# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

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### FORM 10-K

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

FOR FISCAL YEAR ENDED DECEMBER 31, 1999

|\_| TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM \_\_\_\_ TO \_\_\_

COMMISSION FILE NUMBER 000-21326

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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 or any amendment to this Form 10-K. |

The aggregate market value of voting stock held by non-affiliates of the Registrant as of March 20, 2000 was \$83,556,297 based on the last sale price of Common Stock of \$8.53 as reported by the NASDAQ National Market. At March 20, 2000 there were issued and outstanding 9,795,580 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 to be held on June 7, 2000. Such Proxy Statement shall not be deemed to be "filed" as part of this Annual Report on Form 10-K except for the parts therein which have been specifically incorporated by reference herein.

# FORM 10-K ANIKA THERAPEUTICS, INC. FOR FISCAL YEAR ENDED DECEMBER 31, 1999

THIS FORM 10-K CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933 AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934. THE WORDS "BELIEVE," "EXPECT," "ANTICIPATE," "INTEND," "ESTIMATE" 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, POSSIBLE REGULATORY APPROVAL OF ORTHOVISC-REGISTERED TRADEMARK- AND NEW OR POTENTIAL PRODUCTS, CAPACITY OF MANUFACTURING FACILITIES AND PERFORMANCE UNDER SUPPLY AGREEMENTS, INCLUDING THOSE WITH ZIMMER, INC. AND BAUSCH AND LOMB SURGICAL. 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 IF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" BEGINNING ON PAGE 12 OF THIS FORM 10-K AND ELSEWHERE IN THIS ANNUAL REPORT ON FORM 10-K. THE COMPANY UNDERTAKES NO OBLIGATION TO PUBLICLY UPDATE OR REVISE ANY FORWARD-LOOKING STATEMENT WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR OTHERWISE.

#### PART T

### 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-Registered Trademark-, which is an HA product used in the treatment of some forms of osteoarthritis IN humans and HYVISC-Registered Trademark-, which is an HA product used in the treatment of equine osteoarthritis. ORTHOVISC-Registered Trademark- is currently approved for sale and marketed in CANada, Europe, Turkey, Israel and Iceland. In the U.S. ORTHOVISC-Registered Trademark- is currently limited to investigational use only and the Company commenced a Phase III clinical trIAL in the U.S. and Canada in late April 1999 and the final patient completed the six month follow-up period in late February 2000. The Company manufactures AMVISC-Registered Trademark-1 and AMVISC-Registered Trademark-Plus, which are HA products used as viscoelastic supplements in ophthalmic surgery, for Bausch & Lomb Surgical, a subsidiary of Bausch & Lomb. THE Company is currently developing INCERT-Registered Trademark-, 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-Registered Trademark-2, an injectable formulation of basic fibroblast growth factor combined with HA designed TO accelerate the healing of bone fractures.

### AMVISC PRODUCTS

AMVISC-Registered Trademark- and AMVISC-Registered Trademark-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-Registered Trademark- product line for Bausch & Lomb Surgical, a unit of Bausch & Lomb Incorporated, under and exclusive five-year supPLY agreement that has fixed selling prices and stated minimum annual purchase obligations through December 31, 2001 (the "AMVISC"

Supply Contract"). In addition, 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-Registered Trademark- products, effective on December 31, 2001, the termination date of the AMVISC Supply Contract. There can be no assurances that Bausch & Lomb Surgical wILL not seek renegotiation of the terms of the

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- 1 AMVISC-Registered Trademark- is a registered trademark of Bausch & Lomb Incorporated; the parent of Bausch & Lomb Surgical
- 2 OSSIGEL-Registered Trademark- is a registered trademark of Orquest, Inc.

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AMVISC Supply Contract before the expiration of the agreement on terms less favorable to the Company. Upon expiration of the AMVISC Supply Contract, there can be no assurance that Bausch & Lomb Surgical will continue to use the Company to manufacture AMVISC-Registered Trademark- and AMVISC-Registered Trademark-PLUS. If either of those events were to occur, the Company's business, financial condition and results of operations could be materially and adversely affected. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - DEPENDENCE ON MARKETING PARTNERS" AND "--RELIANCE ON A SMALL NUMBER OF CUSTOMERS."

### ORTHOVISC

ORTHOVISC-Registered Trademark- 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-Registered Trademark- 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-Registered Trademark- is approved for sale and marketed in Canada, Turkey, Israel and Iceland. In Europe ORTHOVISC-Registered Trademark- is sold under Communautee European ("CE MArk") authorization. The CE mark, a certification required under European Union ("EU") medical device regulation, allows ORTHOVISC-Registered Trademark- 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-Registered Trademark- is limited to investigational use only. In October 1998 the Company was notified by the U.S. Food and Drug Administration (THE "FDA") that its Pre-Market Approval Application ("PMA") was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC-Registered Trademark-. 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 trials has not yet been completed and the data has not yet been validated. Furthermore, there can be no assurances that the results of this second Phase III clinical study will be adequate to demonstrate the effectiveness of

ORTHOVISC-Registered Trademark- to obtain FDA approval.

The Company has licensed ORTHOVISC-Registered Trademark- marketing and distribution rights to Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company for the territorIES of United States, Canada, Latin America, most of Europe and Asia. ORTHOVISC-Registered Trademark- is also licensed to Grupo Ferrer, Inc. for Spain and Portugal, to BiomEKS Pharmaceuticals in Turkey and to Rafa Laboratories in Israel. See "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OVERVIEW."

#### HYVISC

HYVISC-Registered Trademark- 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-Registered Trademark-has viscoelastic properties that lubricate and protect the tissues in horse joints. HYVISC-Registered Trademark- is distributed by Boehringer InGELheim Vetmedica, Inc. in the United States under an agreement terminating in 2002.

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### 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-Registered Trademark— 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.

INCERT-Registered Trademark- is placed in a wound site and intended to serve as a barrier between adjacent tissues. Anika co-owns an issued United States patent covering THE use of INCERT-Registered Trademark- for adhesion prevention. The Company has received notification from the U.S. Patent and Trademark Office ("PTO") that a third party is attemptING to provoke interference with respect to the Company's patent covering INCERT-Registered Trademark-. The Company has tested INCERT-Registered Trademark- in pre-clinical animal studies. Anika cuRREntly plans to commence human testing of INCERT-Registered Trademark- during 2000. However, the Company has not yet obtained FDA approval to commence human testing and there can be NO assurances that it will obtain such approval on a timely basis.

### OSSIGEL

In June of 1997, the Company executed a multi-year collaboration agreement with Orquest to develop and manufacture OSSIGEL-Registered Trademark-, a formulation of baSIC fibroblast growth factor and HA designed to accelerate the healing of bone fractures. Orquest is a privately held orthobiologics company headquartered in Mountain View, California, and was founded in 1994 to develop products for bone and cartilage regeneration. OSSIGEL-Registered Trademark- has been shown in pre-clinical animal models TO accelerate the healing of bone fractures. Orquest commenced human clinical testing of OSSIGEL-Registered Trademark- in Europe during 1998. Orquest has filed a patent application wITH the U.S. Patent and Trademark Office for the use of OSSIGEL-Registered Trademark- in accelerating fracture healing.

### HA FOR NERVE REGENERATION

The Company is conducting collaborative research with the Lahey Clinic to study the effect of HA on nerve regeneration. A pre-clinical animal model

demonstrated that the Company's highly purified HA formulation enhanced peripheral nerve regeneration. The Company is also collaborating with the Lahey Clinic to study the use of HA in a spinal cord regeneration pre-clinical model.

### 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 yields high molecular weight, highly purified HA.

A substantial supply of rooster combs is available and the Company believes 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 generally keeps sufficient syringes in its inventory to meet anticipated demand for at least six months. The Company believes that its facility in Woburn, Massachusetts has the manufacturing capacity to accommodate anticipated demand through at least 2003.

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### 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 application which has been granted a notice of allowance by the U.S. Patent Office 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. To date, the Company has not 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 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 has received notice from the PTO that a third party is attempting to provoke a patent interference with respect to one of the Company's co-owned patents covering the use of INCERT-Registered Trademark- FOR post-surgical adhesion prevention. Although the Company believes that an interference may be declared by the PTO, it is too early to determine the merits of the interference or the effect, if any, the interference will have on the Company's sales, use and marketing of INCERT-Registered Trademark- for this use. The existence of THE interference proceeding may have a negative impact on the marketing of the INCERT-Registered Trademark- 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-Registered Trademark- 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-Registered Trademark- products, which could have a material adverse effect on the Company's future operatING results.

In addition, the Company has not obtained FDA approval for its INCERT-Registered Trademark- product and there can be no assurances such approval will be obtaIned.

The Company also relies upon trade secrets and proprietary know-how for certain unpatented 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-Registered Trademark- products, effective on December 31, 2001, the termination date of the AMVISC Supply Contract. There can be no assurances that Bausch & LOMB Surgical will not seek renegotiation of the terms of the AMVISC Supply Contract before the expiration of the agreement on terms less favorable to the Company. Upon expiration of the AMVISC Supply Contract, there can be no assurance that Bausch & Lomb Surgical will continue to use the Company to manufacture AMVISC-Registered Trademark- AND AMVISC-Registered Trademark-Plus. If Bausch & Lomb Surgical discontinues the use of the Company as a manufacturer after such time, or seeks renegotiation of its existing contract, THE Company's business, financial condition and results of operations could be materially and adversely affected.

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### 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, manufacture, labeling, storage, record keeping, approval, 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 upon a determination that the subjects or patients are being exposed to an unacceptable adverse health risk ascribable to Anika's products. 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 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 regulations, 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. Manufacturing establishments also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies.

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 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-Registered Trademark- is approved as a Class III device IN the United States for ophthalmic surgical procedures in intraocular use in humans. HYVISC-Registered Trademark- 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 have been regulated as medical devices. Anika believes that if FDA approval is obtained, its ORTHOVISC-Registered Trademark- for osteoarthritis and INCERT-Registered Trademark- 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. Medical devices are classified as Class I, II, or III devices. In general, Class I devices require compliance with labeling and record keeping regulations and are subject to other general controls. Class II devices may be subject to special controls, such as market surveillance and are subject to general controls. Class II devices also may be subject to clinical testing for purposes of premarket notification to the FDA. Class III devices require clinical testing to assure safety and effectiveness prior to marketing and distribution.

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At least 90 days prior to marketing, 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," the device manufacturer must file a PMA application with the FDA based on 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 issuance of a PMA from the FDA prior to commercial sale.

The PMA process requires the performance of human clinical studies under an IDE. Upon completion of required clinical studies, 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 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 physicians and others with expertise in the relevant field. The FDA will also conduct an inspection to determine whether an applicant conforms with the FDA's current Quality Systems Regulations. 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 of 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.

### DRUGS

Medical devices may meet both the definition of a medical device and a drug. 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 safety and tolerance in a small group of healthy volunteers.
- Phase II involves testing for efficacy and identifying possible side effects in a target patient group.
- Phase III involves additional testing for efficacy, optimal dosage 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 PLA. 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.

### 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

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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 Genzyme Corp. (which announced March 6, 2000 that it will be acquiring Biomatrix, Inc.), Biomatrix, Inc., Hyal Pharmaceutical Corp., Fidia S.P.A., LifeCore Biomedical, Inc. and Seikagaku, 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). In the U.S., two HA products for the treatment of osteoarthritis in the knee, Hyalgan and Synvisc, have received FDA approval and have been marketed in the

U.S. since the fourth quarter of 1997. Hyalgan is manufactured by Fidia S.P.A. and is distributed in the United States by Sanofi Pharmaceuticals and OrthoLogic Corp. In addition, Fidia S.P.A. is selling the product throughout Europe. Synvisc is manufactured by Biomatrix Inc. 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. Artz is manufactured by Seikagaku Corporation and is distributed in Japan, Spain, Sweden 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 Seikagako Corporation for distribution in the U.S. 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, 1999, 1998 and 1997, research and development expenses were \$4.2 million, \$2.0 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, 1999 the Company had twelve employees engaged primarily in research and development.

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.

### EMPLOYEES

As of December 31, 1999, the Company had approximately 73 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.

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# 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 \$1,000,000 per occurrence and \$5,000,000 in aggregate, there can be no assurance 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 11,000 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, 1999 the Company had aggregate lease costs of approximately \$489,000. Anika believes that its existing facilities are adequate to meet its requirements through 2003.

### ITEM 3. LEGAL PROCEEDINGS

The Company has no material pending litigation.

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

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

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#### PART II

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

### COMMON STOCK INFORMATION

The Company's common stock par value \$0.01 per share (the "Common Stock") has traded on the Nasdaq National Market since November 25, 1997 under the symbol "ANIK". The following table sets forth, for the periods indicated, the high and low sale 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.

|                                     | PRICE RANGE |        |
|-------------------------------------|-------------|--------|
| FISCAL YEAR ENDED DECEMBER 31, 1998 | HIGH        | LOW    |
|                                     |             |        |
| First Ouarter                       | \$10 13     | \$7.25 |
| Second Quarter                      |             | 9.56   |
| Third Quarter                       | . 18.19     | 13.00  |
| Fourth Quarter                      | . 12.38     | 3.94   |

|                                     | PRICE RANGE |        |
|-------------------------------------|-------------|--------|
| FISCAL YEAR ENDED DECEMBER 31, 1999 | HIGH        | LOW    |
|                                     |             |        |
| First Quarter                       | . \$5.50    | \$4.50 |
| Second Quarter                      | 9.00        | 4.69   |
| Third Quarter                       | . 8.75      | 5.00   |
| Fourth Quarter                      | 7.69        | 5.50   |

At December 31, 1999, there were 319 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.

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ITEM 6. SELECTED FINANCIAL DATA

# STATEMENTS OF OPERATIONS DATA: (IN THOUSANDS, EXCEPT PER SHARE DATA)

|   |   | ÆARS ENDED<br>DECEMBER 31,       |                                      | FOUR-MONTH<br>TRANSITIONAL<br>PERIOD ENDED<br>DECEMBER 31, |                                  | D AUGUST 31,          |
|---|---|----------------------------------|--------------------------------------|--|----------------------------------|-----------------------|
|   |   | 1998                             | 1997                                 | 1996   |                                  | 1995                  |
|   |   | (AS RESTATED)                    |                                      |  |                                  |                       |
| Total revenue  Cost of sales  Gross profit (loss)  Total operating expenses  Income (loss) before cumulative effect of change in accounting principle  Cumulative effect of change in accounting principle  Net income (loss) | 6,440<br>7,042<br>7,184<br>1,129<br>(3,625) | 6,014<br>7,259<br>4,687<br>3,752 | 4,744<br>7,211<br>4,050<br>3,344<br> | \$ (2,658)   | 4,472<br>141<br>3,104<br>(2,849) | 3,118<br>238<br>2,222 |
| Diluted income (loss) per common share: Income (loss) before cumulative effect of change in accounting principle Cumulative effect of change in accounting principle  Net income (loss)                                       |   | <br>\$ 0.34                      | \$ 0.44                              | <br>\$ (0.56)  | <br>\$ (0.76)                    | \$ (0.63)             |
| Diluted common shares outstanding   | 10,221                                      | 11,006                           | 7,587                                |  | 4,053                            | 3,225                 |

## BALANCE SHEET DATA:

|  |           | DECEMB       | ER 31,    |          | AUGU     | ST 31,   |
|--|-----------|--------------|-----------|----------|----------|----------|
|  | 1999      | 1998         | 1997      | 1996     | 1996     | 1995     |
|  |           | AS RESTATED) |           |          |          |          |
| Cash and cash equivalents              | \$ 6,441  | \$ 10,713    | \$ 22,680 | \$ 2,705 | \$ 3,651 | \$ 2,825 |
| Investments                            | 13,743    | 12,008       |           |          |          |          |
| Working capital                        | 18,973    | 26,480       | 25,329    | 4,226    | 5,858    | 4,972    |
| Total assets                           | 32,511    | 32,393       | 28,749    | 6,920    | 8,580    | 8,046    |
| Redeemable convertible preferred stock |           |              |           | 2,603    | 2,523    | 2,326    |
| Accumulated deficit                    | (4,773)   | (2,277)      | (6,029)   | (9,374)  | (6,716)  | (3,867)  |
| Treasury stock                         | (960)     | (1,890)      |           |          |          |          |
| Stockholder's equity                   | \$ 25,712 | \$ 29,298    | \$ 26,224 | \$ 2,369 | \$ 4,415 | \$ 3,544 |

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THE FOLLOWING DISCUSSION SHOULD BE READ IN CONJUNCTION WITH THE CONSOLIDATED FINANCIAL STATEMENTS OF ANIKA THERAPEUTICS, INC. AND THE NOTES THERETO APPEARING ELSEWHERE HEREIN.

#### OVERVIEW

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-Registered Trademark-, which is an HA product used in the treatment of some forms of osteoarthritis in humans and HYVISC-Registered Trademark-, which is an HA product USEd in the treatment of equine osteoarthritis. ORTHOVISC-Registered Trademark- is currently approved for sale and marketed in Canada, Europe, Turkey, Israel and Iceland. In the U.S., ORTHOVISC-Registered Trademark- is currently limited to investigational use only, and the Company commenced a Phase III clinical trial in the U.S. and Canada in April 1999 and THE final patient completed the six month follow-up period in late February 2000. The Company manufactures AMVISC-Registered Trademark- and AMVISC-Registered Trademark-Plus, which are HA products USEd as viscoelastic supplements in ophthalmic surgery, for Bausch & Lomb Surgical. The Company is currently developing INCERT-Registered Trademark-, 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-Registered Trademark-; an injectaBLE formulation of basic fibroblast growth factor combined with  ${\tt HA}$ designed to accelerate the healing of bone fractures.

The Company receives a substantial portion of its revenue from the sale of AMVISC-Registered Trademark- and AMVISC-Registered Trademark-Plus to Bausch & Lomb Surgical. For the yearS Ended December 31, 1999 and 1998, AMVISC-Registered Trademark- sales accounted for 63.9% and 68.7% of product revenue, respectively.

The Company manufactures AMVISC-Registered Trademark- for Bausch & Lomb Surgical under a five-year supply contract that became effective on January 1, 1997 and expires ON December 31, 2001. Bausch & Lomb Surgical assumed the AMVISC Supply Contract when it purchased Chiron Vision in January 1998. The current AMVISC Supply Contract has stated minimums with substantially higher unit selling prices than a previous six-year supply contract with Chiron Vision which expired on December 31, 1996. Under the previous supply contract, the Company was obligated to supply AMVISC-Registered Trademark- at unit selling prices that approximated the Company's unit manufacturing coST. (See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS--DEPENDENCE UPON MARKETING PARTNERS" beginning on page 21.)

In November 1997, the Company entered into a long-term distribution agreement with Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company, that was subsequently amended in June 1998 and June 1999, (the "Zimmer Distribution Contract"). The Zimmer Distribution Contract provides Zimmer with exclusive marketing and distribution rights to ORTHOVISC-Registered Trademark- in the United States, Canada, Latin America, Asia and most of Europe. To date the Company has received up-frONT non-refundable licensing payments totaling \$4.0 million. In addition, under the Zimmer Distribution Contract, the Company has the potential to receive additional payments aggregating up to \$19.5 million upon the achievement of certain regulatory approvals, reimbursement approvals and enumerated sales milestones. As an alternative to a \$2.5 million milestone payment due upon FDA approval for the U.S. Market, Zimmer has the right to elect to acquire shares of the Company's common stock equal to the greater of: (a) \$2,500,000 divided by 125% of the average daily closing price of the Common Stock for the prior sixty (60) calendar days or (b) 9.9% of the then outstanding common stock (but not to exceed 19.9% of the then outstanding common stock). There can be no assurance that any of such milestones will be met on a timely basis or at all. In addition, Zimmer has the right to terminate the Zimmer Distribution Contract within sixty (60) days of the occurrence of any of the following events: (i) ORTHOVISC-Registered Trademark- is not approved by the FDA by January 1, 2001, (ii) there is a material recall of ORTHOVISC-Registered Trademark-, (iii) ZimmeR'S net sales of ORTHOVISC-Registered Trademark- failed to meet the minimums specified in the Zimmer Distribution Contract for two

consecutive years beginning with the calendar year of 1998 or (iv) a court of competent jurisdiction rules that ORTHOVISC-Registered Trademark- or any of its related patents is infringing the patents or proprietary rights of a third parTY. For the years ended December 31, 1999 and 1998, ORTHOVISC-Registered Trademark- sales to Zimmer accounted for 2.8% and 10.3%, respectively, of product revenue.

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As a result of an informal inquiry from the Securities and Exchange Commission, the Company and its independent auditors conducted a review of its revenue recognition policy for revenue received from the Zimmer Distribution Contract. As a result of this review, and after consultation with the SEC, Anika revised its revenue recognition policy for ORTHOVISC-Registered Trademark- sales to Zimmer and restated its operating results for 1998 and the first three quarters of 1999. Under THE revised revenue recognition policy, revenue will be recognized at the time of shipment to Zimmer based upon the minimum per unit price under the Zimmer Distribution Contract at the time of sale to Zimmer. Anika had previously recognized revenue for ORTHOVISC-Registered Trademarksales to Zimmer based upon an estimate of the averAGE selling price which would be obtained by Zimmer upon sale of the ORTHOVISC-Registered Trademark- to its customers, as specified under the Zimmer Distribution Contract. Any additioNAL amounts earned by Anika above the contractual minimum per unit price will be recognized when Zimmer sells the ORTHOVISC-Registered Trademark- to its customers and Anika is able TO determine its share of the actual per unit sales price. Anika had also recognized revenue in 1998 and the first three quarters of 1999 for ORTHOVISC-Registered Trademark- which WAS held in its refrigerators at Zimmer's request. Under the Company's revised revenue recognition policy, this revenue will be recorded when the ORTHOVISC-Registered Trademark- IS shipped to Zimmer. Amounts paid by Zimmer in excess of the amount recognized under the revised revenue recognition policy is recorded by Anika as deferred revenue and amounted to \$1,420,000 at December 31, 1999. (See Note 2 of Financial Statements.)

The Company also adopted the provisions of SEC Staff Accounting Bulletin 101 (SAB 101) in its restated 1999 operating results. The issuance of SAB 101 in December 1999 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, respectively, received from Zimmer in the fourth quarter of 1997 and the second quarter of 1998. These amounts were previously recognized in the period received. In accordance with SAB 101, the company has retroactively recorded the cumulative effect of the change in accounting principle of \$3,625,000 as a charge in the first quarter of 1999. These payments will be recognized as revenue ratably over the 10-year term of the distribution agreement including \$400,000 recognized in 1999. The amount received and deferred to future periods is \$3,225,000 at December 31, 1999 and is included in deferred revenue.

# RESULTS OF OPERATIONS

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

### STATEMENT OF OPERATIONS DETAIL

|                 | YEARS ENDED             | DECEMBER 31,               |
|-----------------|-------------------------|----------------------------|
|                 | 1999                    | 1998                       |
|                 |                         | (AS RESTATED)              |
| Product revenue |                         | \$ 11,773,343<br>1,500,000 |
| Total revenue   | 13,482,662<br>6,440,166 | 13,273,343<br>6,014,181    |

| Gross profit Operating expenses:                    | 7,042,496      | 7,259,162 |
|---|----------------|-----------|
| 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                       | (141,377)      | 2,572,080 |
| Interest income, net                                | 1,068,430      | 1,307,825 |
| Gain on sale of securities                          | 233,633        |           |
| 0411 011 0410 01 0004110100 11111111111             |                |           |
| Income before income taxes                          | 1,160,686      | 3,879,905 |
| Income taxes  | 31,412         | 127,557   |
|   |                |           |
| Income before cumulative effect of change in        |                |           |
| accounting principle                                | 1,129,274      | 3,752,348 |
| Cumulative effect of change in accounting principle | (3,625,000)    |           |
|   |                |           |
| Net income (loss)                                   | \$ (2,495,726) |           |
|   |                |           |
|   |                |           |

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PRODUCT REVENUE. Product revenue for the year ended December 31, 1999 was \$13,082,662 an increase of \$1,309,319 or 11.1%, over the \$11,773,343 recorded in the prior year. The increase was primarily attributable to an increase of \$805,352 or 22.0% in sales of ORTHOVISC-Registered Trademark-. At Zimmer's request, the Company has been holding an inventory of ORTHOVISC-Registered Trademark- in its refrigerators for purchase orders placed by Zimmer in 1999 for Zimmer's anticipated future sales. The Company will record revenue for this Orthovisc when shipped to Zimmer. There can be no assurance that Zimmer will place additional orders in the year 2000. Under the Zimmer Distribution Contract, Zimmer or the Company has the right to terminate the contract if Zimmer's sales of ORTHOVISC-Registered Trademarkfail to meet specified minimums for 1998 and 1999. Zimmer was below the minimum for 1998 and the Company expects Zimmer'S sales to be below the minimum for 1999. There can be no assurance that Zimmer will not terminate the contract. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS--RELIANCE ON A SMALL NUMBER OF CUSTOMERS." Sales of AMVISC-Registered Trademark- products also increased by \$294,606 or 3.7%.

LICENSING FEES. For the year ended December 31, 1999, licensing fees of \$400,000 represent 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-Registered Trademark- 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 \$7,042,496, a decrease of \$216,666 or 3.0% from \$7,259,162 recorded in the prior year. The decrease was primarily due to the decrease in licensing fees. Gross profit from product revenues increased as a percentage of product revenue to 50.8% for the year ended December 31, 1999 as compared to 48.9% 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 costs 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-Registered Trademark- Phase III trials. The Company expeCTS to incur approximately \$700,000 over the next three quarters to complete the trial.

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-Registered Trademark- 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 carryforwards to offset taxable income earned during these years. The Company has no net operating loss carryforwards available for federal income tax purposes after 1999. For state income taxes, the Company has net operating loss carryforwards of \$1,403,000 which may be used to offset future state income taxes, if any.

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YEAR ENDED DECEMBER 31, 1998 (AS RESTATED) COMPARED TO YEAR ENDED DECEMBER 31, 1997

### STATEMENT OF OPERATIONS DETAIL

|  | YEARS ENDED               | DECEMBER 31,              |
|--|---------------------------|---------------------------|
|  | 1998                      | 1997                      |
|  | (AS RESTATED)             |                           |
| Product revenue  | \$11,773,343<br>1,500,000 | \$ 9,255,338<br>2,700,000 |
| Total revenue  | 13,273,343<br>6,014,181   | 11,955,338<br>4,744,123   |
| Gross profit   | 7,259,162                 | 7,211,215                 |
| Research and development Selling, general and administrative | 1,955,940<br>2,731,142    | 1,957,796<br>2,092,467    |
| Total operating expenses                                     | 4,687,082                 | 4,050,263                 |
| Income from operations Interest income, net                  | 2,572,080<br>1,307,825    | 3,160,952<br>262,162      |
| Income before income taxes Income taxes                      | 3,879,905<br>127,557      | 3,423,114<br>78,677       |
| Net income   | \$ 3,752,348              | \$ 3,344,437              |
|  |                           |                           |

PRODUCT REVENUE. Product revenue for the year ended December 31, 1998 was \$11,773,343 an increase of \$2,518,005, or 27.2%, over the \$9,255,338 recorded in the prior year. The increase was primarily attributable to an increase of \$2,322,317 or 172.8% in sales of ORTHOVISC-Registered Trademark-. Sales of AMVISC-Registered Trademark- products also increased by \$280,662 or 3.6%.

LICENSING FEES. Licensing fees of \$1,500,000 and \$2,700,000 were received for the years ended December 31, 1998 and 1997, respectively. During 1998, the Company received a non-refundable \$1.5 million licensing payment from Zimmer for the expansion of territories under the Zimmer Distribution Agreement. During 1997, the Company received a non-refundable \$2.5 million licensing payment from Zimmer for ORTHOVISC-Registered Trademark- distribution rights and \$200,000 from Orquest for THE development of OSSIGEL-Registered Trademark-. The payments under the Zimmer Distribution Agreement underly the 1999 charge against earnings under the caption "Cumulative effect OF change in accounting principle."

GROSS PROFIT. Gross profit for the year ended December 31, 1998 was \$7,259,162 an increase of \$47,947 or .7% over the \$7,211,215 recorded in the prior year. The increase was primarily due to the increase in product revenue and the gross profit percentage on product revenue partially offset by a decrease in licensing fee. Gross profit from product revenues increased as a percentage of product revenue to 48.9% for the year ended December 31, 1998 as compared to 48.7% in the prior year.

RESEARCH AND DEVELOPMENT. Research and development expenses for the year ended December 31, 1998 decreased by \$1,856 to \$1,955,940 from \$1,957,796 recorded in the prior year. An increase in research and development staffing during 1998 was offset by a reduction in ORTHOVISC-Registered Trademark-regulatory and clinical cosTS. The Company expects that research and development expenses will increase substantially during 1999 due to ORTHOVISC-Registered Trademark- clinical trial costs.

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the year ended December 31, 1998, increased by \$638,675, or 30.5%, to \$2,731,142 from \$2,092,467 in the prior year. The increase was primarily attributable to increases in consulting, recruiting, selling and marketing costs and the amortization of unearned stock compensation.

NET INTEREST INCOME. The Company's net interest income increased by \$1,045,663 to \$1,307,825 for the year ended December 31, 1998 from \$262,162 in the prior year. The increase is attributable to an increase in average cash available for investment during the 1998 as compared to 1997, as a result the Company's December 1997 stock offering.

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INCOME TAXES. The Company recorded an effective tax rate of 3.2% for 1998 versus 2.3% for the prior year. The Company utilized net operating loss carryforwards to offset taxable income generated during these years.

YEAR ENDED DECEMBER 31, 1997 COMPARED TO YEAR ENDED DECEMBER 31, 1996

### STATEMENT OF OPERATIONS DETAIL

|  | YEARS ENDED               | DECEMBER 31,           |
|--|---------------------------|------------------------|
|  | 1997                      | 1996                   |
|  |                           | (UNAUDITED)            |
| Product revenue  | \$ 9,255,338<br>2,700,000 | \$ 4,633,743           |
| Net revenue Cost of product revenue  | 11,955,338<br>4,744,123   | 4,633,743<br>4,517,591 |
| Gross profit   | 7,211,215                 | 116,152                |
| Operating expenses: Research and development Selling, general and administrative | 1,957,796<br>2,092,467    | 2,488,657<br>2,393,623 |

| Total operating expenses                                    | 4,050,263              | 4,882,280                |
|---|------------------------|--------------------------|
| Income (loss) from operations Interest income, net          | 3,160,952<br>(262,162) | (4,766,128)<br>(166,908) |
| <pre>Income (loss) before income taxes . Income taxes</pre> | 3,423,114<br>78,677    | (4,599,220)              |
| Net income (loss)   | \$ 3,344,437           | \$ (4,599,220)           |
|   |                        |                          |

PRODUCT REVENUE. Product revenue for the year ended December 31, 1997 was \$9,255,338 an increase of \$4,621,595 or 99.7% over the \$4,633,743 in the prior year. The increase was primarily attributable to increased AMVISC-Registered Trademark- sales. Sales of AMVISC-Registered Trademark- as measured in units increased by 6.5% while the average selling Price of AMVISC-Registered Trademark- increased by 70% under the new AMVISC Supply Contract. Future increased selling prices under the AMVISC Supply Contract will be limited to annUAL adjustment based on the producer price index.

LICENSING FEES. Licensing fees of \$2,700,000 were received for the year ended December 31, 1997. The Company received a \$2.5 million licensing payment from Zimmer for ORTHOVISC-Registered Trademark- distribution rights and \$200,000 from Orquest for the development of OSSIGEL-Registered Trademark-.

GROSS PROFIT. The Company's gross profit for the year ended December 31, 1997 was \$7,211,215 an increase of \$7,095,063 over the \$116,152 recorded in the prior year. The increase was primarily due to the 70% increase in the average unit selling price of AMVISC-Registered Trademark- under the new AMVISC Supply Contract, increased saLES volume of ORTHOVISC-Registered Trademark- and the \$2,700,000 licensing fee received in 1997. Gross profit from product revenues increased as a percentage of product revenues to 48.7% for the year ended December 31, 1997 as compared to 2.5% in the prior year due primarily to the increase in average unit selling price of AMVISC-Registered Trademark-.

RESEARCH AND DEVELOPMENT. Research and development expenses for the year ended December 31, 1997 decreased by \$530,861, or 21.3% to \$1,957,796 from \$2,488,657 recorded in the prior year. The decrease was primarily due to a reduction in expenses associated with the ORTHOVISC-Registered Trademark-clinical trial which was compleTED in June 1997.

SELLING, GENERAL AND ADMINISTRATIVE. Selling, general and administrative expenses for the year ended December 31, 1997, decreased by \$301,156, or 12.6%, to \$2,092,467 from \$2,393,623 in the prior year. Staffing levels were substantially the same for each of these years. The decrease is primarily attributable to severance payments to the Company's former president incurred in 1996 and a \$544,000 write-off of leasehold improvements and lease expenses resulting from the closing of one of the Company's facilities in 1996 which was partially offset by an increase in general expense levels in 1997.

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NET INTEREST INCOME. The Company's net interest income increased to \$262,162, or 56.9%, in the year ended December 31, 1997 from \$166,908 in the prior year. The increase is attributable to an increase in average cash available for investment in the year ended December 31, 1997 as compared to 1996.

TAX EXPENSE. The Company recorded tax expense for the year ended December 31, 1997 of approximately \$78,677, or 2.3% of pretax income. Net operating loss carryforwards were utilized to offset taxable income generated during the year. At December 31, 1997 the company has a remaining tax benefit of \$3,256,000\$ from net operating loss carryforwards to offset future tax expense.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 1999, the Company had cash, cash equivalents and short

and long-term investments of \$20.2 million and working capital of \$19.0 million versus cash, cash equivalents and short-term investments of \$22.7 million and working capital of \$26.5 million at December 31, 1998. During 1999, the Company made investments of \$5.6 million in long-term marketable securities, consisting of commercial paper. Also during 1999, the Company generated approximately \$813,000 of cash from operating activities, which consisted primarily of the net loss adjusted for depreciation and amortization and by changes in other working capital items. Cash flow from working capital items includes a positive \$3.8 million in 1999 for deferred revenue arising from the revenue restatements discussed above.

During 1999, the Company utilized \$1,740,000 for capital expenditures, primarily for the expansion of its manufacturing facility. The Company expects to continue to incur costs during 2000 to complete the expansion of its manufacturing facility to meet currently expected demand through the year 2003.

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. During the years ended December 31, 1999 and 1998 the Company received \$516,000 and \$1,071,000 respectively from the exercise of stock options and warrants.

In December 1997, the Company completed a secondary public offering of 2,725,000 shares of Common Stock that resulted in net proceeds to the Company of approximately \$17 million.

The Company believes that its cash on hand will be sufficient to meet its operating requirements until December 2001. Expenditures required to fund the ORTHOVISC-Registered Trademark- clinical trial will adversely impact the Company's financial results in 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, 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. Although the Company achieved profitability for the years ended December 31, 1998 and 1997 there can be no assurance that the Company will record profits in future periods. For 1999, 1998 and 1997, the Company's unit sales of AMVISC-Registered Trademark- substantially exceeded the minimum obligations under the AMVISC Supply Contract. For 2000, THE Company can provide no assurance that unit sales of AMVISC-Registered Trademark- for 2000 will exceed minimum annual purchase obligations. Furthermore, there can be no assurances thaT Bausch & Lomb Surgical will not seek to renegotiate its existing agreement on terms less favorable to the Company. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS - DEPENDENCE ON MARKETING PARTNERS" and "--RELIANCE ON A SMALL NUMBER OF CUSTOMERs."

In addition, at Zimmer's request, the Company has been holding an inventory of ORTHOVISC-Registered Trademark- in its refrigerators for purchase orders placed by Zimmer in 1999 for Zimmer's anticipated future sales. The Company will record revenue for this Orthovisc when shipped to Zimmer. There can be assurance that Zimmer will place additional orders in the year 2000. Under the Zimmer Distribution Contract, Zimmer or the Company has the right to terminate the contract if Zimmer's sales of ORTHOVISC-Registered Trademark- fail to meet specified

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minimums for 1998 and 1999. Zimmer was beLOw the minimum for 1998 and the Company expects Zimmer's sales to be below the minimum for 1999. There can be no assurance that Zimmer will not terminate the contract. See "RISK FACTORS AND CERTAIN FACTORS AFFECTING FUTURE OPERATING RESULTS--DEPENDENCE UPON MARKETING PARTNERS."

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 generally.

#### YEAR 2000 DISCLOSURE

The term "Year 2000 issue" is a general term used to describe various problems that may result from the improper processing by computer systems of dates after 1999. These problems arise from the inability of some hardware and software to distinguish dates before the year 2000 from the dates in and after the year 2000. This could result in a system failure or miscalculations causing disruptions of operations. The Year 2000 issue affects virtually all companies and all organizations.

The Company's efforts to address its Year 2000 issues prior to January 1, 2000, were focused in the following three areas: (i) reviewing and taking any necessary steps to attempt to correct the Company's computer information systems (i.e., software applications and hardware platforms), (ii) evaluating and making any necessary modifications to other computer systems that do not relate to information technology but include embedded technology, such as telecommunications, security, HVAC, elevator, fire and safety systems, and (iii) communicating with certain significant third-party service providers to determine whether there will be any interruption in their systems that could affect the Company. In October 1999, the Company implemented a new financial planning system to replace an older system that did not address the Year 2000 issue.

The Company has not experienced any business or service disruptions as a result of any Year 2000 issues, nor has the Company been contacted by any vendors or customers as to any Year 2000 issues with respect to their various products or services. Costs incurred to date related to Year 2000 issues were approximately \$90,000 and have not been material, nor does the Company expect to incur additional material costs related to Year 2000 issues. The Company is continuing to evaluate potential disruptions or complications that might result in the future from Year 2000 related problems; although at this time, the Company has not identified any specific business functions that are likely to suffer material disruption as a result of Year 2000 related issues. Due to the unique and pervasive nature of the Year 2000 issue, however, it is not possible to anticipate each of the wide variety of Year 2000 issues that might arise, particularly outside of the Company, which might have a material adverse impact on the Company's business, financial condition and results of operations.

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### 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, manufacturing, labeling, recordkeeping, and reporting activities for such products.

Medical products regulated by the FDA are generally classified as medical devices and/or 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 if 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's review process typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

The Company anticipates that once FDA approval for their ORTHOVISC-Registered Trademark- product is obtained, ORTHOVISC-Registered Trademark- 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 by the FDA to ensure their safety and effectiveness (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-Registered Trademark- 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-Registered Trademark- in December 1997. In October 1998, the Company was notified by THE FDA that the Company's PMA application for ORTHOVISC-Registered Trademark- was not approvable and that additional clinical data would be required to demonstrate the effectiveness OF ORTHOVISC-Registered Trademark-. 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 ORTHOVISC-Registered Trademark- clinical trial commenced in late April 1999 and completed patient enrollment for the trial in August 1999. The final patient completed the six moNTH follow-up period in late February 2000. There can be no assurance that Anika will file a PMA. In addition, there can be no quarantee that the FDA will approve a PMA application for ORTHOVISC-Registered Trademark- on a timely basis, if at all, or that the FDA review will not involve delays that will affect the Company's ability TO commercialize additional products or expand permitted uses of existing products. Furthermore, even if granted, the approval may include significant limitations on the indications and other claims sought for use for which the product may be marketed.

The Company's developmental HA products, including INCERT-Registered Trademark-, have not obtained regulatory approval in the U.S. for investigational use and/or commercIAL marketing and sale. The Company believes that INCERT-Registered Trademark- will be regulated as a Class III medical device. Before undertaking clinical trials in the U.S. to supporT A PMA, the Company must apply for and obtain FDA and/or institutional review board ("IRB") approval of an IDE. There can be no assurance that the Company will be permitted to undertake clinical trials of these or other future products in the U.S. or that clinical trials will demonstrate that the products are safe and effective or otherwise satisfy the FDA's pre-market approval requirements. Orquest has not received regulatory approval in the U.S. for the commercial marketing and sale of OSSIGEL-Registered Trademark-. OSSIGEL-Registered Trademark- will be regulated as a Class III medical device with the FDA's Center of Biologics Research and Review as the lead review CENter. There can be no assurance that Orquest will be permitted to undertake clinical trials of OSSIGEL-Registered Trademark- or, if clinical trials are permitted, that such clinical triALS will demonstrate that OSSIGEL-Registered Trademark- is safe and effective or otherwise satisfy FDA requirements.

Once obtained, marketing clearance can be withdrawn by the FDA due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial clearance. 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, changes in manufacturing methods or quality control systems and changes in performance or design specifications. 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 clearance to market products, any FDA limitations on the use of the Company's products, or any withdrawal or suspension 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 products manufactured by the Company must be manufactured in compliance with FDA's Good Manufacturing Practices ("GMP") regulations or, for medical devices, FDA's Quality System Regulations ("QSR"). Ongoing compliance with GMP, QSR and other applicable regulatory requirements is monitored 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-Registered Trademark- 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 entitles the Company to affix a CE marking on ORTHOVISC-Registered Trademark- for the treatment of osteoarthritis in synovial 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 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 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, the Company had incurred annual operating losses. As of December 31, 1999, the Company had an accumulated deficit of approximately \$4,773,000. 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. 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 for certain of its products. There can be no assurance that the Company will be able to achieve sustained profitability.

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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 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.

UNCERTAINTY REGARDING SUCCESS OF CLINICAL TRIALS. Several of the Company's products, including ORTHOVISC-Registered Trademark- and INCERT-Registered Trademark-, as well as the products OF the Company's collaborative partners, including OSSIGEL-Registered Trademark-, will require clinical trials to determine their safety and efficacy in humans for various conditions. 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 of any of these products. In addition, there can be no assurance that such clinical trials, if completed, will ultimately demonstrate these products to be safe and efficacious.

DEPENDENCE UPON MARKETING PARTNERS. The Company does not plan to directly market and sell its current products to end-users. Therefore, 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. The Company currently manufactures AMVISC-Registered Trademark- and AMVISC-Registered Trademark-Plus for Bausch & Lomb Surgical under an exclusive fixed price, five-year supply agreement which cONTains stated minimum annual purchase obligations and terminates on December 31, 2001. Since January 1, 1997, Bausch & Lomb Surgical has purchased AMVISC-Registered Trademark- AND AMVISC-Registered Trademark-Plus in amounts substantially in excess of the minimum purchase obligations set forth in the AMVISC Supply Contract. There can be no assurance that BauscH & Lomb, Surgical will continue to purchase AMVISC-Registered Trademark- and AMVISC-Registered Trademark-Plus at levels beyond the stated minimum annual purchase obligations or that future unit sale PRices will not be subject to negotiated reductions. Any such decrease in orders or prices under the AMVISC Supply Contract could have a material adverse effect on the Company's business, financial condition and results of operations. For the years ended December 31, 1999 and 1998, sales of AMVISC-Registered Trademark- products to Bausch & LOMB Surgical accounted for 63.9% and 68.7% of product revenues.

The Zimmer Distribution Contract provides Zimmer with exclusive marketing and distribution rights to ORTHOVISC-Registered Trademark- in the United States, Canada, LaTIN America, Asia and most of Europe. To date the Company has received up-front non-refundable licensing payments totaling \$4.0 million. In addition, under the Zimmer Distribution Contract the Company has the potential to receive payments aggregating up to an additional \$19.5 million upon the achievement of certain regulatory approvals and enumerated sales milestones. As an alternative to a \$2.5 million milestone payment due upon receipt of FDA approval for the U.S. market, Zimmer has the right to elect to acquire shares of the Company's Common Stock equal to the greater of: (a) \$2,500,000 divided by

125% of the average daily closing price of the Common Stock for the prior sixty (60) calendar days or (b) 9.9% of the then outstanding Common Stock (but not to exceed 19.9% of the then outstanding Common Stock) at a 25% premium to the market price for the 60 days prior to the milestone. There can be no assurance that any of such milestones will be met on a timely basis or at all. In addition, Zimmer has the right to terminate the Zimmer Distribution Contract within sixty (60) days of the occurrence of any of the following events: (i) ORTHOVISC-Registered Trademark- is not approved by the FDA by January 1, 2001, (ii) there is a material recall of ORTHOVISC-Registered Trademark-, (iii) Zimmer's net sales of ORTHOVISC-Registered Trademark- failed to meet the minimums specified in the Zimmer Distribution Contract for two consecutive years beginning with the calendar year of 1998 or (iv) a court of competent jurisdiction rules that ORTHOVISC-Registered Trademark- or any of its related patents is infringing the patents or proprietary rights of a third party. There can be no assurance tHAT any of these events will not occur, or, even if any such event does not occur, that Zimmer will not elect to terminate the agreement. In fact, Zimmer's sales of ORTHOVISC-Registered Trademark- for 1999 and 1998, are less than the minimums for this consecutive two-year period. Despite the fact that Zimmer has not given notice within THE requisite sixty (60) day period, there can be no assurances that Zimmer will not terminate the Zimmer Distribution Contract or seek to renegotiate the agreement on terms less favorable to the Company. Any such termination is likely to have a material adverse effect on the Company's ability to market  ${\tt ORTHOVISC-Registered}$ Trademark-, which MAY have a material adverse effect on the Company's future operating results. ORTHOVISC-Registered Trademark- sales to Zimmer accounted for 10.3% and 2.8% of product revenue for the yeARS ended December 31, 1998 and 1999, respectively.

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The Company will need to obtain the assistance of additional marketing partners for new products which are brought to market and 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.

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 payors. 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 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 and a patent application which claim certain adhesion prevention uses and certain drug delivery uses of HA, and solely owns patents directed to certain manufacturing processes. The Company also 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.

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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, the Company has received notice from the PTO that a third party is attempting to provoke a patent interference with respect to one of the Company's co-owned patents covering the use of INCERT-Registered Trademark- FOR post-surgical adhesion prevention. Although the Company believes that an interference may be declared by the PTO, it is too early to determine the merits of the interference or the effect, if any, the interference will have on the Company's marketing of INCERT-Registered Trademark- for this use. The existence of the interference proceedING may have a negative impact on the marketing of the INCERT-Registered Trademark- 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-Registered Trademark- 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-Registered Trademark- 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 unpatented 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 AMVISC Supply Contract, the Company has agreed to grant Bausch & Lomb Surgical a royalty-free, worldwide, exclusive license to the Company's manufacturing and product inventions which relate to AMVISC-Registered Trademark- products, effective on December 31, 2001, the termination date of the AMVISC supPLY contract (which became effective on January 1, 1997). Upon expiration of the AMVISC Supply Contract, there can be no assurance that Bausch & Lomb Surgical will continue to use the Company to manufacture AMVISC-Registered Trademark- and AMVISC-Registered Trademark-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 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.

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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 payors, 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. Reimbursement by a third party payor may depend on a number of factors, including the payor's determination that the use of the Company's products are 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 payors 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 payors for the Company' products and services could have a material adverse effect on the Company's business, financial condition and results of operations.

NEED FOR ADDITIONAL FUNDS; LIQUIDITY. The Company had cash, cash equivalents and short- and long-term investments of \$20.2 million as of December 31, 1999. 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 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. To the extent that funds generated from the Company's operations, together with the Company's existing capital resources and 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 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 \$1,000,000 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 whom 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. 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.

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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. Approximately 31.4% and 20.9% of the Company's product sales during 1999 and 1998 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. Such changes in the volume of sales 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-Registered Trademark- was not approvable and that additional clinical data would be required to demonstrate the effectiveness of ORTHOVISC-Registered Trademark-. To the extent the COMpany experiences any other adverse developments in the process of seeking FDA approval for ORTHOVISC-Registered Trademark-, the price of the Common Stock will likely be subject to furthER, and perhaps substantial, declines. 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, 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 acquiror from acquiring control of the Company and its Board of Directors.

POTENTIAL SECURITIES CLASS ACTION LITIGATION. As a result of an informal inquiry from the Securities and Exchange Commission, the Company has revised its revenue recognition policies and has restated its operating results for 1998 and the first three quarters of 1999. In the past, companies that have restated their financial information have been subject to

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securities class action litigation. The Company may be involved in a securities class action litigation in the future. Such litigation often results in significant costs and a diversion of management's attention and resources and could harm the Company's business, financial condition and results of operations.

RELIANCE ON A SMALL NUMBER OF CUSTOMERS. The Company has historically derived the majority of our revenues from a small number of customers, most of whom resell our products to end users and most of whom are significantly larger companies. Our failure to generate as much revenue as expected from these customers or the failure of these customers to purchase our products would seriously harm our business. For the year ended December 31, 1999, Bausch & Lomb Surgical accounted for 63.9% of our product revenues and 42% of our account receivables balance and Biomeks accounted for 28.4% of our product revenues and 49% of our accounts receivable balance. Accordingly, present and future customers may terminate their purchasing arrangements with us, significantly reduce or delay their orders or seek to renegotiate their agreements on terms less favorable to the Company. Furthermore, in any future negotiations the Company may be subject to the perceived or actual leverage the customers may have given their relative size and importance to the Company. Any termination, change, reduction or delay in orders could seriously harm our business, financial condition and results of operations. Accordingly, unless and until we diversify and expand our customer base, our future success will significantly depend upon the timing and size of future purchases by our largest customers and the financial and operational success of these customers.

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

ITEM 7A. QUANTITIVE AND QUALITIVE DISCLOSURES ABOUT MARKET RISK.

None.

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### ITEM 8. FINANCIAL STATEMENTS

# ANIKA THERAPEUTICS, INC. BALANCE SHEETS

|                           | DECEMBER 31, |               |
|---------------------------|--------------|---------------|
|                           | 1999         | 1998          |
|                           |              | (AS RESTATED) |
| ASSETS                    |              |               |
| Current assets:           |              |               |
| Cash and cash equivalents | \$ 6,440,705 | \$ 10,712,520 |
| Short-term investments    | 8,184,870    | 12,007,503    |
| Accounts receivable, net  | 2,106,452    | 3,032,737     |
| Inventories               | 5,493,701    | 3,522,019     |
| Prepaid expenses          | 721,206      | 250,023       |
|                           |              |               |
| Total current assets      | 22,946,934   | 29,524,802    |
|                           |              |               |

| Property and equipment Less: accumulated depreciation   | 8,116,233<br>4,587,692                            | 6,376,405<br>3,809,723                                |
|---|---|---|
| Net property and equipment Long-term investments Notes receivable from officers   | 3,528,541<br>5,558,029<br>353,000                 | 2,566,682<br><br>193,000                              |
| Deposits  | 124,600   | 108,500   |
| Total assets  | \$ 32,511,104                                     | \$ 32,392,984   |
| LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities: Accounts payable Accrued expenses   | \$ 629,080<br>1,552,661                           | \$ 891,493<br>1,356,586                               |
| Deferred revenue  | 1,792,505   | 796,368   |
| Total current liabilities   | 3,974,246   | 3,044,447   |
| Advance rent payment Long-term deferred revenue Commitments (Note 8) Stockholders' equity:  | 2,825,000   | 50,215  |
| Redeemable convertible preferred stock; \$.01 par value: authorized 750,000 shares; no shares issued and outstanding  |   |   |
| and outstanding   |   |   |
| and 1998, respectively Additional paid-in capital Deferred compensation Treasury stock (at cost, 200,863 and 344,500 shares in 1999 and 1998, respectively) Accumulated deficit | 99,919 31,959,316 (615,001) (959,870) (4,772,506) | 99,919 34,439,676 (1,074,699) (1,889,794) (2,276,780) |
| Total stockholders' equity  | 25,711,858  | 29,298,322  |
| Total liabilities and stockholders' equity  | \$ 32,511,104                                     | \$ 32,392,984   |
|   |   |   |

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

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# ANIKA THERAPEUTICS, INC. STATEMENTS OF OPERATIONS

|   | YEARS ENDED DECEMBER 31,          |                           |                          |
|---|-----------------------------------|---------------------------|--------------------------|
|   | 1999                              | 1998                      | 1997                     |
|   |                                   | (AS RESTATED)             |                          |
| Product revenue. Licensing fees.  | \$13,082,662<br>400,000           | \$11,773,343<br>1,500,000 | \$9,255,338<br>2,700,000 |
| Total revenue   | 13,482,662<br>6,440,166           | 13,273,343<br>6,014,181   | 11,955,338<br>4,744,123  |
| Gross profit Operating expenses:  | 7,042,496                         | 7,259,162                 | 7,211,215                |
| Research and development<br>Selling, general and administrative   | 4,154,479<br>3,029,394            | 1,955,940<br>2,731,142    | 1,957,796<br>2,092,467   |
| Total operating expenses  | 7,183,873                         | 4,687,082                 | 4,050,263                |
| Income (loss) from operations.  Interest income, net.  Gain on sale of securities.  | (141,377)<br>1,068,430<br>233,633 | 2,572,080<br>1,307,825    | 3,160,952<br>262,162<br> |
| Income before provision for income taxes  | 1,160,686<br>31,412               | 3,879,905<br>127,557      | 3,423,114<br>78,677      |
| Income before cumulative effect of change in accounting principle   | 1,129,274<br>(3,625,000)          | 3,752,348<br>             | 3,344,437                |
| Net income (loss)   | \$(2,495,726)                     | \$3,752,348               | \$3,344,437              |
| Basic income (loss) per share: Income before cumulative effect of change in accounting principle. Cumulative effect of change in accounting principle | \$0.12<br>(0.38)                  | \$0.38<br>                | \$0.60<br>               |
| Net income (loss)   | \$(0.26)                          | \$0.38                    | 0.60                     |
| Basic weighted average common shares outstanding  | 9,740,560                         | 9,885,724                 | 5,436,474                |

| Diluted income (loss) per share: Income before cumulative effect of change in accounting principle | \$0.11<br>(0.35) | \$0.34<br> | \$0.44<br> |
|--|------------------|------------|------------|
| Net income (loss)  | \$(0.24)         | \$0.34     | \$0.44     |
|  |                  |            |            |
| Diluted weighted average common and potential common shares outstanding                            | 10,220,584       | 11,006,276 | 7,587,393  |
|  |                  |            |            |

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

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# ANIKA THERAPEUTICS, INC. STATEMENTS OF STOCKHOLDERS' EQUITY

|   | COMMON              | N STOCK            | ADDITIONAL         |                          |                   |                        | TOTAL                   |
|---|---------------------|--------------------|--------------------|--------------------------|-------------------|------------------------|-------------------------|
|   | NUMBER OF<br>SHARES | \$.01 PAR<br>VALUE | PAID-IN<br>CAPITAL | DEFERRED<br>COMPENSATION | TREASURY<br>STOCK | ACCUMULATED<br>DEFICIT | STOCKHOLDERS'<br>EQUITY |
|   |                     |                    |                    |                          |                   |                        |                         |
| Balance, December 31, 1996  | 4,930,719           | \$49,307           | \$11,693,070       | ş                        | \$                | \$ (9,373,566)         | \$ 2,368,811            |
| Exercise of common stock options Sale of common stock, net of issuance          | 228,047             | 2,281              | 583,394            |                          |                   |                        | 585,675                 |
| costs of \$2,043,519  |                     | 27,250             |                    |                          |                   |                        | 17,031,481              |
| Issuance of common stock to 401(k) plan<br>Issuance of common stock to Board of | 25,795              | 258                | 133,147            |                          |                   |                        | 133,405                 |
| Directors   | 8,000               | 80                 | 43,670             |                          |                   |                        | 43,750                  |
| preferred stock   | 1,773,530           | 17,735             | 2,802,027          |                          |                   |                        | 2,819,762               |
| preferred stock   |                     |                    | (103,035)          |                          |                   |                        | (103,035)               |
| Net income  |                     |                    |                    |                          |                   | 3,344,437              | 3,344,437               |
| Balance, December 31, 1997  | 9,691,091           | 96,911             | 32,156,504         |                          |                   | (6,029,129)            | 26,224,286              |
| Exercise of common stock options  | 112,153             | 971                | 368,099            |                          | 34,024            |                        | 403,094                 |
| Exercise of common stock warrants   | 203,700             | 2,037              | 666,099            |                          |                   |                        | 668,136                 |
| Expenses from sale of common stock, net   |                     |                    | (107,293)          |                          |                   |                        | (107,293)               |
| Unearned stock compensation<br>Purchase of 359,500 shares of common             |                     |                    | 1,356,267          | (1,074,699)              |                   |                        | 281,568                 |
| stock   |                     |                    |                    |                          | (1,923,818)       |                        | (1,923,818)             |
| Net income (as restated)  |                     |                    |                    |                          |                   | 3,752,348              | 3,752,348               |
| Balance, December 31, 1998  | 9,991,943           | 99,919             | 34,439,676         | (1,074,699)              | (1,889,794)       | (2,276,780)            | 29,298,322              |
| Exercise of common stock options  |                     |                    | (2,362,544)        |                          | 2,878,913         |                        | 516,369                 |
| Amortization of deferred compensation<br>Purchase of 402,600 shares of common   |                     |                    |                    | 342,464                  |                   |                        | 342,464                 |
| stock   |                     |                    |                    |                          | (1,948,989)       |                        | (1,948,989)             |
| Reversal of unearned stock compensation   |                     |                    | (117,234)          | 117,234                  |                   |                        |                         |
| Net loss  |                     |                    |                    |                          |                   | (2,495,726)            | (2,495,726)             |
| Balance, December 31, 1999  | 9,991,943           |                    |                    |                          |                   |                        | \$25,711,858            |
|   |                     |                    |                    |                          |                   |                        |                         |

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

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ANIKA THERAPEUTICS, INC. STATEMENTS OF CASH FLOWS

|      | YEARS ENDI | ED DEC. | 31,  |  |
|------|------------|---------|------|--|
|      |            |         |      |  |
| 1999 | 1998       | 3       | 1997 |  |
|      |            |         |      |  |
|      | (AC DE     | (Garare |      |  |

| Cash flows from operating activities:  |                    |                          |                                |
|--|--------------------|--------------------------|--------------------------------|
| Net income (loss)  | \$ (2,495,726)     | \$ 3,752,348             | \$ 3,344,437                   |
| Adjustments to reconcile net income (loss) to net cash provided by operating                     |                    |                          |                                |
| activities:  | 777 060            | 101 100                  | 070 025                        |
| Depreciation and amortization  | 777,969<br>342,464 | 484,402<br>281,568       | 279,035                        |
| Amortization of deferred compensation  | 342,464            |                          |                                |
| Provision for doubtful accounts  |                    | 57,000                   |                                |
| Common stock issued to 401(k) plan and Board of Directors  | (50,215)           |                          | 177,155                        |
| Advance rent payment   | (50,215)           | (53,697)                 | (38,863)                       |
| Changes in operating assets and liabilities:   | 926,285            | (1 171 444)              | (1,379,289)                    |
| Accounts receivable  | (1,971,682)        | (1,171,444)<br>(980,467) |                                |
| Prepaid expenses   | (471,183)          | 360,341                  | (59,906)<br>(303,827)          |
| Accounts payable   | (262,413)          | (76,493)                 | 417,672                        |
| Accrued expenses   | 196,075            | 103,432                  | 197,920                        |
| Deferred revenue   | 3,821,137          | 596,368                  | 197,920                        |
| pererred revenue   | 3,021,137          | 330,300                  |                                |
| Net cash provided by operating activities  | 812,711            | 3,353,359                | 2,634,334                      |
| Cash flows from investing activities:  |                    |                          |                                |
| Deposits   | (16,100)           | 2,765                    | (42,500)                       |
| Purchase of long-term investments  | (5,558,029)        | 2,703                    | (42,300)                       |
| Purchase of short-term investments   | (35,079,915)       | (39,832,074)             |                                |
| Sale of short-term investments   | 38,902,548         | 27,824,571               |                                |
| Purchase of property and equipment   | (1,739,828)        | (2,238,040)              | (273,035)                      |
| Notes receivable from officers   | (160,000)          | (118,000)                | (75,000)                       |
| Notes receivable from officers   | (100,000)          | (110,000)                | (73,000)                       |
|  |                    |                          |                                |
| Net cash used in investing activities  | (3,651,324)        | (14,360,778)             | (390,535)                      |
| Net cash used in investing activities  | (3,031,324)        | (14,300,770)             | (390,333)                      |
| Cash flows from financing activities:  |                    |                          |                                |
| Proceeds from sale of common stock, net  |                    |                          | 17,031,481                     |
| Expenses from issuance of stock  |                    | (107,293)                |                                |
| Proceeds from exercise of preferred stock warrants   |                    |                          | 114,200                        |
| Purchase of 402,600 and 359,500 shares of common stock, respectively                             | (1,948,989)        | (1,923,818)              | ,                              |
| Proceeds from exercise of stock options and warrants   | 516,369            | 1,071,230                | 585,675                        |
| ***************************************  |                    |                          |                                |
| Net cash (used in) provided by financing activities  | (1,432,620)        | (959,881)                | 17,731,356                     |
|  |                    |                          |                                |
| (Decrease) increase in cash and cash equivalents   | (4,271,815)        | (11,967,300)             | 19,975,155                     |
| Cash and cash equivalents at beginning of period   | 10,712,520         | 22,679,820               | 2,704,665                      |
|  |                    |                          |                                |
| Cash and cash equivalents at end of period   | \$ 6,440,705       | \$ 10,712,520            | \$ 22,679,820                  |
|  |                    |                          |                                |
| Supplemental disclosure of cash flow information:  |                    |                          |                                |
| Cash paid for interest   | \$                 | \$                       | \$ 2,771                       |
|  |                    |                          |                                |
|  |                    |                          |                                |
| Cash paid for taxes  | \$ 131,206         | \$ 75,000                |                                |
|  |                    |                          |                                |
|  |                    |                          |                                |
|  |                    |                          |                                |
| Supplemental disclosure of non cash items:   |                    |                          |                                |
| Supplemental disclosure of non cash items:  Conversion of redeemable convertible preferred stock | ş                  | \$                       | \$ 2,819,762                   |
|  | \$                 | \$                       | \$ 2,819,762                   |
| Conversion of redeemable convertible preferred stock   | \$<br>             | \$<br>                   | \$ 2,819,762                   |
|  | \$<br><br>\$       | \$<br><br>\$             | \$ 2,819,762<br><br>\$ 103,035 |
| Conversion of redeemable convertible preferred stock   | \$<br>             | \$<br>                   | \$ 2,819,762                   |

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

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# ANIKA THERAPEUTICS, INC. NOTES TO 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-Registered Trademark-, which is an HA product used in the treatment of some forms of osteoarthritis in humans AND HYVISC-Registered Trademark-, which is an HA product used in the treatment of equine osteoarthritis. In the U.S., ORTHOVISC-Registered Trademark- is currently approved for sale and marketed in CANada, Europe, Turkey, Israel and Iceland. In the U.S., ORTHOVISC-Registered Trademark- is currently limited to investigational use and the Company commenced a Phase III clinical trial IN the U.S. and Canada in late April 1999 and the final patient completed the six month follow-up period in late February 2000. The Company manufactures AMVISC-Registered Trademark- AND AMVISC-Registered Trademark-Plus, which are HA products used as viscoelastic supplements in ophthalmic surgery, for Bausch &

Lomb Surgical, a subsidiary of Bausch & Lomb. The CompANY is currently developing INCERT-Registered Trademark-, 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-Registered Trademark-; an injectable formulation of basic fibroblast growth factor combined with HA designed to accelerate THE healing of bone fractures.

In the fourth quarter of 1999, the Company performed a review of its revenue recognition policy for revenue received from Zimmer, Inc., a division of Bristol-Myers Squibb Co., under a distribution agreement for ORTHOVISC-Registered Trademark-, Anika's osteoarthritis product. As a result of this review, and after consultation wITH the SEC, Anika revised its revenue recognition policy for ORTHOVISC-Registered Trademark- sales to Zimmer and restated its operating results for 1998 and the first three quarters OF 1999. (See REVENUE RECOGNITION below.)

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The following tables present a summary of restated results for 1998 and the first three quarters of 1999.

# QUARTERLY FINANCIAL DATA (Unaudited) 1998

|  | AS REPORTED  | AS RESTATED  | CHANGE                                  |
|--|--------------|--------------|---|
| QUARTER ENDED MARCH 31, 1998                             |              |              |   |
| Total revenue.   | \$2,754,419  | \$2,702,484  | (\$51,935)                              |
| Cost of sales  | 1,343,472    | 1,343,472    |   |
| Gross profit   | 1,410,947    | 1,359,012    | (51,935)                                |
| Net income (loss)  | \$637,006    | \$585,071    | (\$51,935)                              |
|  |              |              |   |
| Diluted income(loss) per common share: Net income (loss) | \$0.06       | \$0.05       | (\$.01)                                 |
|  |              |              |   |
| Diluted common shares outstanding                        | 10,863,410   | 10,863,410   |   |
| QUARTER ENDED JUNE 30, 1998                              |              |              |   |
| Total revenue.   | \$4,595,966  | \$4,575,608  | (\$20,358)                              |
| Cost of sales  | 1,564,569    | 1,564,569    |   |
| Gross profit   | 3,031,397    | 3,011,039    | (20,358)                                |
| Net income (loss)  | \$2,201,455  | \$2,181,097  | (\$20,358)                              |
| Diluted income(loss) per common share:                   |              |              |   |
| Net income (loss)  | \$0.20       | \$0.19       | (\$.01)                                 |
|  |              |              | (11.2-)                                 |
| Diluted common shares outstanding                        | 11,197,949   | 11,197,949   |   |
| QUARTER ENDED SEPTEMBER 30, 1998                         |              |              |   |
| Total revenue.   | \$3,179,901  | \$2,592,671  | (\$587,230)                             |
| Cost of sales.   | 1,425,270    | 1,201,273    | (223, 997)                              |
| Gross profit.  | 1,754,631    | 1,391,398    | (363,233)                               |
| Net income (loss)  | \$741,053    | \$377,820    | (\$363,233)                             |
|  |              |              |   |
| Diluted income (loss) per common share:                  |              |              |   |
| Net income (loss)  | \$0.07       | \$0.03       | (\$0.04)                                |
| Diluted common shares outstanding                        | 11,316,539   | 11,316,539   |   |
| OUARTER ENDED DECEMBER 31, 1998                          |              |              |   |
| Total revenue.   | \$3,339,426  | \$3,402,581  | \$63,155                                |
| Cost of sales.   | 1,680,870    | 1,904,867    | 223,997                                 |
| Gross profit.  | 1,658,556    | 1,497,714    | (160,842)                               |
| Net income (loss)  | \$769,203    | \$608,361    | (\$160,842)                             |
|  |              | ,            | ,, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| Diluted income(loss) per common share:                   |              |              |   |
| Net income (loss)  | \$0.07       | \$0.06       | (\$0.01)                                |
| Diluted common shares outstanding                        | 10,564,628   | 10,564,628   |   |
| VIDEO DISPOSITION OF TAXABLE PARTIES.                    |              |              |   |
| YEAR ENDED DECEMBER 31, 1998 Total revenue               | 612 060 712  | 612 272 244  | (CEOC 200)                              |
|  | \$13,869,712 | \$13,273,344 | (\$596,368)                             |
| Cost of sales  | 6,014,181    | 6,014,181    |   |
| Gross profit   | 7,855,531    | 7,259,163    | (596,368)                               |
| Net income (loss)  | \$4,348,717  | \$3,752,348  | (\$596,368)                             |
| Diluted income(loss) per common share:                   |              |              |   |
| Net income (loss)  | \$0.40       | \$0.34       | (\$0.06)                                |
| Diluted common shares outstanding                        | 11,006,276   | 11,006,276   |   |

# QUARTERLY FINANCIAL DATA (Unaudited) 1999

|  | AS REPORTED | AS RESTATED   | CHANGE            |
|--|-------------|---------------|-------------------|
| QUARTER ENDED MARCH 31, 1999   |             |               |                   |
| Total revenue.   | \$3,224,578 | \$3,335,650   | \$111,072         |
| Cost of sales.   | 1,708,171   | 1,708,171     | Ψ111 <b>,</b> 072 |
| Gross profit.  | 1,516,407   | 1,627,479     | 111,072           |
|  |             |               |                   |
| Income (loss) before cumulative effect of change in accounting principle | 344,749     | 455,821       | 111,072           |
| Cumulative effect of change in accounting principle                      | 0           | (3,625,000)   | (3,625,000)       |
| Net income (loss)  | \$344,749   | (\$3,169,179) | (\$3,513,928)     |
| Diluted income (loss) per common share:                                  |             |               |                   |
| Income before cumulative effect of change in accounting principle        | \$0.03      | \$0.05        | \$0.02            |
| Cumulative effect of change in accounting principle                      |             |               |                   |
| Net income (loss)  | \$0.03      | (\$0.31)      | (\$0.34)          |
| Diluted common shares outstanding  | 10,077,488  | 10,077,488    |                   |
| QUARTER ENDED JUNE 30, 1999  |             |               |                   |
| Total revenue  | \$3,750,275 | \$3,533,346   | (\$216,929)       |
| Cost of sales.   | 1,896,633   | 1,688,714     | (207,919)         |
| Gross profit   | 1,853,642   | 1,844,632     | (9,010)           |
| Income (loss) before cumulative effect of change in accounting principle | \$406,898   | 397,888       | (9,010)           |
| Cumulative effect of change in accounting principle                      |             |               |                   |
| Net income (loss)  | \$406,898   | \$397,888     | (\$9,010)         |
| Diluted income (loss) per common share:                                  |             |               |                   |
| Income before cumulative effect of change in accounting principle        | \$0.04      | \$0.04        |                   |
|  | 70.04       | ŞU.U4<br>     |                   |
| Cumulative effect of change in accounting principle                      |             |               |                   |
| Net income (loss)  | \$0.04      | \$0.04        |                   |
| Diluted common shares outstanding  | 10,075,826  | 10,075,826    |                   |
| OUARTER ENDED SEPTEMBER 30, 1999   |             |               |                   |
| Total revenue  | \$3,481,637 | \$2,995,350   | (\$486,287)       |
| Cost of sales.   | 1,818,807   | 1,429,587     | (389,220)         |
|  | 1,662,830   | 1,565,763     |                   |
| Gross profit   |             |               | (97,067)          |
| Income (loss) before cumulative effect of change in accounting principle | 4,186       | (92,881)      | (97 <b>,</b> 067) |
| Cumulative effect of change in accounting principle                      |             |               |                   |
| Net income (loss)  | \$4,186     | (\$92,881)    | (\$97,067)        |
| Diluted income (loss) per common share:                                  |             |               |                   |
| Income before cumulative effect of change in accounting principle        | \$0.01      | (\$0.01)      | (\$0.02)          |
| Cumulative effect of change in accounting principle                      |             |               |                   |
| Net income (loss)  | \$0.01      | (\$0.01)      | (\$0.02)          |
| Diluted common shares outstanding  | 10,374,349  | 9,940,228     |                   |

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# 2. 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.

# CASH AND CASH EQUIVALENTS

Cash and cash equivalents consists of cash and investments with original maturities of  $90\ \mathrm{days}$  or less.

## SHORT-TERM AND LONG-TERM INVESTMENTS

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 investments consist of debt securities with original maturities between three and twelve months. The Company classifies these short-term investments 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, 1999 and 1998 is as follows:

|   |                   | DECEMBER 31, 1999                   |              |
|---|-------------------|-------------------------------------|--------------|
|   | AMORTIZED<br>COST | GROSS<br>UNREALIZED<br>HOLDING GAIN | FAIR VALUE   |
| Commercial Paper (weighted average maturity of 7.64 months) | \$8,184,870       | \$60,209                            | \$8,245,079  |
|   |                   |                                     |              |
|   |                   | DECEMBER 31, 1998                   |              |
|   | AMORTIZED<br>COST | UNREALIZED<br>HOLDING GAIN          | FAIR VALUE   |
|   |                   | HOLDING GAIN                        | TAIR VALUE   |
| Commercial Paper (weighted average maturity of 2.57         |                   |                                     |              |
| months)   | \$12,007,503      | \$ (6,593)                          | \$12,000,910 |
|   |                   |                                     |              |

Long-term investments consist of debt securities with original maturities greater than twelve months. The Company classifies these long-term investments 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, 1999 is as follows:

|  | AMORTIZED<br>COST | GROSS<br>UNREALIZED<br>HOLDING GAIN | FAIR VALUE  |
|--|-------------------|-------------------------------------|-------------|
| Commercial Paper (weighted average maturity of 1.67 years) | \$5,558,029       | \$30,764                            | \$5,588,793 |
|  |                   |                                     |             |

During 1999, the Company sold securities classified as held for maturity with an amortized cost aggregating \$38,902,548. Total proceeds from these sales were \$39,403,879 with total interest and realized gain of \$501,331 which is included in interest income on the Statement of Operations. In addition, during 1999, the Company acquired and sold certain equity securities and realized a gain of \$233,633 which is shown separately 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 investments, accounts receivable, notes receivable from officers and accounts payable. The estimated fair value of these financial instruments approximates their carrying value, and in the case of cash equivalents, short-term and long-term investments, is based on market quotes. The Company's cash equivalents, short-term and long-term investments are generally obligations of the federal government or investment-grade corporate issuers. The Company, by policy, limits the amount of credit exposure to any one financial institution.

#### INVENTORIES

Inventories are stated at the lower of cost or market, with cost being determined using the first-in, first-out (FIFO) method.

### REVENUE RECOGNITION

Product revenue is recognized upon shipment of commercial product and represents sales of AMVISC-Registered Trademark- products, HYVISC-Registered Trademark- and ORTHOVISC-Registered Trademark-. ORTHOVISC-Registered Trademarkis sold under several supply contracts, including one with Zimmer, Inc., a division of Bristo-Myers Squibb (Zimmer), for Zimmer's distribution in Canada and Europe. The Company has revised its revenue recognition policy for sales of ORTHOVISC-Registered Trademark- under its contract with Zimmer. Under the revised revenue recognition policy, reveNUE will be recognized at the time of shipment to Zimmer based upon the minimum per unit price under the Distribution Agreement at the time of sale to Zimmer. Anika had previously recognized revenue for ORTHOVISC-Registered Trademark- sales to Zimmer based upon an estimate of the average selling price which would be obtained by Zimmer upon sALE of the ORTHOVISC-Registered Trademark- to its customers, as specified under the Distribution Agreement. Any additional amounts earned by Anika above the contractual minimum per uNIT price will be recognized when Zimmer sells the ORTHOVISC-Registered Trademark- to its customers and Anika is able to determine its share of the actual per unit sales price. Anika HAD also recognized revenue in 1998 and the first three quarters of 1999 for ORTHOVISC-Registered Trademarkwhich was held in its refrigerators at Zimmer's request. Under the CompanY'S revised revenue recognition policy, this revenue will be recorded when the ORTHOVISC-Registered Trademark- is shipped to Zimmer. Amounts paid by Zimmer in excess of the amoUNT recognized under the revised revenue recognition policy is recorded by Anika as deferred revenue and amounted to \$1,420,000 at December 31, 1999.

The Company has also adopted the provisions of SEC Staff Accounting Bulletin 101 (SAB 101) in its 1999 operating results. The issuance of 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, respectively, received from Zimmer in the fourth quarter of 1997 and the second quarter of 1998. These amounts were previously recognized in the period received. In accordance with SAB 101, the company has retroactively recorded the cumulative effect of the change in accounting principle of \$3,625,000 as a charge in the first quarter of 1999. These payments will be recognized as revenue ratably over the 10-year term of the distribution agreement including \$400,000 recognized in 1999. The amount received and deferred to future periods is \$3,225,000 at December 31, 1999 and is included in deferred revenue.

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  | 4-10 vears |

Amortization on leasehold improvements is calculated using the straight-line method over the shorter of the lease term or estimated life of the asset.  $\,$ 

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, 1999, 1998, and 1997 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.

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, 1999, 1998, and 1997:

|   | YEARS ENDED DECEMBER 31, |                        |                                   |  |
|---|--------------------------|------------------------|-----------------------------------|--|
|   | 1999                     | 1998                   | 1997                              |  |
|   |                          | (AS RESTATED)          |                                   |  |
| Net income (loss) Less: Redeemable convertible preferred stock dividend   | \$(2,495,726)<br>        | \$3,752,348<br>        | \$3,344,437<br>103,035            |  |
| Net income (loss) available to common shareholders  | \$ (2,495,726)           | \$3,752,348            | \$3,241,402                       |  |
| Basic weighted average common shares outstanding  Dilutive effect of assumed exercise of stock options and warrants  Dilutive effect of assumed conversion of preferred stock | 9,740,560<br>480,024     | 9,885,724<br>1,120,552 | 5,436,474<br>952,432<br>1,198,437 |  |
| Diluted weighted average common and potential common shares outstanding   | 10,220,584               | 11,006,276             | 7,587,393                         |  |

### 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.

#### STOCK-BASED COMPENSATION

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

In March 1999, the Financial Accounting Standards Board (FASB) issued a proposed interpretation, ACCOUNTING FOR CERTAIN TRANSACTIONS INVOLVING STOCK COMPENSATION -- AN INTERPRETATION OF APB OPINION NO. 25. The Proposed Interpretation would clarify the application of APB 25 in certain situations, as defined. The Proposed Interpretation would be effective upon issuance (expected to be in early 2000) but would cover certain events that occur after December 15, 1998. To the extent that events covered by this Proposed Interpretation occur during the period after December 15, 1998, but before issuance of the final interpretation, the effects of applying this Proposed Interpretation would be recognized on a prospective basis from the effective date. Accordingly, upon initial application of the final interpretation, (a) no adjustments would be made to financial statements for periods before the effective date and (b) no expense would be recognized for any additional compensation cost measured that is attributable to periods before the effective date. The Company expects that the adoption of this Interpretation will not have a material affect on the financial statements.

## CONCENTRATION OF CREDIT RISK

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 and credit risk concentrations. The Company has no significant off-balance-sheet or concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Sales of AMVISC-Registered Trademark- products to Bausch & Lomb Surgical accounted for 63.9%, 68.7% and 84.1% of product revenue for the years ended December 31, 1999, 1998, and 1997, respectively. ORTHOVISC-Registered Trademark- sales to another customer accounted for 28.4%, 19.2% and 14.5% of product revenue for the years ended December 31, 1999, 1998 and 1997, respectively. ORTHOVISC-Registered Trademark- sales to Zimmer accounted for 10.3% and 2.8% of product revenue for the years ended December 31, 1998 and 1999, respectiveLY. Additionally, as of December 31, 1999, two customers, one of which is an international customer, represented 49% and 42%, respectively, of the Company's accounts receivable balance. As of December 31, 1998 three customers represented 100% of the Company's accounts receivable balance with one international customer representing 14% 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 nonowner 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, 1999, 1998 and 1997.

# 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

Revenues by country of the customer in total and as a percentage of total revenues are as follows for the years ended December 31, 1999, 1998 and 1997, respectively:

|  |                                     |                       | EARS ENDED DEC                       | •                     |                           |                       |
|--|-------------------------------------|-----------------------|--------------------------------------|-----------------------|---------------------------|-----------------------|
|  | 1:                                  | 999                   | 1998                                 |                       | 1997                      |                       |
| COUNTRY:                               |                                     |                       | (AS REST                             | ATED)                 |                           |                       |
|  | REVENUE                             | PERCENT OF<br>REVENUE | REVENUE                              | PERCENT OF<br>REVENUE | REVENUE                   | PERCENT OF<br>REVENUE |
| United States Middle East Other/Europe | \$9,381,073<br>3,948,839<br>152,750 | 69.6%<br>29.3<br>1.1  | \$10,816,248<br>2,307,095<br>150,000 | 81.5%<br>17.4<br>1.1  | \$10,615,518<br>1,339,820 | 88.8%<br>11.2<br>     |
| Total                                  | \$13,482,662                        | 100.0%                | \$13,273,343                         | 100.0%                | \$11,955,338              | 100.0%                |

### 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, is effective for all fiscal quarters beginning with the quarter ending September 30, 2000. SFAS No. 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. The Company will adopt SFAS No. 133 in its quarter ending September 30, 2000 and does not expect that such adoption to have an impact on the Company's results of operations, financial position or cash flows.

As noted above the Company adopted the provisions of SEC Staff Accounting Bulletin 101 (SAB 101) in its restated 1999 operating results. The issuance of SAB 101 changes revenue recognition practices for non-refundable up-front payments received as part of broad supply, distribution and marketing agreements. Such amounts were previously recognized in the period received. In accordance with SAB 101, such payments will be recognized as revenue ratably over the term of the distribution agreement.

## 3. ALLOWANCE FOR DOUBTFUL ACCOUNTS

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

|   | DECEMBER 31,       |                   |
|---|--------------------|-------------------|
|   | 1999               | 1998              |
| Balance, beginning of the year Amounts provided | \$57,000<br>12,000 | \$<br>57,000      |
| Amounts written off                             | (8,000)            |                   |
| Balance, at the end of the year                 | \$61,000<br>       | \$57 <b>,</b> 000 |

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# 4. INVENTORIES

Inventories consist of the following:

| Total           | \$5,493,701  | \$3,522,019     |  |
|-----------------|--------------|-----------------|--|
|                 |              |                 |  |
| Finished goods  | 1,121,147    | 75 <b>,</b> 834 |  |
| Work in-process | 3,690,618    | 3,013,930       |  |
|                 |              |                 |  |
| Raw materials   | \$ 681,936   | \$ 432,255      |  |
|                 |              |                 |  |
|                 | 1999         | 1998            |  |
|                 |              |                 |  |
|                 | DECEMBE      | K 31,           |  |
|                 | DECEMBER 31, |                 |  |
|                 |              |                 |  |

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## 5. PROPERTY & EQUIPMENT

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

|   | DECEMBER 31,                        |                                     |  |
|---|-------------------------------------|-------------------------------------|--|
|   | 1999<br>                            | 1998<br>                            |  |
| Machinery and equipment  Furniture and fixtures  Leasehold improvements | \$5,704,663<br>1,773,390<br>638,180 | \$4,145,013<br>564,621<br>1,666,771 |  |
| Total   | \$8,116,233                         | \$6,376,405                         |  |
|   |                                     |                                     |  |

# 6. NOTES RECEIVABLE FROM OFFICERS

Notes receivable from officers consists of loans made to three officers. The loan amounts are due at the earlier of the end of five years from the date of the note or at the termination of the officers' employment. Interest accrues at annual rates between 4.42% to 6.0% and is payable monthly over the term of the loans.

# 7. ACCRUED EXPENSES

Accrued expenses consists of the following:

DECEMBER 31,

| Total                  | \$1,552,661     | \$1,356,586         |
|------------------------|-----------------|---------------------|
|                        |                 |                     |
| Other accrued expenses | 732,031         | 665 <b>,</b> 992    |
| Federal taxes          | 30 <b>,</b> 530 | 130,324             |
| Accrued compensation   |                 | \$ 560 <b>,</b> 270 |
| Account company tion   | ć 700 100       | ¢ 500 070           |
|                        |                 |                     |
|                        | 1999            | 1998                |
|                        |                 |                     |

# 8. LEASE OBLIGATIONS

The Company leases three facilities with one lease expiring in October 2001, another in January 2004 and the third lease in February 2004. As of December 31, 1999, one facility is being partially sublet. These leases are accounted for as operating leases in the accompanying statements of operations. Net rental expense in connection with the leases, totaled \$489,000, \$377,000 and \$353,000 for the years ended December 31, 1999, 1998 and 1997, respectively. Future minimum lease payments under the operating leases, net of sublease income for the years ending December 31st are as follows:

|          | AMOUNT                                   |
|----------|--|
| 2000     | 616,000<br>643,000<br>626,000<br>655,000 |
| 2004     | 109,000                                  |
| Total\$2 | 2,649,000                                |
|          |  |

# 9. STOCK OPTION PLAN

The Company has reserved 3,000,000 shares of Common Stock for the grant of stock options to employees, directors, consultants and advisors under the Anika Therapeutics, Inc. Stock Option Plan (the "Plan"). In addition, the Company also established the Directors Stock Option Plan (the "Director's 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

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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 was required to record compensation expense with respect to the 269,000 options granted equal in an amount to the difference between the exercise price and the fair market value of the common stock at the time of such approval. The Company recorded deferred compensation of \$1,490,061 of which \$415,362 and \$342,464 was amortized to expense during 1998 and 1999, respectively. The unamortized deferred compensation of \$615,002 at December 31, 1999 will be amortized on a straight-line basis over the options' remaining vesting period.

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

|                                  |            | WEIGHTED AVG EXERCISE |
|----------------------------------|------------|-----------------------|
|                                  | SHARES     | PRICE PER SHARE       |
|                                  |            |                       |
| Outstanding at December 31, 1996 | 1,779,395  | \$2.99                |
| Granted                          | 309,500    | \$7.40                |
| Canceled                         | (14,333)   | \$2.42                |
| Exercised                        | (228,047)  | \$2.54                |
|                                  |            |                       |
| 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                |
|                                  |            |                       |
|                                  |            |                       |

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 201,717 options available for future grant at December  $31,\ 1999$ .

The following table summarizes significant ranges of outstanding options under both Plans at December 31, 1999:

|               | OPTION      | S OUTSTANDING |          | OPTIONS E   | XERCISABLE |
|---------------|-------------|---------------|----------|-------------|------------|
|               |             |               |          |             |            |
|               |             | WEIGHTED      |          |             |            |
|               |             | AVERAGE       | WEIGHTED |             | WEIGHTED   |
| RANGES OF     | NUMBER      | REMAINING     | AVERAGE  |             | AVERAGE    |
| EXERCISE      | OUTSTANDING | CONTRACTUAL   | EXERCISE | NUMBER      | EXERCISE   |
| PRICE         |             | LIFE          | PRICE    | EXERCISABLE | PRICE      |
|               |             |               |          |             |            |
| \$1.07 - 3.00 | 246,592     | 4.14          | \$2.63   | 246,592     | \$2.63     |
| 3.13 - 4.78   | 401,776     | 6.84          | 4.29     | 261,776     | 4.04       |
| 4.91 - 5.81   | 644,183     | 7.91          | 5.22     | 252,766     | 5.25       |
| 6.16 - 8.13   | 302,500     | 8.37          | 7.38     | 109,250     | 7.63       |
|               |             |               |          |             |            |
|               | 1,595,051   | 7.15          | \$4.99   | 870,384     | \$4.44     |
|               |             |               |          |             |            |
|               |             |               |          |             |            |

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The Company has determined that it will continue to account for stock-based compensation for employees under Accounting Principles Board ("APB") Opinion No. 25 and elect the disclosure-only alternative under SFAS No. 123 for stock-based compensation awarded in 1999, 1998 and 1997 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The underlying assumptions used are as follows:

|                                  | YEARS ENDED DECEMBER 31, |         |         |
|----------------------------------|--------------------------|---------|---------|
|                                  | 1999 1998                |         | 1997    |
|                                  |                          |         |         |
| Risk-free interest rate          | 5.56%                    | 5.45 %  | 6.0%    |
| Expected dividend yield          |                          |         |         |
| Expected lives                   | 6                        | 6       | 6       |
| Expected volatility              | 65.1%                    | 50.0%   | 54.8%   |
| Weighted average value of grants | \$ 3.21                  | \$ 4.07 | \$ 7.40 |

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

|   | YEARS ENDED DECEMBER 31, |               |             |  |
|---|--------------------------|---------------|-------------|--|
|   | 1999 1998 1997           |               |             |  |
|   |                          |               |             |  |
|   |                          | (AS RESTATED) |             |  |
| Net income (loss):                        |                          |               |             |  |
| As reported                               | \$(2,495,726)            | \$3,752,348   | \$3,344,437 |  |
| Pro forma                                 | \$(3,165,031)            | \$3,105,462   | \$2,644,895 |  |
| Net income (loss) per share, as reported: |                          |               |             |  |
| Basic                                     | \$(0.26)                 | \$0.38        | \$0.60      |  |
| Diluted                                   | \$(0.24)                 | \$0.34        | \$0.44      |  |
| Net income (loss) per share, pro forma:   |                          |               |             |  |
| Basic                                     | \$(0.32)                 | \$0.31        | \$0.48      |  |
| Diluted                                   | \$(0.31)                 | \$0.28        | \$0.35      |  |

# 10. COMMON STOCK

On December 1, 1997 the Company completed a secondary offering of common stock. In connection with the offering the Company issued 2,725,000 shares of common stock and received total gross proceeds of \$19,075,000, and net proceeds of \$17,031,481.

## 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 the Company is acquired in a merger or other business combination transaction after any such event, each holder of a Right would then be entitled to purchase, at the then-current exercise price, shares of the acquiring company's common stock having a value of twice the exercise price of the Right. The current exercise price per Right is \$45.00.

The Rights will expire at the close of business on April 6, 2008 (the "Expiration Date"), unless previously redeemed or exchanged by the Company as described below. The Rights may be redeemed in whole, but not in part, at a price of \$0.01 per Right (payable in cash, shares of the Company's Common Stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (i) the time at which any person becomes an "acquiring person" or (ii) the Expiration Date. At any time after any person becomes an "acquiring person," the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of the Company's Common Stock at an exchange ratio specified in the Rights Plan. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to 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.

#### 11. WARRANTS

In connection with the private placement in March 1996, the Company issued warrants to Leerink, Swann, Garrity, Sollami, Yaffe and Wynn, Inc. ("Leerink Swann & Company"), for 146,664 shares of common stock exercisable at \$3.00 per share and warrants for 57,036 shares of common stock exercisable at \$4.00 per share. On January 8, 1998, the notice for mandatory exercise of the warrants by the Company was sent in accordance with the warrant provisions and all warrants were converted into common stock resulting in net proceeds to the Company of \$668,136.

## 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, 1999, the Company had repurchased a total of 762,100 shares at a net cost of approximately \$3,873,000 and has reissued 561,237 shares upon exercise of employee stock options.

## 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 year ended December 31, 1999 and 1998 the Company's matching contribution was in the form of cash of \$160,142 and \$130,644, respectively. For the year ended December 31, 1997, the Company's matching contribution to the plan was in the form of the Company's common stock. The Company's total 401(k) savings plan expense for 1997 was \$133,405.

# 14. LICENSING AND DISTRIBUTION AGREEMENT

In November 1997, the Company entered into a long-term distribution agreement with Zimmer, Inc., a subsidiary of Bristol-Myers Squibb Company, that was subsequently amended in June 1998 and June 1999, (the "Zimmer Distribution Contract"). The Zimmer Distribution Contract provides Zimmer with exclusive marketing and distribution rights to ORTHOVISC-Registered Trademark- in the United States, Canada, Asia and most of Europe. To date, the Company has received up-front non-refundable licensING payments from Zimmer totaling \$4.0 million. In addition, under the Zimmer Distribution Contract the Company has the potential to receive payments aggregating up to \$19.5 million upon the achievement of certain regulatory approvals, reimbursement approvals and enumerated sales milestones. As an alternative to a \$2.5 million milestone payment due upon FDA approval for the U.S. market, Zimmer has the right to elect

to acquire shares of the Company's Common Stock equal to the greater of: (a) \$2,500,000 divided by 125% of the average daily closing price of the Common Stock for the prior sixty (60) calendar days or (b) 9.9% of the then outstanding Common Stock (but not to exceed 19.9% of the then outstanding common stock). There can be no assurance that any of such milestones will be met on a timely basis or at all.

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The Zimmer Distribution Contract provides that the amount Zimmer will pay to the Company for ORTHOVISC-Registered Trademark- will be based on a fiXED percentage of Zimmer's actual average selling price, subject to a floor. Additionally, the Zimmer Distribution Contract contains certain annual minimum purchase requirements that Zimmer must order.

## 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, 1999, the Company has net operating loss carryforwards for state tax purposes of approximately \$1,403,000. These carryforwards expire in 2001, and are subject to review and possible adjustment. The Company has no net operating loss carryforwards available for Federal income tax purposes after 1999.

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

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

|  | YEARS ENDED DECEMBER 31, |               |
|--|--------------------------|---------------|
|  | 1999                     | 1998          |
|  |                          |               |
|  |                          | (AS RESTATED) |
| Deferred tax assets (liabilities):     |                          |               |
| Depreciation                           | \$430,006                | \$312,754     |
| Accrued expenses and other             | (5,097)                  | (17,585)      |
| Inventory loss reserve                 | 120,690                  | 60,429        |
| Nonqualified stock option amortization | 112,627                  | 113,387       |
| Deferred revenue                       | 1,847,002                | 318,547       |
| Net operating loss carryforwards       | 84,181                   | 583,915       |
| Credit carryforward                    |                          | 275,901       |
|  |                          |               |
| Gross deferred tax assets              | 2,589,409                | 1,647,348     |
| Less: valuation allowance              | (2,589,409)              | (1,647,348)   |
|  |                          |               |
| 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. However, approximately \$113,000 of the valuation allowance relates to the excess tax benefit of disqualifying dispositions and the exercise of non-qualified stock

options. If the valuation allowance is reduced in the future periods, this benefit will be recorded in additional paid in capital at that time.

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Income tax expense was \$31,412, \$127,557 and \$78,677 for the years ended December 31, 1999, 1998 and 1997, 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, |                    |             |
|--|--------------------------|--------------------|-------------|
|  | 1999                     | 1999 1998          |             |
|  |                          | (AS RESTATED)      |             |
| Computed expected tax expense (benefit)              | \$(837,867)              | \$1,319,168        | \$1,163,859 |
| State tax (benefit) expense (net of federal benefit) | (147,859)                | 232,794            | 215,329     |
| Nondeductible expenses                               | 44,944                   | 12,069             | 3,804       |
| Unrealized gain on short-term investments            |                          | (80,702)           |             |
| Other  | 30,133                   | (58,829)           | (7,660)     |
| benefit  | 942,061                  | (1,296,943)        | (1,296,655) |
| Tax expense  | \$31,412                 | \$127 <b>,</b> 557 | \$78,677    |
|  |                          |                    |             |

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# INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying balance sheet of Anika Therapeutics, Inc. (the "Company") as of December 31, 1999 and 1998, as restated, and the related statements of operations, stockholders' equity and cash flows for the years then ended. 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. as of December 31, 1999 and 1998, as restated, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States.

ARTHUR ANDERSEN LLP

Boston, Massachusetts February 11, 2000

#### INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying statement of operation, stockholders' equity, and cash flow of Anika Therapeutics, Inc. for the year ended December 31, 1997. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements base on our audit.

We conducted our audit in accordance with generally accepted auditing standards. 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operation and cash flow of Anika Therapeutics, Inc. for the year ended December 31, 1997, in conformity with generally accepted accounting principles.

KPMG LLP

Boston, Massachusetts February 18, 1998

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by Item 10 is hereby incorporated by reference to the Registrant's Proxy Statement (the "Proxy Statement") for the Annual Meeting of Stockholders to be held on June 7, 2000 under the headings "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 Voting 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 "Employment Arrangements with Senior Executives" and "Certain Relationships."

PART IV

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

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

#### (1) Financial Statements

| Report of Independent Public Accountants        | 45-46 |
|---|-------|
| Consolidated Balance Sheets                     | 27    |
| Consolidated Statements of Operations           | 28    |
| Consolidated Statements of Stockholder's Equity | 29    |
| Consolidated Statements of Cash Flows           | 30    |
| Notes to Consolidated Financial Statements      | 31-44 |

Notes to 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

KPMG LLP's Reports with respect to the above listed financial statements and financial statements schedules are included herein on Item 8 and Exhibit 23.2

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(3) Exhibits required to be filed by Item 601 of Regulation S-K and by Item 14 (c)

The list of Exhibits filed as a part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately preceding such Exhibits, and is incorporated herein by reference.

(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 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, filed with the Securities and Exchange Commission on January 14, 1997.
  - Amendment to the Amended and Restated Articles of Organization of the Company, incorporated herein by reference to Exhibit 3.1 to the Company's Form quarterly report on Form 10-QSB for the period ended November 30, 1996, 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 of the Company's Current Report of Form 8-A12B (File no. 001-14022), 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.
- Third Amendment to Distribution Agreement dated as of January 11, 1991 between the Company and IOLAB Corporation, incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form 10 (file no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
- 10.3 Fourth Amendment to Distribution Agreement dated as of August 1, 1994 between the Company and IOLAB Corporation, incorporated herein by reference to Exhibit 10.24 to the Company's annual report on Form 10-K for the fiscal year ended August 31, 1994, filed with the Securities and Exchange Commission on November 25, 1994.
- Supply Agreement dated as of August 1, 1994 between the Company and IOLAB, incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K for the fiscal year ended August 31, 1994, filed with the Securities and Exchange Commission on November 25, 1994.
- 10.5 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, filed with the Securities and Exchange Commission on March 5, 1993.

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- 10.6 Form of TMJ Agreement dated as of April 29, 1993 between the Company and MedChem, incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form 10 (file no. 000-21326), filed with the Securities and Exchange Commission on March 5, 1993.
- 10.7 Sublease Agreement dated as of April 29, 1993 between the Company and MedChem, incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form 10 (file no. 000-21326), filed on March 5, 1993.
- 10.8 1993 Stock Option Plan, incorporated herein by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-QSB for the period ended June 30, 1998, filed with the Securities and Exchange Commission on August 14, 1998.
- 10.9 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.
- 10.10 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.
- 10.11 Lease dated March 10, 1995 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 August 31, 1995, filed with the Securities and Exchange Commission on November 29, 1995.
- 10.12 Employment 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, filed with the Securities and Exchange Commission on November 27, 1996

- 10.13 Change of Control Agreement dated as of June 3, 1999 between the Company and J. Melville Engle is filed herewith as Exhibit 10.13.
- 10.14 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.
- 10.15 Exclusive Distribution Agreement dated as of November 7, 1997 between the Company and Zimmer, Inc., incorporated herein by reference to Exhibit 10.26 to the Company's Registration Statement on Form SB-2/A, filed with the Securities and Exchange Commission on November 10, 1997. Confidential treatment was granted to certain portions of this Exhibit.
- 10.16 First Amendment to Exclusive Distribution Agreement dated as of June 1, 1998 between the Company and Zimmer, Inc., incorporated herein by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-QSB for the quarterly period ended June 30, 1998, filed with the Securities and Exchange Commission on August 14, 1998.
- (23) Consent of ARTHUR ANDERSEN LLP is filed herewith as Exhibit 23.1.

  Consent of KPMG LLP is filed herewith as Exhibit 23.2.
- (27) Financial Data Schedule.

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# SIGNATURES

Pursuant to the requirements of Section 13 or  $15\,\mathrm{(d)}$  of the Securities Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized in Woburn, Massachusetts on March 30, 2000.

ANIKA THERAPEUTICS, INC.

By: /s/ Kathleen A. Theriault

Kathleen A. Theriault
PRINCIPAL FINANCIAL & ACCOUNTING OFFICER
March 30, 2000

## 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, on March 30, 2000.

| SIGNATURE              | TITLE   | DATE<br>       |
|------------------------|---|----------------|
| /s/ J. MELVILLE ENGLE  | Chairman, President & Chief<br>Executive Officer<br>PRINCIPAL EXECUTIVE OFFICER | March 30, 2000 |
| /s/ JOSEPH L. BOWER    | Director  | March 30, 2000 |
| Joseph L. Bower        |   |                |
| /s/ EUGENE A. DAVIDSON | Director  | March 30, 2000 |
|                        |   |                |

Eugene A. Davidson

| /s/ JONATHAN D. DONALDSON | Director                              | March 30, 2000 |
|---------------------------|---------------------------------------|----------------|
| Jonathan D. Donaldson     |                                       |                |
| /s/ SAMUEL F. MCKAY       | Director                              | March 30, 2000 |
| Samuel F. McKay           |                                       |                |
| /s/ HARVEY S. SADOW       | Director                              | March 30, 2000 |
| Harvey S. Sadow           |                                       |                |
| /s/ STEVEN E. WHEELER     | Director                              | March 30, 2000 |
| Steven E. Wheeler         |                                       |                |
| /s/ KATHLEEN A. THERIAULT | Controller<br>PRINCIPAL FINANCIAL AND | March 30, 2000 |
| Kathleen A. Theriault     | ACCOUNTING OFFICER                    |                |

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## EXHIBIT INDEX

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- (23) Consent of ARTHUR ANDERSEN LLP is filed herewith as Exhibit 23.1. Consent of KPMG LLP is filed herewith as Exhibit 23.2.
- (27) Financial Data Schedule.

## ANIKA THERAPEUTICS, INC.

### CHANGE IN CONTROL, BONUS AND SEVERANCE AGREEMENT

AGREEMENT made as of June 3, 1999 by and among Anika Therapeutics, Inc., a Massachusetts corporation with its principal place of business in Woburn, Massachusetts (the "Company"), and J. Melville Engle of Acton, Massachusetts (the "Executive"), an individual presently employed as the Chairman, President and Chief Executive Officer of the Company.

- PURPOSE. The Company considers it essential to the best interests of its stockholders to foster the continuous employment of key management personnel. The Board of Directors of the Company (the "Board") recognizes, however, that, as is the case with many publicly held corporations, the possibility of a Change in Control (as defined in Section 2 hereof) exists and that such possibility, and the uncertainty and questions which it may raise among management, may result in the departure or distraction of management personnel to the detriment of the Company and its stockholders. Therefore, the Board has determined that appropriate steps should be taken to reinforce and encourage the continued attention and dedication of members of the Company's management, including the Executive, to their assigned duties without distraction in the face of potentially disturbing circumstances arising from the possibility of a Change in Control. Nothing in this Agreement shall be construed as creating an express or implied contract of employment and, except as otherwise agreed in writing between the Executive and the Company, the Executive shall not have any right to be retained in the employ of the Company.
- 2. CHANGE IN CONTROL. A "Change in Control" shall mean the occurrence of any one of the following events:
  - (a) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934 (the "Act") (other than the Company, any of its subsidiaries, any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 51% or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Company's Board of Directors ("Voting Securities"); or
  - (b) persons who, as of the date hereof, constitute the Company's Board of Directors (the "Incumbent Directors") cease for any reason, including, without limitation, as a result of a tender offer, proxy contest, merger or similar transaction, to constitute at least a majority of the Board, provided that any person becoming a director of the Company subsequent to the date hereof whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors shall, for purposes of this Agreement, be considered an Incumbent Director; or
  - (c) the stockholders of the Company shall approve (A) any consolidation or merger of the Company where the shareholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate 51% of the voting shares of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), (B) any sale, lease, exchange or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of

the Company or (C) any plan or proposal for the liquidation or dissolution of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (a) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate voting power represented by the Voting Securities beneficially owned by any person to 51% or more of the combined voting power of all then outstanding Voting Securities; PROVIDED, HOWEVER, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a share split, stock dividend or similar transaction or direct purchase from the Company), then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (a).

- 3. TERMINATING EVENT. A "Terminating Event" shall mean any of the events provided in this Section 3 occurring within eighteen (18) months subsequent to a Change in Control as defined in Section 2:
  - (a) termination by the Company of the employment of the Executive with the Company for any reason other than for Cause or the death of the Executive. "Cause" shall mean, and shall be limited to, the occurrence of any one or more of the following events:
    - (i) a willful act of dishonesty by the Executive with respect to any matter involving the Company; or
    - (ii) conviction of the Executive of a crime involving moral turpitude; or  $% \left( 1\right) =\left( 1\right) \left( 1\right) =\left( 1\right) \left( 1\right)$
    - (iii) the deliberate or willful failure by the Executive (other than by reason of the Executive's physical or mental illness, incapacity or disability) to substantially perform the Executive's duties with the Company and the

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continuation of such failure for a period of 30 days after delivery by the Company to the Executive of written notice specifying the scope and nature of such failure and its intention to terminate the Executive for Cause.

A Terminating Event shall not be deemed to have occurred pursuant to this Section 3(a) solely as a result of the Executive being an employee of any direct or indirect successor to the business or assets of the Company, rather than continuing as an employee of the Company following a Change in Control.

- (b) termination by the Executive of the Executive's employment with the Company for Good Reason. "Good Reason" shall mean the occurrence of any of the following events:
  - (i) a substantial adverse change in the nature or scope of the Executive's responsibilities or duties from the responsibilities or duties exercised by the Executive immediately prior to the Change in Control, it being understood by the parties hereto, that so long as the Executive retains primary management responsibilities for the business conducted by Anika immediately prior to the Change in Control, Good Reason shall not exist under this Section 3(b)(i); or
  - (ii) a reduction in the Executive's annual base salary and/or benefits as in effect on the date hereof or as the same may be increased from time to time except for across-the-board salary and/or benefits reductions similarly affecting all or substantially all management employees.

For purposes of this Section 3, unless the context otherwise requires, Company shall mean the Company or any successor thereto or to the business thereof in a transation involving a Change in Control.

- 4. SPECIAL TERMINATION PAYMENTS. In the event a Terminating Event occurs within eighteen (18) months after a Change in Control in lieu of any payments under the Employment Letter (as hereinafter defined),
  - (a) the Company shall pay to the Executive, in addition to the payment, if any, required by Section 5, an amount equal to 100% of the Executive's annual salary as in effect immediately prior to the Change in Control, said amount shall be paid in one lump sum payment no later than thirty-one (31) days following the Date of Termination (as such term is defined in Section 9(b)); and

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- (b) the Company shall forgive all outstanding loans from the Company to the Executive, although the Executive understands that this is a taxable event; and
- (c) the Company shall continue to provide health, dental, long-term disability, life insurance and other fringe benefits to the Executive, on the same terms and conditions as though the Executive had remained an active employee, for twelve (12) months; and
- (d) the Company shall provide COBRA benefits to the Executive following the end of the period referred to in Section 4(c) above, such benefits to be determined as though the Executive's employment had terminated at the end of such period.
- 5. PAYMENT UPON EFFECTIVE DATE OF CHANGE IN CONTROL. Upon the effective date of a Change in Control, regardless of whether a Terminating Event has occurred, in addition to any other payment required by Section 4, the Company shall pay the Executive an amount in cash representing one hundred and fifty percent (150%) of the Executive's annual salary as in effect immediately prior to the Change in Control. Said amount shall be paid in one lump sum payment no later than thirty-one (31) days following the effective date of a Change in Control.
- CERTAIN LIMITATIONS. It is the intention of the Executive and of the Company that no payments by the Company to or for the benefit of the Executive under this Agreement or any other agreement or plan, if any, pursuant to which the Executive is entitled to receive payments or benefits shall be nondeductible to the Company by reason of the operation of Section 280G of the Code relating to parachute payments or any like statutory or regulatory provision. Accordingly, and notwithstanding any other provision of this Agreement or any such agreement or plan, if by reason of the operation of said Section 280G or any like statutory or regulatory provision, any such payments exceed the amount which can be deducted by the Company, such payments shall be reduced to the maximum amount which can be deducted by the Company. To the extent that payments exceeding such maximum deductible amount have been made to or for the benefit of the Executive, such excess payments shall be refunded to the Company with interest thereon at the applicable Federal rate determined under Section 1274(d) of the Code, compounded annually, or at such other rate as may be required in order that no such payments shall be nondeductible to the Company by reason of the operation of said Section 280G or any like statutory or regulatory provision. To the extent that there is more than one method of reducing the payments to bring them within the limitations of said Section 280G or any like statutory or regulatory provision, the Executive shall determine which method shall be followed, provided that if the Executive fails to make such determination within forty-five (45) days after the Company has given notice of

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the need for such reduction, the Company may determine the method of such reduction in its sole discretion.

7. TERM. This Agreement shall take effect on the date first set forth

above and shall terminate upon the earliest of (a) the termination by the Company of the employment of the Executive for Cause; (b) the resignation or voluntary termination of the Executive for any reason prior to a Change in Control; or (c) the resignation of the Executive after a Change in Control for any reason other than for Good Reason.

- 8. WITHHOLDING. All payments made by the Company under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.
  - 9. NOTICE AND DATE OF TERMINATION; DISPUTES; ETC.
  - (a) NOTICE OF TERMINATION. After a Change in Control and during the term of this Agreement, any purported termination of the Executive's employment (other than by reason of death) shall be communicated by written Notice of Termination from one party hereto to the other party hereto in accordance with this Section 9. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon and the Date of Termination. Further, a Notice of Termination for Cause is required to include a copy of a resolution duly adopted by the affirmative vote of not less than a majority of the entire membership of the Board (exclusive of the Executive) at a meeting of the Board (after reasonable notice to the Executive and an opportunity for the Executive, accompanied by the Executive's counsel, to be heard before the Board) finding that, in the good faith opinion of the Board, the termination met the criteria for Cause set forth in Section 3(a) hereof.
  - (b) DATE OF TERMINATION. "Date of Termination," with respect to any purported termination of the Executive's employment after a Change in Control and during the term of this Agreement, shall mean the date specified in the Notice of Termination. In the case of a termination by the Company other than a termination for Cause (which may be effective immediately), the Date of Termination shall not be less than 30 days after the Notice of Termination is given. In the case of a termination by the Executive, the Date of Termination shall not be less than 15 days from the date such Notice of Termination is given. Notwithstanding Section 3(a) of this Agreement, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a second Terminating Event for purposes of Section 3(a) of this Agreement.

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- (c) NO MITIGATION. The Company agrees that, if the Executive's employment by the Company is terminated during the term of this Agreement, the Executive is not required to seek other employment or to attempt in any way to reduce any amounts payable to the Executive by the Company pursuant to Sections 4 and 5 hereof. Further, the amount of any payment provided for in this Agreement shall not be reduced by any compensation earned by the Executive as the result of employment by another employer, by retirement benefits, by offset against any amount claimed to be owed by the Executive to the Company, or otherwise.
- (d) MEDIATION OF DISPUTES. The parties shall endeavor in good faith to settle within 90 days any controversy or claim arising out of or relating to this Agreement or the breach thereof through mediation with JAMS/Endispute or similar organizations. If the controversy or claim is not resolved within 90 days, the parties shall be free to pursue other legal remedies in law or equity.
- 10. ASSIGNMENT; PRIOR AGREEMENTS; NON-SOLICITATION. Except for an assignment by the Company in connection with a Change in Control in which the successor, if other than the Company, shall assume and agree to perform this Agreement in writing, neither the Company nor the Executive may make any assignment of this Agreement or any interest herein, by operation of law or otherwise, without the prior written consent of the other party, and without such consent any attempted transfer shall be null and void and of no effect. This Agreement shall inure to the benefit of and be binding upon the Company and

the Executive, their respective successors, executors, administrators, heirs and permitted assigns. In the event of the Executive's death after a Terminating Event but prior to the completion by the Company of all payments due him under Sections 4 and 5 of this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to his death (or to his estate, if the Executive fails to make such designation). This Agreement supercedes all prior Agreements, whether written or oral with respect to the subject matter hereof. Notwithstanding the foregoing: (A) Section 4 of that certain Employment Letter dated September 24, 1996 (the "Employment Letter"), shall govern any termination of the Executive's employment with the Company (i) prior to the effective date of a Change in Control or (ii) following the expiration of eighteen (18) months after a Change in Control; this Agreement shall govern in the event of any termination of Executive's employment with the Company during the eighteen (18) months after a Change in Control; and (B) that certain Non-Disclosure and Non-Competition Agreement of August 1997 by and between Executive and the Company shall remain in full force and effect in accordance with its terms.

Executive covenants to the Company that during his employment with the Company and until one (1) year from the date he is no longer employed by the Company, any

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affiliate thereof or any successor thereto, he will not in any manner, on his own behalf, or as a partner, officer, director, employee, agent or entity, directly or indirectly, induce or attempt to influence any person serving as an employee of the Company or any successor thereto to leave its employ or hire any such person.

- 11. ENFORCEABILITY. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.
- 12. WAIVER. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.
- 13. NOTICES. Any notices, requests, demands, and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by registered or certified mail, postage prepaid, to the Executive at the last address the Executive has filed in writing with the Company, or to the Company at its main office, attention of the Board of Directors.
- 14. EFFECT ON OTHER PLANS. Except as provided in Section 10 hereof, nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies.
- 15. AMENDMENT. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.
- 16. GOVERNING LAW. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts.
- 17. OBLIGATIONS OF SUCCESSORS. In addition to any obligations imposed by law upon any successor to the Company, the Company will use its commercially reasonable efforts to require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

IN WITNESS WHEREOF, this Agreement has been executed as a sealed instrument by the Company by their duly authorized officers and by the Executive, as of the date first above written.

COMPANY:

ANIKA THERAPEUTICS, INC.

By: /s/ Sean Moran

\_\_\_\_\_

Name: Sean Moran

Title: Chief Financial Officer

EXECUTIVE:

/s/ J. Melville Engle

\_\_\_\_\_

J. Melville Engle

# Exhibit 23.1

# CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation of our report in this Form 10-K into the Company's previously filed Registration Statement File Nos. 33-66831 and 33-79047.

ARTHUR ANDERSEN LLP

Boston, Massachusetts March 30, 2000

## CONSENT OF INDEPENDENT ACCOUNTANTS

The Board of Directors Anika Therapeutics, Inc.:

We consent to incorporation by reference in the registration statement (No. 33-66831) on Form S-8 of Anika Therapeutics, Inc. of our report dated February 18, 1998, relating to the statements of operations, stockholders' equity, and cash flows for the year ended December 31, 1997, which report appears in the December 31, 1999 annual report on Form 10-K of Anika Therapeutics, Inc.

KPMG LLP

Boston, Massachusetts March 30, 2000

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