stock	(280)	(960)	(1,890)	-	-
Stockholder's equity	26,712	25,712	29,179	26,224	2,369

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/A 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/A AND UNDER THE HEADING "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS" BEGINNING ON PAGE 19. THE FOLLOWING DISCUSSION SHOULD ALSO BE READ IN CONJUNCTION WITH THE CONSOLIDATED FINANCIAL STATEMENTS OF ANIKA THERAPEUTICS, INC. AND THE NOTES THERETO APPEARING ELSEWHERE HEREIN.

OVERVIEW

On August 14, 2001, the Company announced the restatement of its financial results for the fourth quarter of 1998 and the first quarter of 1999. This restatement involves the timing of recognition of revenues for the sale of ORTHOVISC(R) to Zimmer, formerly an ORTHOVISC(R) distributor. As a result of the SEC's ongoing investigation and the review of certain information, the Company and its independent auditors determined that certain revenue previously recognized in the fourth quarter of 1998 should have been recognized in the first quarter of 1999. Accordingly, revenue for the fourth quarter of 1998 is reduced by $343,000 to $3,060,000 and revenue for the first quarter of 1999 is increased by the same amount to $3,679,000. The impact on earnings in the fourth quarter of 1998 is a reduction of $119,000, or $.01 per share, to income of $489,000. The impact on earnings in the first quarter of 1999 is an increase of $119,000, or $.01 per share, to a loss of $3,050,000. The restated revenue for the years ended December 31, 1998 and 1999 is $12,930,000 and $13,826,000, respectively. The restated results for the years ended December 31, 1998 and 1999 include, respectively, net income of $3,633,000, or $.33 per share, and a net loss of $2,377,000, or $.23 per share.

The Company develops, manufactures and commercializes therapeutic products and devices intended to promote the repair, 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(R), which is an HA product used in the treatment of some forms of osteoarthritis in humans; and HYVISC(R), which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC(R) is currently approved for sale and marketed in Canada, Europe, Turkey, and Israel. In the U.S., ORTHOVISC(R) is currently limited to investigational use. The Company commenced a Phase III clinical trial in the U.S. and Canada in February 2001. The Company manufactures AMVISC(R) and AMVISC(R)Plus, which are HA products used as viscoelastic supplements in ophthalmic surgery, for Bausch & Lomb. The Company is currently developing INCERT(R), which is an HA-based product designed for use in the prevention of post-surgical adhesions, and in March 2001, the Company received IDE approval to commence a clinical trial. In collaboration with Orquest, Inc., Anika also has exclusive rights to produce OSSIGEL(R), an injectable formulation of basic fibroblast growth factor combined with HA designed to accelerate the healing of bone fractures.

The Company receives a substantial portion of its revenue from the sale of AMVISC(R) and AMVISC(R)Plus to Bausch & Lomb. For the years ended December 31, 2000 and 1999, AMVISC(R) sales accounted for 54.1% and 62.3% of product revenue, respectively.

The Company currently manufactures AMVISC(R) for Bausch & Lomb under the BLS Agreement. Under the terms of the BLS Agreement, effective January 1, 2001, the Company became Bausch & Lomb Surgical's exclusive provider of AMVISC(R) and AMVISC(R) Plus, ophthalmic viscoelastic products, in the U.S. and certain international markets. The BLS Agreement expires December 31, 2007, superseding an existing supply contract with Bausch & Lomb Surgical that was set to expire December 31, 2001. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS Agreement lifts 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 effective to April 1, 2000 and the elimination of minimum unit purchase obligations by BLS. (See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS--DEPENDENCE UPON MARKETING PARTNERS" beginning on page 19.)

In November 1997, the Company entered into a marketing and distribution agreement with Zimmer, Inc., which was subsequently amended in June 1998 and June 1999 (the "Zimmer Distribution Agreement"), and terminated in November 2000. The Zimmer Distribution Agreement provided Zimmer with exclusive marketing and distribution rights to ORTHOVISC(R) in the United States, Canada, Latin America, Asia and most of Europe. Following an informal inquiry by the Securities and Exchange Commission, the Company and its independent auditors conducted a review of its revenue recognition policy for revenue received under the Zimmer Distribution Agreement. As a result of this review, and after consultation with the SEC, Anika revised its revenue recognition policy for ORTHOVISC(R) sales to Zimmer and restated its operating results for 1998 and the first three quarters of 1999. (This restatement was previously announced on March 15, 2000 and was disclosed in the Company's Form 10-K for the year ended December 31, 1999.) Under the revised revenue recognition policy, revenue is recognized based upon the minimum per unit price under the Zimmer Distribution Agreement at the time of sale to Zimmer. Prior to the restatement announced on March 15, 2000, Anika had recognized revenue for ORTHOVISC(R) sales to Zimmer based upon an estimate of the average selling price, which was obtained by Zimmer upon sale of ORTHOVISC(R) to its customers, as specified under the Zimmer Distribution Agreement. Also, Anika had previously recognized revenue in 1998 and the first three quarters of 1999 for ORTHOVISC(R) from sales of units which had previously been purchased and paid for by Zimmer, but was being held in Anika's refrigerators at Zimmer's request. In accordance with the revised revenue recognition policy, this revenue is recorded in the periods when the ORTHOVISC(R) being held was shipped to Zimmer from Anika's refrigerators. Amounts paid by Zimmer in excess of the amounts recognized as revenue are recorded by Anika as deferred revenue.

On November 10, 2000 the Company entered into an agreement with Zimmer, Inc. to terminate the Zimmer Distribution Agreement for ORTHOVISC. . Under the terms of the termination agreement, Zimmer had rights to distribute ORTHOVISC(R) through the end of the year in the countries where it was previously sold. As a result of the termination of the Zimmer Distribution Agreement, Anika recognized $4,249,000 of revenue in the fourth quarter of 2000 for amounts previously received from Zimmer, which included a one-time payment received under the termination agreement. The termination eliminated all obligations under the distribution agreement with respect to milestone payments, minimum purchases, unit pricing adjustments based on market prices and provided for the disposal by January 31, 2001 of all units previously purchased by Zimmer, including units held in Anika's refrigerators at Zimmer's request. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - DEPENDENCE ON MARKETING PARTNERS" AND "--RELIANCE ON A SMALL NUMBER OF CUSTOMERS."

The Company also adopted the provisions of SEC Staff Accounting Bulletin 101 (SAB 101) in its restated 1999 operating results. SAB 101 changed revenue recognition practices for non-refundable up-front payments received as part of broad supply, distribution and marketing agreements, and is applicable to $2,500,000 and $1,500,000 payments received from Zimmer in the fourth quarter of 1997 and the second quarter of 1998, respectively. Prior to March 15, 2000, these amounts were recognized in the period received. In accordance with SAB 101, the Company recorded the cumulative effect of the change in accounting principle of $3,625,000 as a charge in the first quarter of 1999. Under the new revenue recognition policy prescribed by SAB 101, these payments were recognized as revenue ratably over the 10-year term of the Zimmer Distribution Agreement.

The amount received and deferred to future periods, $2,925,000 at September 30, 2000, was recorded as licensing revenue in the fourth quarter of 2000 as a result of the early termination of the Zimmer Distribution Agreement. Also, included in revenue in the fourth quarter of 2000 is a one-time payment received from Zimmer upon termination of the Zimmer Distribution Agreement.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2000 COMPARED TO YEAR ENDED DECEMBER 31, 1999 (AS RESTATED)

STATEMENT OF OPERATIONS DETAIL

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

PRODUCT REVENUE. Product revenue for the year ended December 31, 2000 was $12,935,222, a decrease of $490,420 or 4%, compared with $13,425,642 recorded in the prior year. The decrease was partially attributable to reduced sales of AMVISC(R) products to Bausch & Lomb of $1,363,968 compared with the prior year, reflecting lower prices effective April 1, 2000 under the BLS

Agreement. The Company expects unit volumes to increase in 2001 but will be partially offset by lower unit selling prices. Product revenue associated with ORTHOVISC(R) increased by $600,504 compared to 1999 as a result of the recognition of approximately $1.1 million of revenue upon termination of the Zimmer Distribution Agreement as described above, and was partially offset by decreased sales to the Company's Turkish distributor. The Company does not expect to recognize additional revenue from Zimmer in future periods. Also, ORTHOVISC(R) product revenue may be impacted by economic uncertainties associated with the Turkish market. Furthermore, future sales of ORTHOVISC(R) to our Turkish distributor will be at lower unit selling prices, as negotiations to establish a new long-term distribution agreement for this territory are ongoing. The Company's sales of HYVISC(R) 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. The Company does not anticipate that it will receive any licensing revenue in 2001.

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, 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(R) 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 June 30, 2000 to $4.7 million at December 31, 2000. Cost of sales during the second half of 2000 included charges of approximately $2.1 million to reflect this underutilization of manufacturing capacity. The company's gross margin is expected to continue to be adversely affected

by underutilization of manufacturing capacity in 2001. Second, the price reduction associated with the BLS Agreement, effective April 1, 2000, reduced gross margin by approximately $2.2 million, as compared to the prior year. The Company expects to continue to experience reduced gross margins through 2001, reflective of the reduced unit selling price under the BLS Agreement and the reduced per unit selling prices of ORTHOVISC(R) to its Turkish distributor.

RESEARCH AND DEVELOPMENT. Research and development expenses for the year ended December 31, 2000 decreased by $894,495 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(R) Phase III trial was completed during the first half of 2000. Costs of new trials during 2000 were minimal. Research and development expenses during 2001 are expected to be approximately twice the level of spending in 2000 due to the commencement of clinical trials for ORTHOVISC(R) and INCERT(R), as well as expected additions to headcount.

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, contractual negotiations relating to various distribution agreements and other matters.

NET INTEREST INCOME AND GAIN ON SALE OF SECURITIES. The Company's net interest income increased by $104,429 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, 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. Interest income in 2001 is expected to be adversely affected by lower market interest rates as well as lower average cash and investment balances.

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. 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. The Internal Revenue Code (IRC) contains provisions that may limit the amount of net operating loss and 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.

YEAR ENDED DECEMBER 31, 1999 (AS RESTATED) COMPARED TO YEAR ENDED DECEMBER 31, 1998 (AS RESTATED)

STATEMENT OF OPERATIONS DETAIL

	YEARS ENDED DECEMBER 31,	
	1999 (AS RESTATED)	1998 (AS RESTATED)
Product revenue	$13,425,642	$11,430,363
Licensing revenue	400,000	1,500,000
Total revenue	13,825,642	12,930,363
Cost of product revenue	6,664,163	5,790,184
Gross profit	7,161,479	7,140,179
Operating expenses:		
Research and development	4,154,479	1,955,940
Selling, general and administrative	3,029,394	2,731,142
Total operating expenses	7,183,873	4,687,082
Income (loss) from operations	(22,394)	2,453,097
Interest income, net	1,068,430	1,307,825

Gain on sale of securities	233,633	-
Income before provision for income taxes	1,279,669	3,760,922
Provision for Income taxes	31,412	127,557
Income before cumulative effect of change in accounting principle	1,248,257	3,633,365
Cumulative effect of change in accounting principle	(3,625,000)	-
Net income (loss)	$(2,376,743)	$3,633,365

PRODUCT REVENUE. Product revenue for the year ended December 31, 1999 was $13,425,642, an increase of $1,995,279 or 17.5%, over the $11,430,363 recorded in the prior year. The increase was primarily attributable to an increase of $1,491,312, or 45.0% in sales of ORTHOVISC(R). See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS--RELIANCE ON A SMALL NUMBER OF CUSTOMERS." Sales of AMVISC(R) products increased BY $294,606 or 3.7%.

LICENSING REVENUE. For the year ended December 31, 1999, licensing revenue of $400,000 represents the annual amortization of amounts received in 1997 and 1998 in accordance with the Company's change in accounting for such fees. The $1,500,000 included in licensing fees in 1998 was received from Zimmer for the extension of marketing rights for ORTHOVISC(R) to include most of Europe and Latin America under the Zimmer Distribution Agreement. This amount, along with $2,500,000 received in 1997, underlies the charge against earnings in 1999 under the caption "Cumulative effect of change in accounting principle."

GROSS PROFIT. Gross profit for the year ended December 31, 1999 was $7,161,479, an increase of $21,300 or 0.3% from $7,140,179 recorded in the prior year. Gross profit from product revenues increased as a percentage of product revenue to 50.4% for the year ended December 31, 1999 as compared to 49.3% in the prior year. The increase in the gross profit percentage on product revenues primarily reflects the impact of capital spending and resulting scale-up efforts during 1998 and 1999 to increase manufacturing capacity and other efforts to improve efficiencies.

RESEARCH AND DEVELOPMENT. Research and development expenses for the year ended December 31, 1999 increased by $2,198,539 to $4,154,479 from $1,955,940 recorded in the prior year. The increase in research and development during 1999 was primarily for the cost of ORTHOVISC(R) Phase III trials.

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the year ended December 31, 1999 increased by $298,252 or 10.9% to $3,029,394 from $2,731,142 in the prior year. The increase was primarily attributable to ORTHOVISC(R) selling and marketing costs, headcount increases, and the amortization of deferred stock compensation.

NET INTEREST INCOME AND GAIN ON SALE OF SECURITIES. The Company's net interest income decreased by $239,395 to $1,068,430 for the year ended December 31, 1999 from $1,307,825 in the prior year. The decrease is attributable to lower

average cash balances on hand in 1999 versus 1998 and lower average interest rates. 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, 1999 of $31,412 and $127,557 for the year ended December 31, 1998. The Company has utilized net operating loss and credit carry-forwards to offset taxable income earned during these years.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, the Company had cash, cash equivalents and investments in marketable securities of $18.3 million versus cash, cash equivalents and investments in marketable securities of $20.2 million at December 31, 1999. During 2000, the Company's net income plus depreciation and amortization of unearned stock compensation, less the change in deferred revenue used $3.3 million of cash. During fiscal year 2000, this utilization of cash was partially offset by a reduction of cash utilized in working capital items, primarily inventories and accounts receivable, amounting to $1.4 million.

During 2000, the Company utilized $505,000 for capital expenditures. Proceeds from the exercise of stock options were $540,000. Capital expenditures in 2001 are expected to include approximately $500,000 to construct certain manufacturing and laboratory facilities as well as customary capital spending for manufacturing, laboratory, and office equipment.

In October 1998, the Board of Directors approved a stock repurchase program under which the Company was authorized to repurchase up to $4 million of Anika common stock with the total number of shares repurchased under the plan not to exceed 9.9% of the total issued and outstanding shares. Through December 31, 1999, the Company had repurchased 762,100 shares at an average cost per share of $5.08 for an aggregate cash purchase price of approximately $3,873,000. No shares of the Company's stock were repurchased during 2000.

The Company has announced plans for increased research and product development spending, including two clinical trials, during 2001. Such currently planned expenditures will increase the Company's aggregate utilization of its cash resources. In addition, as described in the section entitled "Legal Proceedings" elsewhere in this document, the Company is a defendant in a shareholder class action lawsuit, which if settled, may require the Company to contribute funds. However, the Company believes that its cash and investments on hand will be sufficient to meet its requirements through at least 2002.

The Company's future capital requirements and the adequacy of available funds will depend, however, 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, timing requirements of its efforts to expand its manufacturing capabilities; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; competing technological and market developments; and 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. 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 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. The Company's estimate of the time period for which cash and cash equivalents will be adequate to fund operations is a forward looking statement within the meaning of the Private Securities Litigation Reform Act of 1995 and is subject to risks and uncertainties. Actual results may differ materially from those contemplated in such forward-looking statements. In addition to those described above, factors which may cause such a difference are set forth under the caption "Risk Factors and Certain Factors Affecting Future Operating Results" as well as in this Annual Report on Form 10-K/A generally.

RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS

COMPREHENSIVE GOVERNMENT REGULATION; NO ASSURANCE OF FDA APPROVAL. The Company's products, product development activities, manufacturing processes, and current and future sales and marketing are subject to extensive and rigorous regulation by the FDA and comparable agencies in foreign countries. In the United States, the FDA regulates the marketing, advertising, promotion, and distribution of medical devices, drugs, and biologics, as well as testing, safety, effectiveness, clearance, approval, manufacturing, labeling, packaging, storage, record keeping, and reporting activities for such products.

Medical products regulated by the FDA are generally classified as medical devices, drugs and/or biologics. 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 the Company's new products on a timely basis or at all, or that FDA review will not involve delays that will adversely affect the Company's 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 the Company's product development process which may adversely affect approval of or delay an application or require additional expenditures by the Company. In the event the Company's future products are regulated as human drugs or biologics, the FDA review process typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

The Company's ORTHOVISC(R) product will have to meet regulatory requirements of a Class III device by the FDA. Class III devices are those that generally must receive pre-market approval (PMA) by 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 the Company to commercially distribute ORTHOVISC(R) in the U.S., it must obtain FDA approval of a PMA. The PMA approval process can be expensive, uncertain and lengthy. A number of devices for which pre-market approval has been sought have never been approved for marketing. The review of an application often occurs over a protracted time period and may take two years or more from the filing date to complete. The Company submitted a PMA for ORTHOVISC(R) in December 1997. In October 1998, the Company was notified by the FDA that the Company's PMA application for ORTHOVISC(R) was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC(R). The Company submitted an IDE to the FDA in February 1999 and received approval in late March 1999 to commence a second Phase III clinical study. The Company received initial results from the Phase III clinical trial in late May 2000 that the Company determined did not show sufficient efficacy to support the filing of a PMA application. The Company has evaluated available information and announced its intention to

pursue further clinical trials. In February 2001, the Company commenced another Phase III clinical trial of ORTHOVISC(R). The trial is expected to be conducted in up to 20 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 (i) any additional clinical data will support the efficacy of ORTHOVISC(R), (ii) the Company will complete any additional clinical trials of ORTHOVISC(R), (iii) the Company will be able to successfully complete the FDA approval process, or (iv) 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 the Company's competitive position. Furthermore, even if the Company were to receive a PMA approval, (i) the approval may include significant limitations on the indications and other claims sought for use for which the product may be marketed; (ii) the approval may include other significant conditions to approval such as post-market testing, tracking, or surveillance requirements; and (iii) the Company may not be able to achieve meaningful sales in the U.S.

The Company's HA products under development, including INCERT(R)-S have not obtained regulatory approval in the U.S. for commercial marketing and sale. The Company believes that INCERT(R)-S will be regulated as a Class III medical device and will require FDA approval of a PMA prior to marketing. The Company has received IDE approval from the FDA and plans to commence clinical trials for INCERT(R)-S in the first half of 2001. The planned trial is expected to initially include up to 100 patients in up to 20 centers in the U.S. and, if results from these patients support further development, to expand patient recruitment to up to 380 patients. There can be no assurance that (i) the Company will begin or successfully complete clinical trials of INCERT(R)-S; (ii) the clinical data will support the efficacy of INCERT(R)-S; (iii) it will be able to successfully complete the FDA approval process; or (iv) 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 received FDA approval, (i) the approval may include significant limitations on the indications and other claims sought for use for which the product may be marketed (ii) the approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements; and /or (iii) meaningful sales of INCERT(R)-S may never be achieved.

Orquest has not received regulatory approval in the U.S. for the commercial marketing and sale of OSSIGEL(R). OSSIGEL(R) will be regulated as a Class III medical device with the FDA's Center of Biologics Research and Review as the lead review center and will require PDA approval prior to marketing. There can be no assurance that clinical trials of OSSIGEL(R) will demonstrate that OSSIGEL(R) is safe and effective or otherwise satisfies FDA requirements.

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. The Company may be required to make further filings with the FDA under certain circumstances. The FDA's regulations require agency approval of 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. Failure by the

Company 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, would have a material adverse effect on the Company's business, financial condition, and results of operations. The FDA could also limit or prevent the manufacture or distribution of the Company's products and has the power to require the recall of such products. Significant delay or cost in obtaining, or failure to obtain FDA approval on clearance to market products, any FDA limitations on the use of the Company's products, or any withdrawal or suspension of approval or rescission of clearance by the FDA could have a material adverse effect on the Company's business, financial condition, and results of operations.

In addition, all FDA approved or cleared products manufactured by the Company must be manufactured in compliance with FDA's GMP regulations and, for medical devices, FDA's 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 the Company and its facilities from time to time to determine whether the Company is 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 the Company 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 the Company. In addition, changes in the existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of the Company's 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, the Company is subject to other existing and potential 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. To enable the Company to market ORTHOVISC(R) in Europe, the Company was required to receive a "CE" marking certification, an international symbol of quality and compliance with the applicable European medical device directive. 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(R) as a viscoelastic supplement or a replacement for synovial fluid in human joints. There can be no assurance that the Company 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 or that it will be able to produce its 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. The Company cannot predict what impact, if any, such changes might have on its business. The requirements relating to the conduct of clinical trials, product licensing, pricing and

reimbursement also vary widely from country to country.

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 the Company's products will be granted or that the Company will have the necessary funds to develop certain of such products. Any failure to obtain, or delay in obtaining such approvals or clearances could adversely affect the ability of the Company to market its products.

HISTORY OF LOSSES; UNCERTAINTY OF FUTURE PROFITABILITY. From its inception up until December 31, 1996 and in 1999 and 2000, the Company incurred annual operating losses. As of December 31, 2000, the Company had an accumulated deficit of $4,599,000. The continued development of the Company's 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. The ability of the Company to reach sustained profitability is highly uncertain. To achieve sustained profitability the Company must, among other things, successfully complete development of certain of its products, obtain regulatory approvals, and establish sales and marketing capabilities or distribution arrangements for certain of its products. Increased spending in 2001 on clinical trials and research and development efforts is expected to result in a net loss for the year.

COMPETITION. The Company competes 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 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. Because a number of companies are developing HA products for similar applications, the successful commercialization of a particular product will depend in part upon the ability of the Company to successfully complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to its competitors. There can be no assurance that the Company will be able to compete against current or future competitors or that competition will not have a material adverse effect on the Company's business, financial condition, and results of operations. The Company is currently experiencing pricing pressures in the Turkish market from increased competition, which may hinder its ability to effectively compete in that market. As a result, we have decreased our prices to our Turkish distributor.

UNCERTAINTY REGARDING SUCCESS OF CLINICAL TRIALS. Several of the Company's products, including ORTHOVISC(R), as well as the products of the Company's collaborative partners, including OSSIGEL(R), 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, the Company's initial analysis of the results of its second Phase III clinical trial of ORTHOVISC(R) did not show sufficient efficacy to support the filing of a PMA application to obtain FDA approval. The Company has evaluated available information and announced the commencement of further clinical trials. In order to undertake clinical trials in the U.S. to support a PMA of INCERT-S(R), the Company has received from the FDA approval of an IDE. There can be no assurance that (i) any additional clinical data will support the efficacy of ORTHOVISC(R), (ii) the Company will begin clinical trials of INCERT(R)- S or complete any additional clinical trials of ORTHOVISC(R) or INCERT(R)- S (iii) it will be able to successfully complete the FDA approval process for either ORTHOVISC(R) or INCERT(R)- S, or (iv) additional ORTHOVISC(R) or INCERT(R)- 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 the Company or its collaborative partners will not encounter problems that will cause it to delay, suspend or terminate clinical trials. In addition, the Company cannot provide any assurance that such clinical trials, if completed, will ultimately demonstrate these products to be safe and efficacious.

DEPENDENCE UPON MARKETING AND DISTRIBUTION PARTNERS. The Company's success will be dependent upon the efforts of its marketing partners and the terms and conditions of the Company's relationships with such marketing partners.

In addition, there can be no assurances that such marketing partners will not seek to renegotiate their current agreements on terms less favorable to the Company. Under the terms of the BLS Agreement, effective January 1, 2001,

the Company became Bausch & Lomb Surgical's exclusive provider of AMVISC(R) and AMVISC(R) Plus, ophthalmic viscoelastic products, in the U.S. and international markets. The BLS Agreement expires December 31, 2007, superseding an existing supply contract with Bausch & Lomb Surgical that was set to expire December 31, 2001. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS Agreement lifts 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 BLS.

The Company has not achieved incremental sales of its ophthalmic products to Bausch & Lomb Surgical and/or other companies sufficient to offset the effects of the price reduction to Bausch & Lomb Surgical and there can be no assurances that the Company will be able to do so in the future. The Company expects that, at least through 2001, the reduction in unit prices will result in a decrease in the Company's revenue and gross margin from Bausch & Lomb Surgical. In addition, under certain circumstances, (i) Bausch & Lomb Surgical may have the right to terminate the agreement and/or (ii) the agreement may revert to a non-exclusive basis; in each case, the Company cannot make any assurances that such circumstances will not occur. For the years ended December 31, 2000 and 1999, sales of AMVISC(R) products to Bausch & Lomb Surgical accounted for 54.1% and 62.3% of product revenues, respectively. Although the Company intends to seek new opthalmic product customers, there can be no assurances that the Company will be successful in obtaining new customers and increased sales.

The Zimmer Distribution Agreement provided Zimmer with exclusive marketing and distribution rights to ORTHOVISC(R) in the United States, Canada, Latin America, Asia and most of Europe. On November 10, 2000, the Company reached an agreement with Zimmer, Inc. for an early termination of its marketing and distribution agreement for ORTHOVISC(R). Under the terms of the termination agreement, Zimmer had the right to distribute ORTHOVISC(R) from its existing inventory through the end of 2000 in the countries where it was heretofore sold. The early termination agreement also eliminated, among other things, all obligations with respect to additional milestone payments, minimum purchases, unit pricing adjustments and provided for the disposal of Zimmer units held on Anika premises. The termination may have a material adverse effect on the Company's ability to market ORTHOVISC(R), which may have a material adverse effect on the Company's future operating results. ORTHOVISC(R) sales to Zimmer accounted for 16.4% of product revenue for the year ended December 31, 2000. The Company has relationships with logistics service providers in order to distribute ORTHOVISC(R) to customers in Canada and European countries previously

served by Zimmer. The Company is seeking to establish long-term relationships with new distribution partners in these countries where Zimmer previously sold the product. There can be no assurance that the Company will be able to identify or engage appropriate distribution or collaboration partners or strategic investment opportunities.

The Company will need to obtain the assistance of additional marketing partners for new products, which are brought to market for the replacement of certain marketing partners, such as Zimmer, and for existing products brought to new markets. There can be no assurance that such additional partners will be available or that such partners will agree to market the Company's products on acceptable terms. The failure to establish strategic partnerships for the marketing and distribution of the Company's products on acceptable terms would have a material adverse effect on the Company's business, financial condition, and results of operations.

As a result of the termination of the Zimmer Distribution Agreement, the Company will not earn any additional milestone payments under the Zimmer Distribution Agreement. In addition, there can be no assurance that the Company 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. Furthermore, Anika may experience some difficulties or delays in the transfer of existing business relationships and reimbursement approvals from Zimmer.

UNCERTAINTY OF MARKET ACCEPTANCE OF FUTURE PRODUCTS. The Company's success will depend in part upon the acceptance of the Company's 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 the Company's products as safer, more effective or cost-competitive than other similar products. Ultimately, for the Company's new products to gain general market acceptance, it will also be necessary for the Company to develop marketing partners for the distribution of its products. There can be no assurance that the Company's new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of the Company's future products to achieve significant market acceptance could have a material adverse effect on the Company's business, financial condition, and results of operations.

DEPENDENCE ON PATENTS AND PROPRIETARY TECHNOLOGY. The Company's success will depend, in part, on its ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties when necessary, and conduct its business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical products and biotechnology firms, including the Company, 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, the Company may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office ("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 the Company, such interference proceedings could result in substantial cost to the Company. 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 the Company's 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 the Company to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by the Company, the Company 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 the Company's 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 the Company using the resulting alternative technology.

The Company has a policy of seeking patent protection for patentable aspects of its proprietary technology. The Company co-owns certain United States patents with claims relating to the chemical modification of HA and certain adhesion prevention and drug delivery uses of HA. Two patents in this portfolio have issued in the year 2000. The Company also solely owns patents directed to certain manufacturing processes. The Company holds an exclusive license from Tufts University to use technologies claimed in a United States patent application which has been granted a Notice of Allowance from the U.S. Patent Office for the anti-metastasis applications of HA oligosaccharides. The Company's patents expire between 2007 and 2015 and the license expires upon expiration of all related patents. The Company intends to seek patent protection with respect to 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. 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 the Company 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 the Company's patents. The Company's issued patents and any patents, which arise from the Company's licensed application, would provide competitive protection, if at all, only in the United States. The Company has 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 the Company will not infringe on 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, the Company received notice from the PTO in 1995 that a third party was attempting to provoke a patent interference with respect to one of the Company's co-owned patents covering the use of INCERT(R) 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 the Company's marketing of INCERT(R) for this use. The existence of the interference proceeding may have a negative impact on the marketing of the INCERT(R) product, and no assurance can be given that the Company would be successful in any such interference proceeding. If the third-party interference were to be decided adversely to the Company, involved claims of the Company's patent would be cancelled, the Company's marketing of the INCERT(R) product may be materially and adversely affected and the third party may enforce patent rights against the Company which could prohibit the sale and use of INCERT(R) products, which could have a material adverse effect on the Company's future operating results.

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 provide meaningful protection or that they will not be breached, that the Company would have adequate remedies for any such breach, or that the Company's trade secrets, proprietary know-how, and technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by the Company, others have not and will not obtain access to the Company's proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

Pursuant to the BLS Agreement, the Company has agreed to transfer to Bausch & Lomb Surgical, upon expiration of the term of the agreement on December 31, 2007, or in connection with earlier termination in certain circumstances, the Company's manufacturing process, know-how and technical information, which relate to AMVISC(R) products. Upon expiration of the BLS Agreement, there can be no assurance that Bausch & Lomb Surgical will continue to use the Company to manufacture AMVISC(R) and AMVISC(R) Plus. If Bausch & Lomb Surgical discontinues the use of the Company as a manufacturer after such time, the Company's business, financial condition, and results of operations would likely be materially and adversely affected.

RISKS ASSOCIATED WITH MANUFACTURING. The Company's results of operations are dependent upon the continued operation of its manufacturing facility in Woburn, Massachusetts. The operation of biomedical manufacturing plants involves many risks, including the breakdown, failure or substandard performance of equipment, natural and other disasters, and the need to comply with the requirements of directives of government agencies, including the FDA. In addition, the Company relies 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 its HA products. Furthermore, manufacturing processes and research and development efforts of the Company 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 the Company's 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 the Company's business, financial condition, and results of operations during the period of such operational difficulties.

NO ASSURANCE OF GROWTH OR ABILITY TO MANAGE GROWTH. The Company's 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 the Company's products is achieved, the Company will be able to (i) develop the necessary manufacturing capabilities; (ii) obtain the assistance of additional marketing partners; (iii) attract, retain and integrate the required key personnel; or (iv) implement the financial, accounting and management systems needed to manage growing demand for its products, should it occur. Failure of the Company to successfully manage future growth could have a material adverse effect on the Company's business, financial condition, and results of operations.

THIRD PARTY REIMBURSEMENT AND 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 the Company's 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. The Company depends upon the distributors for its 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 the Company's products is clinically useful and cost-effective, medically necessary and not experimental or investigational. Since reimbursement approval is required from each payor individually, seeking such approvals can be a time consuming and costly process which, in the future, could require the Company or its marketing partners to provide supporting scientific, clinical and cost-effectiveness data for the use of the Company's products to each payor 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 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 the Company. Outside the U.S., the success of the Company's 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 the Company' products and services could have a material adverse effect on the Company's business, financial condition, and results of operations.

NEEDS FOR ADDITIONAL FUNDS; LIQUIDITY. The Company had cash, cash equivalents and short-term investments of $18.3 million as of December 31, 2000. The Company's future capital requirements and the adequacy of available funds will depend, however, 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 preclinical studies, clinical trials and product clearances by the FDA and other agencies; the cost and timing of its efforts to improve its manufacturing capabilities and cost efficiency; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; costs associated with shareholder litigation matters; competing technological and market developments; and the development of strategic alliances for the marketing of certain of its products. To the extent that funds generated from the Company's operations, together with the Company's existing capital resources are insufficient to meet future requirements, the Company 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 the Company's stockholders and the terms of any debt financings may contain restrictive covenants, which may 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.

EXPOSURE TO PRODUCT LIABILITY CLAIMS. 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 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 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 operations.

DEPENDENCE UPON KEY PERSONNEL. The Company is highly dependent on the members of its management and scientific staff, the loss of one or more of who could have a material adverse effect on the Company. In addition, the Company believes that its future success will depend in large part upon its ability to attract and retain highly skilled, scientific, managerial and manufacturing personnel. The Company faces significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. There can be no assurance that the Company will be successful in hiring or retaining the personnel it requires. In particular, the Company can provide no assurances that the results from the recent Phase III clinical trial of ORTHOVISC(R) will not impact its ability to attract the personnel it requires. The failure to hire and retain such personnel could have a material adverse effect on the Company's business, financial condition, and results of operations.

ENVIRONMENTAL REGULATION. The Company is 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 the Company's products. Any failure by the Company to control the use, disposal, removal or storage of hazardous chemicals or toxic substances could subject the Company to significant liabilities, which could have a material adverse effect on the Company's business, financial condition, and results of operations.

RISKS RELATING TO INTERNATIONAL OPERATIONS. During the year ended December 31, 2000 and 1999, approximately 20% and 30%, respectively, of the Company's product sales were generated in international markets through marketing partners. The Company's representatives, agents and distributors, which sell products in international markets, are subject to the laws and regulations of the foreign jurisdictions in which they operate and in which the Company's 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 instability, trade restrictions, changes in tariffs, difficulties in managing international operations, import restrictions and fluctuations in foreign currency exchange rates. Furthermore, the economic conditions in Turkey may have a material adverse effect on the volume of sales of our Turkish distributor, who accounted for 17.7% of product revenues in 2000. Such changes in the volume of sales by any of our customers may have an adverse effect on the Company's business, financial condition, and results of operations.

POTENTIAL VOLATILITY OF STOCK PRICE; NO CONTROL OVER MARKET MAKING. The market price of shares of the Company's Common Stock may be highly volatile. Factors such as announcements of new commercial products or technological innovations by the Company or its 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 the Company and general market conditions may have a significant effect on the market price of the Company's Common Stock. In particular, the Company's stock price declined significantly in October 1998 following the Company's announcement that the FDA had notified the Company that its PMA for ORTHOVISC(R) was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC(R) and again in May 2000 following the Company's announcements that initial analysis of results from the Phase III clinical trial of ORTHOVISC(R) 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 the Company to provide information in connection with certain revenue recognition matters. The trading price of the Company's Common Stock could be subject to wide fluctuations in response to quarter-to-quarter variations in the Company's operating results, material announcements by the Company or its 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 the Company's 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. The Company's operating results in future quarters may be below the expectations of equity research analysts and investors. In such event, the price of the Common Stock would likely decline, perhaps substantially.

No person is under any obligation to make a market in the Common Stock or publish research reports on the Company, and any person making a market in the Common Stock or publishing research reports on the Company may discontinue market making or publishing such reports at any time without notice. There can be no assurance that an active public market in the Common Stock will be sustained.

POSSIBLE ADVERSE EFFECT OF CERTAIN ANTI-TAKEOVER PROVISIONS. Certain provisions of the Company's 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 the Company 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, and 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. The Company also is 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 the Company 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 the Company and its Board of Directors.

SEC INVESTIGATION AND SECURITIES CLASS ACTION LITIGATION. The SEC has issued a formal order of investigation and has required the Company to provide information in connection with certain revenue recognition matters. These matters, relating to the Company's historical accounting for sales of its product under a long-term supply and distribution agreement with Zimmer, Inc., 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. The Company has been cooperating fully. However, the Company is not in a position to predict the probable outcome of this matter or its potential impact on the Company's business or operations. Three putative class action lawsuits were filed against the Company. These lawsuits have been consolidated. The consolidated lawsuit is described more fully in Part II under Legal Proceedings. The Company is not able to predict the probable outcome of this matter or its potential impact on the Company's business or operations.

RELIANCE ON A SMALL NUMBER OF CUSTOMERS. The Company has historically derived the majority of its revenues from a small number of customers, most of who resell its products to end users and most of who are significantly larger companies. The Company's failure to generate as much revenue as expected from these customers or the failure of these customers to purchase Anika's products would seriously harm Anika's business. For the year ended December 31, 2000, Bausch & Lomb Surgical accounted for 54.1% of product revenues and 39% of the accounts receivable balance and Biomeks, Anika's distributor in Turkey, accounted for 17.7% of product revenues and 35% of the accounts receivable balance. Accordingly, if present and future customers terminate their purchasing arrangements with the Company, significantly reduce or delay their orders or seek to renegotiate their agreements on terms less favorable to the Company, the Company will be adversely affected. If the Company accepts terms less favorable than the terms of the current agreement, such renegotiations may have a material adverse affect on Anika's business, financial condition, and/or results of operations. Furthermore, the Company may be subject to the perceived or actual leverage the customers may have given their relative size and importance to the Company in any future negotiations. Any termination, change, reduction or delay in orders could seriously harm the Company's business, financial condition, and results of operations. Accordingly, unless and until the Company diversifies and expands its customer base, Anika's future success will significantly depend upon the timing and size of future purchases by its largest customers and the financial and operational success of these customers. Product revenue in the future may continue to be impacted by economic uncertainties associated with the Turkish market. Furthermore, 2001 sales to our Turkish distributor are at lowered prices and negotiations are ongoing to establish a new long-term distribution agreement for this territory.

The loss of any one of the Company's major customers or the delay of significant orders from such customers, even if only temporary, could reduce or delay the Company's recognition of revenues, harm its reputation in the industry, and reduce its ability to accurately predict cash flow, and, as a consequence, could seriously harm the Company's business, financial condition, and results of operations. Revenue from sales of ORTHOVISC(R) to Zimmer, including recognition in revenue of previously deferred amounts in connection with the termination of the Zimmer agreement in the fourth quarter of 2000, amounted to $5,522,000 and $770,000 in 2000 and 1999, respectively.

The Company distributes ORTHOVISC(R) in territories such as Spain, Portugal, Turkey, and Israel. Due to the result of the unfavorable results of the U.S. ORTHOVISC(R) Phase III clinical trial announced on May 31, 2000, marketing efforts in these countries may be negatively affected. There can be no assurance that past ORTHOVISC(R) 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, 2000, 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.

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 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, 2000. 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

REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

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

We have audited the accompanying consolidated balance sheets of Anika Therapeutics, Inc. (the "Company") and subsidiaries as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity and cash flows for the three years in the period ended December 31, 2000 as restated, see Note 2. 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 financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Anika Therapeutics, Inc. and subsidiaries as of December 31, 2000 and 1999, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

As explained in Note 3 to the consolidated financial statements, effective January 1, 1999, the Company changed its method of accounting for revenue recognition for non-refundable up-front payments through the adoption of Staff Accounting Bulletin No. 101, REVENUE RECOGNITION IN FINANCIAL STATEMENTS.

ARTHUR ANDERSEN LLP

Boston, Massachusetts
February 14, 2001, except with respect to the
matter discussed in Note 2, as to which the
date is August 14, 2001.

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	DECEMBER 31, 2000
ASSETS	
Current Assets:	
Cash and cash equivalents	$ 8,265,936
Short term marketable securities	10,039,849
Accounts receivable, net of reserves of $124,000 and $61,000, at December 31, 2000 and 1999	1,692,457

Inventories	4,737,645
Prepaid expenses and other receivables	612,890
Total current assets	25,348,777
Property and equipment, at cost	8,621,579
Less: accumulated depreciation	(5,498,455)
	3,123,124
Long term marketable securities	-
Long term deposits	124,600
Notes receivable from officers	382,000
Total Assets	$ 28,978,501

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:	
Accounts payable	$ 870,502
Accrued expenses	1,395,677
Deferred revenue, current portion	-
Total current liabilities	2,266,179
Long term deferred revenue	-
Commitments and contingencies (Notes 9 and 16)	-
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	99,919
Additional paid-in capital	31,735,660
Treasury stock (at cost, 57,663 shares and 200,863 shares respectively)	(279,756)
Deferred compensation	(244,549)
Accumulated deficit	(4,598,952)
Total stockholders' equity	26,712,322
Total Liabilities & Stockholder's Equity	$ 28,978,501

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

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31,

	2000	1999

		(AS RESTATED
Product revenue	$12,935,222	$13,425,642
Licensing revenue	3,400,000	400,000
Total revenue	16,335,222	13,825,642
Cost of product revenue	9,870,559	6,664,163
Gross profit	6,464,663	7,161,479
Operating expenses:		
Research & development	3,259,984	4,154,479
Selling, general & administrative	4,188,044	3,029,394
Total operating expenses	7,448,028	7,183,873
Income (loss) from operations	(983,365)	(22,394
Interest income	1,172,859	1,068,430
Gain on sale of securities	-	233,633
Income before provision for income taxes	189,494	1,279,669
Provision for income taxes	15,940	31,412
Income before cumulative effect of change in accounting principle	173,554	1,248,257
Cumulative effect of change in accounting principle	-	(3,625,000
Net income (loss)	$173,554	$(2,376,743
Basic income (loss) per share:		
Income before cumulative effect of change in accounting principle	$0.02	$0.13
Cumulative effect of change in accounting principle	-	(0.37
Net income (loss)	$0.02	$(0.24
Basic weighted average common shares outstanding	9,895,725	9,740,560
Diluted income (loss) per share:		
Income before cumulative effect of change in accounting principle	$0.02	$0.12
Cumulative effect of change in accounting principle	-	(0.35
Net income (loss)	$0.02	$(0.23
Diluted weighted average common shares and potential common shares outstanding	10,041,855	10,220,584

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

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31,

	COMMON STOCK NUMBER OF SHARES	COMMON STOCK $.01 PAR VALUE	ADDITIONAL PAID-IN CAPITAL	DEFERRED COMPENSATION
Balance, December 31, 1997	9,691,091	$96,911	$32,156,504	$ -
Exercise of common stock options	97,152	971	368,098	-
Exercise of common stock warrants	203,700	2,037	666,099	-
Expenses from sale of common stock in 1997, net	-	-	(107,293)	-
Unearned stock compensation	-	-	1,356,267	(1,074,699)
Purchase of common stock	-	-	-	-
Net income (as restated)	-	-	-	-
Balance, December 31, 1998 (as restated)	9,991,943	99,919	34,439,675	(1,074,699)
Exercise of common stock options	-	-	(2,363,125)	-
Amortization of deferred compensation	-	-	-	342,464
Purchase of common stock	-	-	-	
Reversal of 1998 unearned stock compensation	-	-	(117,234)	117,234
Net loss (as restated)	-	-	-	-
Balance, December 31, 1999	9,991,943	99,919	31,959,316	(615,001)
Exercise of common stock options	-	-	(140,181)	-
Amortization of deferred compensation	-	-	-	286,977
Reversal of 1998 unearned stock compensation	-	-	(83,475)	83,475
Net income	-	-	-	-
Balance, December 31, 2000	9,991,943	$99,919	$31,735,660	$(244,549)

	TREASURY STOCK NUMBER OF SHARES	TREASURY STOCK AT COST	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance, December 31, 1997	-	$ -	$(6,029,128)	$26,224,287
Exercise of common stock options	(15,000)	34,025	-	403,094
Exercise of common stock warrants	-	-	-	668,136
Expenses from sale of common stock in 1997, net	-	-	-	(107,293)
Unearned stock compensation	-	-	-	281,568
Purchase of common stock	359,500	(1,923,818)	-	(1,923,818)

Net income (as restated)	-	-	3,633,365	3,633,365
Balance, December 31, 1998 (as restated)	344,500	(1,889,793)	(2,395,763)	29,179,339
Exercise of common stock options	(546,237)	2,878,913	-	515,788
Amortization of deferred compensation	-	-	-	342,464
Purchase of common stock	402,600	(1,948,989)		(1,948,989)
Reversal of 1998 unearned stock compensation	-		-	-
Net loss (as restated)	-	-	(2,376,743)	(2,376,743)
Balance, December 31, 1999	200,863	(959,869)	(4,772,506)	25,711,859
Exercise of common stock options	(143,200)	680,113	-	539,932
Amortization of deferred compensation	-	-	-	286,977
Reversal of 1998 unearned stock compensation	-	-	-	-
Net income	-	-	173,554	173,554
Balance, December 31, 2000	57,663	$(279,756)	$(4,598,952)	$26,712,322

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

ANIKA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	FOR THE YEARS ENDED	
	2000	19
		(AS REST
Cash flows from operating activities:		
Net income (loss)	$173,554	($2,376,
Adjustments to reconcile net income (loss) to net cash (used for) provided by operating activities:		
Depreciation and amortization	910,763	777,
Amortization of deferred compensation	286,977	342,
Provision for doubtful accounts	63,000	12,
Advance rent payment	-	(50,
Changes in operating assets and liabilities:		
Accounts receivable	350,994	914,
Inventories	756,056	(1,747,
Prepaid expenses	108,316	(471,
Accounts payable	241,423	(262,
Accrued expenses	(156,983)	196,
Deferred revenue	(4,617,505)	3,478,
Net cash (used for) provided by operating activities	(1,883,405)	812,

Cash flows from investing activities:		
Proceeds of short-term marketable securities	49,914,742	38,902,
Purchase of short term marketable securities	(46,211,692)	(35,079,
Purchase of property and equipment	(505,346)	(1,740,
Notes receivable from officers	(29,000)	(160,
Deposits	-	(16,
Proceeds from long-term marketable securities	-	
Purchase of long term marketable securities	-	(5,558,
Net cash (used for) provided by investing activities	3,168,704	(3,651,
Cash flows from financing activities:		
Expenses from 1997 issuance of stock	-	
Purchase of treasury stock	-	(1,948,
Proceeds from exercise of stock options and warrants	539,932	516,
Net cash provided by (used for) financing activities	539,932	(1,432,
Increase (decrease) in cash and cash equivalents	1,825,231	(4,271,
Cash and cash equivalents at beginning of period	6,440,705	10,712,
Cash and cash equivalents at end of year	$8,265,936	$6,440,
Supplemental disclosure of cash flow information:		
Cash paid for taxes	$ -	$ 131,

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(R), which is an HA product used in the treatment of some forms of osteoarthritis in humans and HYVISC(R), which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC(R) is currently approved for sale and is being marketed in Canada, parts of Europe, Turkey, and Israel. In the U.S., ORTHOVISC(R) is currently limited to investigational use. The Company manufactures AMVISC(R) and AMVISC(R) Plus for Bausch & Lomb

Surgical, which are HA products used as viscoelastic supplements in ophthalmic surgery. The Company is currently developing INCERT(R)-S, which is an HA based product designed for use in the prevention of post-surgical adhesions. In collaboration with Orquest, Inc., Anika also has exclusive rights to produce OSSIGEL(R); an injectable formulation of basic fibroblast growth factor combined with HA designed to accelerate the healing of bone fractures.

2. RESTATED FINANCIAL RESULTS

On August 14, 2001, the Company announced the restatement of its financial results for the fourth quarter of 1998 and the first quarter of 1999. This restatement involves the timing of recognition of revenues for the sale of ORTHOVISC(R) to Zimmer, formerly an ORTHOVISC(R) distributor. As a result of the SEC's ongoing investigation and the review of certain information, the Company and its independent auditors determined that certain revenue previously recognized in the fourth quarter of 1998 should have been recognized in the first quarter of 1999. Accordingly, revenue for the fourth quarter of 1998 is reduced by $343,000 to $3,060,000 and revenue for the first quarter of 1999 is increased by the same amount to $3,679,000. The impact on earnings in the fourth quarter of 1998 is a reduction of $119,000, or $.01 per share, to income of $489,000. The impact on earnings in the first quarter of 1999 is an increase of $119,000, or $.01 per share, to a loss of $3,050,000. The restated revenue for the years ended December 31, 1998 and 1999 is $12,930,000 and $13,826,000, respectively. The restated results for the years ended December 31, 1998 and 1999 include, respectively, net income of $3,633,000, or $.33 per share, and a net loss of $2,377,000, or $.23 per share.

A summary of the impact of such restatement on the financial statements for the years ended December 31, 1998 and 1999 is as follows:

	AS PREVIOUSLY REPORTED	AS RESTATED IN THIS FORM 10-K/A
Year Ended December 31, 1998		
Total revenue	$13,273,343	$12,930,363
Cost of product revenue	6,014,181	5,790,184
Gross profit	7,259,162	7,140,179
Net income	3,752,348	3,633,365
Diluted income per share:		
Net income	0.34	0.33
Diluted weighted average common shares and potential common shares outstanding	11,006,276	11,006,276
Total assets	$32,392,984	$32,616,981

2. RESTATED FINANCIAL RESULTS (CONTINUED)

	AS PREVIOUSLY REPORTED	AS RESTATED IN THIS FORM 10-K/A

Year Ended December 31, 1999		
Total revenue	$13,482,662	$13,825,642
Cost of product revenue	6,440,166	6,664,163
Gross profit	7,042,496	7,161,479
Net loss	(2,495,726)	(2,376,743)
Diluted loss per share:		
Net loss	(0.24)	(0.23)
Diluted weighted average common shares and potential common shares outstanding	10,220,584	10,220,584
Total assets	$32,511,105	$32,511,105

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles 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 Corporation and Anika Therapeutics UK, Ltd. All intercompany transactions have been eliminated in consolidation.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents consists of cash and investments with original maturities of 90 days or less such as money market funds, and commercial paper.

SHORT-TERM AND LONG-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 debt securities 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 amortized costs. Aggregate fair value, amortized cost and average maturity for marketable securities held at December 31, 2000 and 1999 is as follows:

	DECEMBER 31, 2000	
AMORTIZED COST	GROSS UNREALIZED HOLDING GAIN	F

Commercial Paper (weighted average maturity of 3.4 months)	$10,039,849	$82,384	$1

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

	DECEMBER 31, 1999		
	AMORTIZED COST	GROSS UNREALIZED HOLDING GAIN	F
Commercial Paper (weighted average maturity of 7.64 months)	$8,184,870	$60,209	$

Long-term marketable securities consist of debt securities with maturities greater than one year from the balance sheet date. The Company classifies these long-term marketable securities as held to maturity, and accordingly they are carried at amortized costs.

During 2000, securities classified as held to maturity, with an amortized cost aggregating $46,211,692, matured during the year. Total proceeds from these maturities were $49,914,742, which includes total interest and realized gain of $1,436,872, which is included in interest income on the Statement of Operations.

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, short-term and long-term marketable securities, accounts receivable, notes receivable from officers and accounts payable. The fair value of short-term marketable securities is presented above. The estimated fair values of the Company's other financial instruments approximate their carrying values.

INVENTORIES

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out (FIFO) method. Work-in-process and finished goods inventories include materials, labor, and manufacturing overhead.

REVENUE RECOGNITION

Product revenue is recognized upon shipment of commercial product and represents sales of AMVISC(R) products, HYVISC(R) and ORTHOVISC(R). ORTHOVISC(R) is sold under several distribution contracts. On March 15, 2000, the Company announced that it had revised its revenue recognition policy for sales of ORTHOVISC(R) under its distribution agreement with Zimmer, and was restating its 1998 financial statements to reflect the revised policy. Under

the revised revenue recognition policy,revenue is recognized based upon the minimum per unit price under the terms of the Zimmer Distribution Agreement at the time of sale to Zimmer. Prior to the restatement announced on March 15, 2000, Anika had recognized revenue for ORTHOVISC(R) sales to Zimmer based upon an estimate of the average selling price, which would be obtained by Zimmer upon sale of the ORTHOVISC(R) to its customers. Also, Anika had previously recognized revenue in 1998 and the first three quarters of 1999 for ORTHOVISC(R), from sales of units which had previously been purchased and paid for by Zimmer but was being held in Anika's refrigerators at Zimmer's request. In accordance with the revised revenue recognition policy, this revenue is recorded in the periods when the ORTHOVISC(R) being held was shipped to Zimmer from Anika's refrigerators. Amounts paid by Zimmer in excess of the amounts recognized as revenue are recorded by Anika as deferred revenue and amounted to $1,390,000 at September 30, 2000. On November 10, 2000, Anika and Zimmer agreed to a termination of the Zimmer Distribution Agreement. In accordance with the termination agreement, no further unit price adjustment was made, Zimmer was permitted to sell from its existing inventory through December 31, 2000, all units previously purchased by Zimmer, including units of ORTHOVISC(R) held in Anika's refrigerators for Zimmer, were destroyed, and Anika had no further obligations to Zimmer as of December 31, 2000. Accordingly, the amounts in deferred revenue related to Zimmer, including the license fees discussed below, total $4,249,000 and were included in revenue in the fourth quarter of 2000 (See Note 14.)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

The Company adopted the provisions of SEC Staff Accounting Bulletin 101 (SAB 101) in its 1999 operating results. SAB 101 changes revenue recognition practices for non-refundable up-front payments received as part of broad supply, distribution, and marketing agreements, including $2,500,000 and $1,500,000 received from Zimmer in the fourth quarter of 1997 and the second quarter of 1998, respectively. Prior to March 15, 2000, these amounts were recognized in the period received. In accordance with SAB 101, issued in December 1999, the Company recorded the cumulative effect of the change in accounting principle of $3,625,000 as a charge in the first quarter of 1999. Amounts received and deferred to future periods was $3,225,000 at December 31, 1999. The Company has recognized as revenue $100,000 of the payments in each of the quarters ended from March 31, 1999 through September 30, 2000. As a result of the early termination of the Zimmer Distribution Agreement, the remaining non-refundable up-front payments in deferred revenue of $2,925,000 was recorded as revenue in the fourth quarter of 2000 (See Note 14.)

Advanced payments received for products are recorded as deferred revenue and are recognized when the product is shipped.

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	3-10 years
Furniture and fixtures	3-5 years
Leasehold improvements	Shorter of estimated useful life or 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.

During the years ended December 31, 2000, 1999, and 1998 the Company did not record losses on impairment.

RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred.

EARNINGS PER SHARE

SFAS No. 128, EARNINGS PER SHARE, establishes standards for computing and presenting earnings (loss) per share.

Basic earnings per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share is 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, the dilutive 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, excluding the cumulative effect of a change in accounting principle, dilutive net loss per share is not presented as it is less than basic net loss per share.

The following illustrates a reconciliation of the number of shares used in the calculation of basic and diluted net income (loss) per share for the years ended December 31, 2000, 1999, and 1998:

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

	YEARS ENDED DECEMBER 31,		
	2000	1999	
		(AS RESTATED)	(AS
Net income (loss)	$173,554	$(2,376,743)	$3,
Basic weighted average common shares outstanding	9,895,725	9,740,560	9,
Dilutive effect of assumed exercise of stock options and warrants	146,130	480,024	1,
Diluted weighted average common and potential common shares outstanding	10,041,855	10,220,584	11,

The Company reports earnings per share in accordance with SFAS No. 128.

Diluted weighted average shares outstanding for 2000, 1999, and 1998 exclude 1,102,214, 1,016,992, and 1,011,360 potential common shares from stock options because to include them would have been anti-dilutive for the year presented.

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.

NEW ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board (FASB) issued SFAS No. 133, Accounting for Derivatives and Hedging Activities. SFAS No. 133, as amended by SFAS No. 137 and SFAS No. 138, is effective for all fiscal quarters of all fiscal years beginning after June 15, 2000. SFAS No. 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. As of December 31, 2000, the Company did not participate in any derivatives, financial instruments, or other financial and commodity instruments for which fair market value disclosure would be required under SFAS 133.

In March 2000, the FASB issued Interpretation No. 44, ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION - AN INTERPRETATION OF APB OPINION NO.25. The interpretation clarifies the application of APB Opinion No. 25 in certain situations, as defined. The interpretation is effective July 1, 2000, but covers certain events that occur after December 15, 1998. The effects of applying this interpretation is applied on a prospective basis from the effective date. The adoption of the interpretation during the third quarter of 2000 did not have a material impact on the Company's results of operations, financial position, or cash flows.

As noted above, under REVENUE RECOGNITION, the Company adopted the provisions of SAB 101 in 1999.

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 10).

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

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, off-balance sheet credit 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:

	PERCENT OF PRODUCT REVENUE YEAR ENDED DECEMBER 31,		
	2000	1999	1998
AMVISCa:			
Bausch & Lomb	54.1%	62.3%	70.8%
ORTHOVISCa:			
Zimmer	16.4%	5.3%	7.6%
Biomeks	17.7%	27.7%	19.8%
	88.2%	95.3%	98.2%

In the fourth quarter of 2000, product revenue included sales of ORTHOVISC(R) to Zimmer of $1,418,000 which had been previously deferred. 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. 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. As of December 31, 1999 two customers, one of whom was an international customer, represented 49% and 42%, respectively, of the Company's accounts receivable balance.

REPORTING COMPREHENSIVE INCOME

SFAS No. 130, REPORTING COMPREHENSIVE INCOME establishes standards for reporting and display of comprehensive income and its components in the financial statements. Comprehensive income is the total of net income and all other non-owner changes in equity including such items as unrealized holding gains/losses on securities, foreign currency translation adjustments and minimum pension liability adjustments. The Company had no such items for the years ended December 31, 2000, 1999, and 1998.

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 how to allocate resources and assess performance. The Company's chief decision-making group consists of the chief executive officer and the chief financial 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 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 country in total and as a percentage of total revenues are as follows for the years ended December 31, 2000, 1999, and 1998, respectively:

COUNTRY:	YEARS ENDED DECEMBER 31, 2000		1999		1998	
	REVENUE	PERCENT OF REVENUE	REVENUE	PERCENT OF REVENUE	REVENUE	PERCENT OF REVENUE
			(AS RESTATED)		(AS RESTATED)	
United States	$13,041,791	79.84%	$9,724,053	70.33%	$10,473,268	81.00%
Middle East	2,445,821	14.97%	3,948,839	28.56%	2,307,095	17.84%
Other/Europe	847,610	5.19%	152,750	1.11%	150,000	1.16%
Total	$16,335,222	100.00%	$13,825,642	100.00%	$12,930,363	100.00%

4. ALLOWANCE FOR DOUBTFUL ACCOUNTS

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

	DECEMBER 31, 2000	1999	1998
Balance, beginning of the year	$61,000	$57,000	$ -
Amounts provided	63,000	12,000	57,000
Amounts written off	-	(8,000)	-
Balance, at the end of the year	$124,000	$61,000	$57,000

5. INVENTORIES

Inventories consist of the following:

DECEMBER 31,

	2000	1999
Raw Materials	$1,386,504	$681,936
Work in-process	3,169,358	3,690,618
Finished goods	181,783	1,121,147
Total	$4,737,645	$5,493,701

6. PROPERTY & EQUIPMENT

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

	DECEMBER 31,	
	2000	1999
Machinery and equipment	$6,071,812	$5,704,663
Furniture and fixtures	670,923	1,773,390
Leasehold improvements	1,878,844	638,180
	8,621,579	8,116,233
Less accumulated depreciation	(5,498,455)	(4,587,692)
Total	$3,123,124	$3,528,541

7. NOTES RECEIVABLE FROM OFFICERS

Notes receivable from officers consists of six loans made to three officers and one former officer. The loan amounts are generally due at the earlier of the end of five years from the date of the note or at the termination of the officers' employment. The note receivable from the former officer is secured by a mortgage on the person's primary residence. Interest accrues at annual rates between 5.54% to 6.22% and is payable monthly over the term of the loans.

8. ACCRUED EXPENSES

Accrued expenses consists of the following:

	DECEMBER 31,	
	2000	1999
Accrued compensation	$587,222	$666,900

Federal taxes	-	30,530
Accrued legal and professional fees	247,000	123,200
Clinical Trials	30,001	383,754
Other accrued expenses	531,454	348,277
	-	
Total	$1,395,677	$1,552,661

9. 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 statements of operations. Net rental expense in connection with the leases, totaled $647,348, $489,000 and $377,000 for the years ended December 31, 2000, 1999, and 1998, respectively. Future minimum lease payments under the operating leases for the years ending December 31st are as follows:

	AMOUNT
2001	$ 570,901
2002	512,204
2003	513,404
2004	74,967
Total	$1,671,476

10. 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 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 2000, 1999, and 1998, $286,975, $342,464 and $415,362 were amortized to expense, respectively. The unamortized deferred compensation of $244,550 at December 31, 2000 will be amortized on a straight-line basis over the options' remaining vesting period of approximately 10 months.

10. STOCK OPTION PLAN (CONTINUED)

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

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE
Outstanding at December 31, 1997	1,846,515	$3.77
Granted	508,500	5.82
Canceled	(68,958)	8.49
Exercised	(112,153)	3.62
Outstanding at December 31, 1998	2,173,904	$4.02
Granted	223,500	5.60
Canceled	(241,116)	5.91
Exercised	(561,237)	2.08
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
Exercisable, December 31, 2000	781,605	$4.99
Exercisable, December 31, 1999	870,384	$4.44
Exercisable, December 31, 1998	1,339,236	$3.04

Generally, options vest in varying 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 412,946 options available for future grant at December 31, 2000.

The following table summarizes significant ranges of outstanding options under both Plans at December 31, 2000:

	Options Outstanding			Options Exercisable	
Ranges of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.19 - 3.00	458,933	8.01	1.94	124,833	2.66

3.12 - 4.94	300,776	6.60	4.24	171,359	3.81
5.00 - 7.00	708,933	7.40	5.74	345,933	5.27
7.63 - 9.75	252,480	7.67	7.75	139,480	7.77
	1,721,122	7.20	4.77	781,605	4.99

10. STOCK OPTION PLAN (CONTINUED)

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 2000, 1999, and 1998 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The underlying assumptions used are as follows:

	DECEMBER 31,		
	2000	1999	1
Risk-Free interest rate	61.80%	5.56%	5
Expected dividend yield	0.00%	0.00%	0
Expected lives	4	6	
Expected volatility	71.60%	65.10%	50
Weighted average grant date, fair value of grants	$2.16	$3.21	$4

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,		
	2000	1999	1998
		(as restated)	
Net income (loss)			
As reported	$173,554	$(2,376,743)	$3,633,3
Pro forma	$(522,111)	$(3,046,048)	$2,986,4
Net income (loss) per share, as reported			
Basic	$0.02	$(0.24)	$0.
Diluted	$0.02	$(0.23)	$0.
Net income (loss) per share, proforma			
Basic	$(0.05)	$(0.31)	$0.
Diluted	$(0.05)	$(0.30)	$0.

11. 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.

11. SHAREHOLDER RIGHTS PLAN (CONTINUED)

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 effect 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.

12. 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 and subject to regulatory considerations. As of December 31, 2000, 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 2000.

13. EMPLOYEE BENEFIT PLAN

Full-time 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 can make annual discretionary contributions. For the years ended December 31, 2000, 1999, and 1998 the Company made matching contributions of $184,049, $160,142, and $130,644, respectively.

14. LICENSING AND DISTRIBUTION AGREEMENTS

On November 10, 2000 the Company entered into an agreement with Zimmer, Inc. to terminate the Zimmer Distribution Agreement for ORTHOVISC(R). Under the terms of the termination agreement, Zimmer had rights to distribute ORTHOVISC(R) through the end of the year in the countries where it was previously sold. As a result of the termination of the Zimmer Distribution Agreement, Anika recognized $4,249,000 of revenue in the fourth quarter of 2000 for amounts previously received from Zimmer which included a one-time payment under the termination agreement. The termination eliminated all obligations under the distribution agreement with respect to milestone payments, minimum purchases, unit pricing adjustments based on market prices and provided for the disposal of all units previously purchased by Zimmer by January 31, 2001, including units held in Anika's refrigerators at Zimmer's request. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - DEPENDENCE ON MARKETING PARTNERS" AND "--RELIANCE ON A SMALL NUMBER OF CUSTOMERS."

14. LICENSING AND DISTRIBUTION AGREEMENTS (CONTINUED)

In July 2000, the Company entered into a new seven-year supply agreement (the "BLS Agreement") with Bausch & Lomb Surgical, a unit of Bausch & Lomb. Under the terms of the BLS Agreement, effective January 1, 2001, the Company became Bausch & Lomb's exclusive provider of AMVISC(R) and AMVISC(R) Plus, ophthalmic viscoelastic products, in the U.S. and international markets. The BLS Agreement expires December 31, 2007, superceding an existing supply contract with Bausch & Lomb Surgical that was set to expire December 31, 2001. The BLS Agreement is subject to early termination and/or reversion to a non-exclusive basis under certain circumstances. The BLS Agreement lifts 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 effective to April 1, 2000, and the elimination of minimum unit purchase obligations by BLS.

15. 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, 2000, the Company has net operating loss carry-forwards for federal and state tax purposes of approximately $4,629,000 and $1,403,000, respectively. These carry-forwards expire through 2020, 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 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 DECE
	2000
Deferred tax assets (liabilities):	
Depreciation	$196,036
Accrued expenses and other	119,354
Inventory reserves	173,757
Nonqualified stock option amortization	112,627
Deferred revenue	--
Net operating loss carry-forwards	1,938,569
Gross deferred tax assets	2,540,343
Less: valuation allowance	(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 placed a full valuation allowance against its net deferred tax asset.

15. INCOME TAXES (CONTINUED)

Income tax expense was $15,940, $31,412, and $127,557 for the years ended December 31, 2000, 1999, and 1998, respectively. The provision for income taxes differs from the amounts computed by applying the U.S. Federal income tax rate of thirty-four percent to pretax income as a result of the following:

	YEARS ENDED DECEMBER 31	
	2000	1999

Computed expected tax expense (benefit).....	$64,562	$(837,867)
State tax (benefit) expense (net of federal benefit)....	10,821	(147,859)
Nondeductible expenses.....	34,837	44,944
Unrealized gain on short-term investments.....	--	--
Other.....	(45,080)	30,133
Change in valuation allowance related to income tax benefit.....	(49,066)	942,061
Tax expense.....	$15,940	$31,412

16. 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. These matters, relating to the Company's historical accounting for sales of its product under a long-term supply and distribution agreement with Zimmer, Inc., 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. The Company has been cooperating fully. However, the Company is not in a position to predict the probable outcome of this matter or its potential impact on the Company's business or operations.

PUTATIVE CLASS ACTION COMPLAINTS. Three putative class action complaints have been filed against the Company, J. Melville Engle, 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 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. The Company is vigorously defending the lawsuit. The Company is not

able to predict the probable outcome of this matter or its potential impact on the Company's business or operations.

17. QUARTERLY FINANCIAL DATA (UNAUDITED)

YEAR 2000	QUARTER ENDED MARCH 31,	QUARTER ENDED JUNE 30,	QUAR SEPT
Total Revenue	$2,720,833	$3,768,765	$ 2
Cost of Product Revenue	1,232,968	2,422,617	2
Gross Profit (Loss)	1,487,865	1,346,148	
Net Income (Loss)	$ (564,087)	$ (218,489)	$(1
Per common share information:			
Basic Net income (loss) per share	$(0.06)	$ (0.02)	$
Basic common shares outstanding	9,804,284	9,918,842	9
Diluted Net income (loss) per share	$(0.06)	$(0.02)	
Diluted common shares outstanding	9,804,284	9,918,842	9

YEAR 1999	QUARTER ENDED MARCH 31, (AS RESTATED IN THIS FORM 10-K/A)	QUARTER ENDED JUNE 30,	QUAR SEPT
Total Revenue	$ 3,678,630	$3,533,346	$2,
Cost of Product Revenue	1,932,168	1,688,714	1,
Gross Profit	1,746,462	1,844,632	1,
Income (loss) before cumulative effect of change in accounting principle	574,804	397,888	
Cumulative effect of change in accounting principle	(3,625,000)	-	
Net Income (loss)	$(3,050,196)	$ 397,888	$
Per common share information:			
Basic:			
Income before cumulative effect of change in accounting principle	$0.06	$ 0.04	$
Cumulative effect of change in accounting principle	(0.38)	-	
Net income (loss)	$(0.32)	$0.04	
Basic common shares outstanding	9,514,381	9,558,024	9,
Diluted:			
Income before cumulative effect of change in accounting principle	$ 0.06	$ 0.04	$
Cumulative effect of change in accounting principle	(0.36)	-	
Net income (loss)	$(0.30)	$0.04	$
Diluted common shares outstanding	10,077,488	10,075,826	9,

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 6, 2001 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/A.

(1) Financial Statements

(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 financial statements or the notes thereto.

Arthur Andersen LLP's Reports 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/A 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.

(c) Exhibit Index

(3) Articles of Incorporation and Bylaws:

3.1 The Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.

3.2 Certificate of Vote of Directors Establishing a Series of Convertible Preferred Stock, incorporated herein by reference to Exhibits to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.

3.3 Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's quarterly report on Form 10-QSB for the period ended November 30, 1996, (File no. 000-21326), filed with the Securities and Exchange Commission on January 14, 1997.

3.4 Certificate of Vote of Directors Establishing a Series of a Class of Stock, incorporated herein by reference to Exhibit 3.1 of the Company's Current Report on Form 8-AB12 (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998.

3.5 Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to the Company's quarterly report on Form 10-QSB for the quarterly period ending June 30, 1998 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 1998.

3.6 The Amended and Restated Bylaws of the Company, incorporated herein by reference to Exhibit 3.4 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.

(4) Instruments Defining the Rights of Security Holders

4.1 Shareholder Rights Agreement dated as of April 6, 1998 between the Company and Firstar Trust Company, incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-A12B (File no. 001-14027), filed with the Securities and Exchange Commission on April 7, 1998.

(10) Material Contracts

10.1 Settlement Agreement dated January 11, 1991 among MedChem Products, Inc., Kabi Pharmacia AB, Pharmacia, Inc., Dr. Endre Balazs and IOLAB Corporation, incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.

10.2 Supply Agreement dated as of July 25, 2000 by and between the Company and Bausch & Lomb Surgical, Inc., incorporated herein by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2000. Confidential treatment was granted to certain portions of this Exhibit.

10.3 Sponsored Research Agreement dated as of June 18, 1992 between Tufts University and the Company, incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.

10.4 TMJ Agreement dated as of April 29, 1993 between the Company and MedChem, incorporated herein by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.5 1993 Stock Option Plan, as amended, incorporated herein by reference to Annex A of the Company's Proxy Statement (File no. 001-14027), filed with the Securities and Exchange Commission on April 28, 2000.

10.6 1993 Directors Stock Option Plan, incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form 10/A (File no. 000-21326), filed with the Securities and Exchange Commission on April 28, 1993.

10.7 License Agreement dated as of July 22, 1992 between the Company and Tufts University, incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form 10 (File no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.

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

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

10.10 Extension of Lease dated November 23, 1999 between the Company and Cummings Properties, incorporated herein by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.11 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 and Exchange Commission on April 2, 2001.

10.12 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 and Exchange Commission on April 2, 2001.

10.13 Termination Agreement and Mutual Release dated as of November 10, 2000 by and between the Company and Zimmer, Inc., incorporated herein by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarterly period ended September 30, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on November 14, 2000. Confidential treatment was granted to certain portions of this Exhibit.

10.14 Letter Agreement dated September 24, 1996 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-KSB for the fiscal year ended August 31, 1996 (File no. 000-21326), filed with the Securities and Exchange Commission on November 27, 1996.

10.15 Non-Disclosure Agreement and Non-Competition Agreement dated August 28, 1997 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.16 Change of Control Agreement dated as of June 3, 1999 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.13 to the Company's Annual Report filed on Form 10-K for the fiscal year ended December 31, 1999 (File no. 001-14027), filed with the Securities and Exchange Commission on March 30, 2000.

10.17 Promissory Note for $75,000 dated as of March 17, 1996 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.

10.18 Promissory Note for $59,000 dated as of July 10, 1998 between the Company and J. Melville Engle, incorporated herein by

reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.19 Promissory Note for $41,000 dated as of December 17, 1999 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.20 Letter Agreement dated February 13, 1998 between the Company and Michael R. Slater, 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, 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 Michael R. Slater, incorporated herein by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarterly period ended June 30, 2000 (File no. 001-14027) filed with the Securities and Exchange Commission on August 14, 2000.

10.22 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 and Exchange Commission on April 2, 2001.

10.23 Promissory Note for $29,000 dated September 29, 2000 between the Company and Michael R. Slater, incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.24 Letter Agreement dated April 15, 1998 between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.3 to the Company's quarterly report on Form 10-Q for the quarterly period ended June 30, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2000.

10.25 Change in Control, Bonus and Severance Agreement dated April 26, 1998 by and between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.4 to the Company's quarterly report on Form 10-Q for the quarterly period ended June 30, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on August 14, 2000.

10.26 Non-Disclosure and Non-Competition Agreement dated May 5, 1998 between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.27 Promissory Note for $59,000 dated May 26, 2000 between the Company and Charles H. Sherwood, incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

10.28 Letter Agreement dated March 30, 2000 by and between the Company and Douglas R. Potter, incorporated herein by reference to Exhibit 10.5 to Exhibit 10.4 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.

10.29 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 Exhibit 10.4 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.

10.30 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.

10.31 Non-Disclosure and Non-Competition Agreement dated December 2, 1996 between the Company and Edward Ross, J., incorporated herein by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

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(11) Statement Regarding the Computation of Per Share Earnings

11.1 Statement Regarding the Computation of Per Share Earnings, incorporated herein by reference to Exhibit 11.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

(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, 2000 (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.

* 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 September 5, 2001.

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
/s/ DOUGLAS R. POTTER Douglas R. Potter	Chief Executive Officer and Chief Financial Officer PRINCIPAL FINANCIAL OFFICER	September 5

EXHIBIT INDEX

3 Articles of Incorporation and Bylaws:

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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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10.18 Promissory Note for $59,000 dated as of July 10, 1998 between the Company and J. Melville Engle, incorporated herein by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (File no. 001-14027), filed with the Securities and Exchange Commission on April 2, 2001.

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10.21 Change in Control, Bonus and Severance Agreement dated April 26, 2000 by and between the Company and Michael R. Slater, incorporated herein by reference to Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarterly period ended June 30, 2000 (File no. 001-14027) filed with the

Securities and Exchange Commission on August 14, 2000.

10.22 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 and Exchange Commission on April 2, 2001.

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10.30	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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(23)	Consent of Experts
*23.1	Consent of ARTHUR ANDERSEN LLP.

* Filed herewith.