OSTEX INTERNATIONAL INC /WA/
Form 10-K
March 29, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ý **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2001

or

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to .

0-25250

Commission File Number

OSTEX INTERNATIONAL, INC.

Exact Name of Registrant as Specified in Its Charter

State of Washington	**91-1450247**
State or Other Jurisdiction of Incorporation or Organization	*I.R.S. Employer Identification Number*

2203 Airport Way South, Suite 400, Seattle, Washington 98134
206-292-8082
Address and Telephone Number of Principal Executive Offices

Securities registered pursuant to Section 12(b) of the Act:	Securities registered pursuant to Section 12(g) of the Act:
(none)	(none)

Title of Class Each *Exchange on Which Registered* **Common Stock, $.01 par value**

Title of Class

-

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant was approximately $25,761,352 on March 14, 2002, based on the per-share closing price of $2.58 on the Nasdaq National Market.

The number of shares of Common Stock outstanding as of March 14, 2002 was 12,558,174.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for the Registrant s Annual Shareholders Meeting to be held Wednesday, May 22, 2002, to be filed pursuant to Regulation 14A, is incorporated by reference into Part III of this Form 10-K.

OSTEX INTERNATIONAL, INC.

INDEX TO FORM 10-K

PART IV

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

SIGNATURES

For the purpose of this Form 10-K, the following capitalized terms shall have the following meanings:

Company or Ostex shall mean Ostex International, Inc., a Washington corporation;

Annual Report to Shareholders shall mean the annual report to shareholders of Ostex International, Inc. for the year ended December 31, 2001; and

Proxy Statement shall mean the proxy statement for the 2002 shareholders meeting of Ostex International, Inc. to be held Wednesday, May 22, 2002, to be filed with the Securities and Exchange Commission (the Commission) pursuant to Regulation 14A.

PART I

When used in this report and in the Company s Annual Report to Shareholders , the words believes, intends , anticipates, plans to and expects similar expressions are intended to qualify as forward-looking statements. Such statements are subject to certain risks and uncertainties and there are a number of important factors that could cause actual results to differ materially from those projected. These factors include, among others, the factors described under the section entitled Risk Factors below and under Part II, Item 7 entitled Management s Discussion and Analysis of Financial Condition and Results of Operations Other Factors that May Affect Operating Results. Readers are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date of this Report, or to reflect the occurrence of unanticipated events.

Item 1. Business

Ostex develops and commercializes products to make disease management a reality with osteoporosis being the first area of focus. The Company s lead product, the OSTEOMARK® NTx test, now available in multiple test formats, incorporates breakthrough and patented technology for the management and prevention of osteoporosis. The Company has formed collaborative relationships with leading reference laboratories and pharmaceutical companies to aid in the commercialization of its Osteomark technology. Ostex was incorporated in the State of Washington in 1989 and, as of December 31, 2001, the Company had 46 employees.

Osteoporosis is a significant health problem. According to the National Osteoporosis Foundation (the NOF), osteoporosis afflicts over 28 million people in the United States alone. Additionally, millions of people are at risk of skeletal degradation associated with Paget s disease of bone, cancer that metastasizes to bone, hyperparathyroidism (overactivity of the parathyroid gland, characterized by a reduction of bone mass) and renal osteodystrophy. In spite of the serious human and economic consequences of these diseases (according to the NOF, the national direct expenditures for osteoporosis and associated fractures exceed $14 billion annually in the U.S. alone), medical intervention usually commences only after pain, immobility, fractures, or other symptoms have appeared. The Company expects the osteoporosis therapeutic market will continue to grow as the population ages.

The Company is the exclusive licensee of the Osteomark technology, known clinically as the NTx test, which is available in multiple formats that can aid in healthcare decision-making at early menopause and beyond. The Osteomark test is a non-invasive test that quantitatively indicates the level of bone resorption. Individuals who are losing bone collagen at accelerated rates may progress to low bone mass, a major cause of osteoporosis. Identification of high levels of bone resorption provides the opportunity to predict skeletal response (bone mineral density) to hormonal antiresorptive therapy, such as American Home Products Corp. s Premarin®, in postmenopausal women, which is intended to prevent the onset of osteoporosis. In addition, the Company s Osteomark test aids clinicians in monitoring the effects of antiresorptive therapies, such as Merck & Co., Inc. s Fosamax®, Eli Lilly and Company s Evista®, and Proctor & Gamble Pharmaceuticals, Inc. s and Aventis Pharmaceuticals, Inc. s Actonel®, in postmenopausal women and those diagnosed with osteoporosis, in a matter of three months versus one to two years with conventional technology.

The Company s first Osteomark test became commercially available in May 1995 as a urinary test that provides a quantitative measure of the excretion of cross-linked N-telopeptides of Type I collagen (NTx) as an indicator of human bone resorption. In July 1996, the Company received expanded claims for the test which allow that an Osteomark test measurement, if taken prior to the initiation of hormonal antiresorptive therapy, can be utilized to predict a patient s response to that therapy, in terms of its effect on bone mineral density. Additionally, the claims allow that the test can be used to measure the effect of antiresorptive therapies in postmenopausal women, as well as in individuals diagnosed with osteoporosis and Paget s disease. In March 1998, the claims were further expanded by allowing that, in addition to the 1996 claims, an Osteomark test measurement can identify the probability for a decrease in bone mineral density in postmenopausal women taking calcium supplements relative to those treated with hormonal antiresorptive therapy.

The Company s second Osteomark test is a serum test that became commercially available in February 1999. This was the first commercially available serum test in the United States that measures specific bone breakdown by osteoclasts using a blood sample. The Company believes that the use of a serum NTx test provides a number of advantages to centralized testing laboratories, including the elimination of the requirement to normalize NTx values to creatinine concentration. The Company is manufacturing and marketing the Osteomark test in an Enzyme-linked Immunosorbent Assay (ELISA) format for testing urine or serum samples.

The Osteomark NTx Point-of-Care device (the NTx Point-of-Care) became commercially available in October 1999 for use in the physician s office. The Company and Metrika, Inc. (Metrika) developed a physician s office Point-of-Care Osteomark test device that is a fully disposable point-of-care NTx test for urine as an indicator of bone resorption that computes an NTx value and displays it digitally. In May 2000, the Company announced it had acquired the exclusive right from Metrika to manufacture the Osteomark NTx Point-of-Care device as well as the exclusive worldwide license to manufacture, market and sell this device for the measurement of other connective tissue markers, including those associated with osteoarthritis. Under the agreement, Metrika receives a royalty based on the sales of the NTx Point-of-Care device. The Company started to work with Procter & Gamble in 2000 to launch a test program in Germany to use with the NTx Point-of-Care device with its osteoporosis drug, Actonel, for the management of osteoporosis. This program has since been expanded by Procter & Gamble and Aventis Pharmaceuticals and is being tested in a number of countries including the United States in September of 2001. In August 2001, the Company announced that it received Rx Home-Use clearance and CLIA Waiver status for its NTx Point-of-Care device from the Food and Drug Administration (FDA). This allows the device to be used in essentially all physician offices, and physicians can write a prescription for the device so that patients may use it in their own homes under the direction of their physician.

The Company manufactures its Osteomark NTx Urine and Serum kits in the ELISA format at its manufacturing facility in Seattle, Washington. During 2000, the Company leased additional space in Seattle, Washington, and began improvements to the facility in preparation for the manufacturing transfer of the Osteomark NTx Point-of-Care device from Metrika. The Company started shipping product that was assembled at its new facility in the fourth quarter of 2001 and, in the first quarter of 2002, the Company anticipates shipping devices with highly specialized subcomponents that are also manufactured in its facility.

The Company and Mochida Pharmaceutical Co., Ltd. (Mochida), a Japanese pharmaceutical company, entered into a research and development agreement and a license agreement in 1992 for the commercialization of the Osteomark NTx urine test in Japan. Under the research and development agreement, Mochida has an option to license the NTx serum test and has paid the Company $3,350,000 in development fees to date. Future payments of $750,000 under the agreement are contingent upon Mochida s decision to exercise its option. Under the license agreement, the Company granted Mochida exclusive marketing and distribution rights to certain products in Japan. Since 1992, Mochida has paid the Company $2,500,000 in licensing fees for the Osteomark test. In January 1998, Mochida launched the Osteomark test in Japan for the management of patients with hyperparathyroidism and for patients with metastatic bone tumors. In December 1999, Mochida received an additional regulatory indication from the Japanese Ministry of Health and Welfare for the Osteomark test for selecting suitable drugs for the treatment of osteoporosis and monitoring efficacy of drug therapy for osteoporosis.

Worldwide promotion of the Osteomark urine test kits is also supported by Johnson & Johnson Clinical Diagnostics, Inc. (Johnson & Johnson). In 1995, the Company entered into research, development, license and supply agreements with Johnson & Johnson. These agreements grant Johnson & Johnson a license to manufacture, sell and distribute certain products using the Company s bone resorption technology. Currently, Johnson & Johnson distributes in the United States and certain foreign countries the Osteomark test in the existing microtiter plate format and, beginning in March 1999, it offered the NTx urine test on its Vitros® automated analyzer. The Company receives payments for materials supplied by the Company and royalties on Johnson & Johnson s sales of products incorporating the Company s technology. Under the Johnson & Johnson license agreement, the Company has the right to license its technology for use on automated instruments to one other company in addition to Johnson & Johnson.

The Company has technology for measuring Type II and Type III collagen degradation. Type II collagen is a primary constituent of joint cartilage. Osteoarthritis, a degenerative disease of joint cartilage, affects over 15 million people in the United States alone. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. The Company s Type II collagen degradation test will be further developed to allow reliable monitoring of joint cartilage changes for validating the effectiveness of drugs under development and for identifying patients with early-stage disease. Similar to the Osteomark NTx test used in connection with osteoporosis, the Company believes that the Type II collagen degradation test will aid in the clinical management of osteoarthritis patients. Type III collagen is a significant constituent of blood vessels such as coronary arteries. Measuring degradation of this type of collagen may be useful in identifying cardiovascular disease. The Company has no immediate plans to commercialize tests for Type II or Type III collagen degradation, but has patents in these areas if it decides to commercialize tests for Type II and III in the future.

The Company also has technology to enhance artificial joint recovery. The Company is the exclusive licensee of U.S. Patent No. 6,190,412, directed to prosthetic devices having hydroxyapatite-coated bone attachment surfaces to which tartrate-resistant acid phosphatase (TRAP) is absorbed. Research supported by the Company established that the human TRAP enzyme has a direct role as a local factor in the recruitment of osteoclasts from hematopoietic cells. Also that recombinantly produced TRAP absorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. The Company may seek collaborations to confirm that such TRAP-induced stimulation of osteoclast recruitment results in osteointegration and enhanced bonding of the graft or prosthesis to the patient s bone.

OSTEOMARK and OSTEX are registered United States trademarks of the Company. The Company has also registered its OSTEOMARK trademark in 45 other countries. The Company s collagen breakdown test technology is covered by 36 U.S. patents, 3 European patents, 5 Japanese patents, and patents in Australia, Canada, Ireland, Korea, Russia, Spain, Norway, Hong Kong, and Singapore. Two of the European patents are in opposition proceedings. Additional patent applications are pending. The Company s patents are variously directed to Type I collagen breakdown products, including NTx, CTx, and deoxypyridinoline, as well as related breakdown products of Type II and Type III collagen. The Company s patents will expire in 2007 or later.

Item 1A. Risk Factors

History of Losses and Limited Operating History

The Company has not been profitable for any year since its formation in 1989. The Company has a limited operating history and had a retained deficit through December 31, 2001 of $38,909,000. For the year-end December 31, 2001, the Company had a net loss of $3,099,000. The Company expects to incur additional costs as it continues with its existing operations, the startup of its new manufacturing facility for the NTx Point-of-Care device, marketing efforts, and research and development activities. The Company s lead product, the Osteomark test, became commercially available in May 1995 in the U.S., but sales to date have not been significant enough to generate net income. The ability to achieve long-term profitability is dependent upon obtaining further regulatory approvals for proposed products and successfully manufacturing,

marketing and commercializing existing and future products. The Company expects to continue to incur

additional losses in the future and the Company is unable to predict when, if at all, it will achieve profitability.

Future Capital Needs and Uncertainty of Additional Financing

The Company s future capital requirements depend upon many factors, including the effectiveness of Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; continued scientific progress in its research and development programs; the costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims; the time and costs involved in developing manufacturing and marketing operations; changes in or terminations of the Company s existing collaborations and licensing arrangements; the emergence of competing technologies and other adverse market developments; its degree of success in commercializing its products, and the time and costs involved in obtaining additional regulatory approvals. Additional funds from equity or debt financing may be required, especially as it relates to the manufacturing scale up of the NTx Point-of-Care device and uncertainty related to the timing of final production validation, market acceptance, and demand for the product. There can be no assurance that such additional funds will be available on favorable terms, if at all. If the Company is unable to raise additional funds when it needs them, it may be required to delay, reduce or eliminate some or all of its research and development programs or products. The Company also may be forced to partner with third parties to develop or commercialize products and technologies that it otherwise would have sought to develop independently. Because of the Company s significant long-term cash requirements, it may seek to raise additional capital if conditions in the public equity markets are favorable or through private placements. If the Company raises additional funds by issuing equity securities, further dilution to shareholders may result, and new investors could have rights superior to current security holders. If additional financing is not available, the Company believes that its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales and interest income from short-term investments will be adequate to fund operations through at least the first quarter of 2003.

Lengthy Regulatory Processes and Uncertainty of Regulatory Approvals

The manufacture and marketing of the Company s products and research and development activities are subject to regulation for safety, efficacy, and quality by the FDA in the United States and comparable authorities in other countries.

The process of obtaining FDA and other required regulatory approvals can be lengthy and expensive. The time required for approvals is uncertain, and often depends on the type, complexity and novelty of the product. There can be no assurance that regulatory agencies will act favorably or quickly in their review of any submission by the Company. Significant difficulties or costs may be encountered by the Company in its efforts to obtain approvals that could delay or preclude the Company from marketing its products. Furthermore, there can be no assurance that the agency will not request the development of additional data following original submissions, causing the Company to incur further cost and delay. Nor can there be any assurance that the FDA will not restrict the intended use of a submitted product as a condition for clearance.

The requirements governing the conduct of clinical studies, manufacturing and marketing of proposed products outside the United States can vary widely from country to country. Foreign approvals may take longer than FDA approvals and can involve additional testing. Foreign regulatory approval processes include all of the risks associated with the FDA approval processes. Also, approval of a product by the FDA does not ensure approval of the same product by health authorities of other countries.

Extensive Continuing Government Regulation

The research, development, manufacturing and marketing of the Company s products are subject to extensive continuing regulation by numerous governmental authorities in the U.S. and certain other countries, and the Company, its products, and its manufacturing facilities are subject to continual review and periodic inspection. The regulatory standards for manufacturing are applied stringently by the FDA. Discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on such product or manufacturer or facility, including warning letters, fines, suspensions of regulatory approvals, product recalls, operating restrictions, delays in obtaining new product approvals, withdrawal of the product from the market, and criminal prosecution. Other violations of FDA requirements can result in similar penalties. The Company is also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Any violation of, and the cost of compliance with, these laws and regulations could adversely impact the Company s operations. The Company is unable to predict the extent or likelihood of adverse government regulation that might arise from future U.S. or foreign government action.

Intense Competitive Environment

Competition from biotechnology companies, diagnostic companies, pharmaceutical companies, and research and academic institutions is intense and is based on price as well as product performance. The Company s main competitors are Osteometer Biotech A/S (aka Nordic Bioscience A/S) (Osteometer) and Quidel Corporation (Quidel) and licensees and distributors of their technologies and products. A number of diagnostic tests and procedures, and other non-invasive tests for osteoporosis and other bone disorders currently exist and others are in development, and the manufacturers of these tests will continue to improve them. In addition, the diagnostic industry is subject to rapid technological change. There can be no assurance that the Company s competitors will not succeed in developing products that are more effective or less expensive than those which have been or are being developed by the Company or which would render the Company s core technology obsolete, unecomonical or non-competitive. Many of the Company s competitors have, or have access to substantially greater financial, technical and human resources than the Company. In addition, many of these competitors have significantly greater experience and resources than the Company in undertaking clinical trials and other regulatory approval procedures, as well as in marketing and achieving manufacturing efficiencies. There are also small companies, academic institutions, governmental agencies and other research organizations that are conducting research in the area of osteoporosis and other collagen-related diseases. These entities are becoming increasingly aware of the commercial value of their findings and more active in seeking patent and other proprietary rights, as well as licensing revenues. The Company s competitors may develop technologies and products that are available for sale prior to the Company s products or at a lower cost or with better technical characteristics rendering the Company s products less competitive.

Dependence on Therapeutics Developed by Others

Acceptance of and demand for the Company s diagnostic products will be affected by the need perceived by physicians to diagnose bone, cartilage and connective tissue disorders for the purposes of treatment. There are currently a limited number of therapies that are effective in preventing osteoporosis or other bone, cartilage or connective tissue disorders, or in treating these disorders once diagnosed. In the event new therapies do or do not receive regulatory approval or experience delayed market acceptance, the Company could be adversely affected. Unfavorable publicity concerning a product of the Company or therapeutic products for osteoporosis could also have an adverse effect on the Company s ability to obtain regulatory approvals or to achieve market acceptance.

Uncertainty of Market Acceptance

The Company s lead product, the Osteomark test, became commercially available in May 1995 in the U.S., but sales have not been significant enough to generate net income. There can be no assurance that the Company s Osteomark test or any of its other products will gain widespread acceptance from the medical community, clinical or hospital laboratories, pharmaceutical companies, physicians or patients as readily as

other forms of diagnosis or any newly developed diagnostic. There can be no assurance that the Company will be able to develop significant market share for its products or maintain or increase its market share. The inability of the Company to achieve further market acceptance for its products would have a material adverse effect on the Company s business, financial condition and results of operation.

Dependence on Core Technology; Uncertainty of Adaptation to Different Formats

The Company currently relies exclusively upon its core technology for the development of diagnostic products associated with osteoporosis and other collagen-related diseases. There can be no assurance that competitors of the Company will not be successful in developing new or more efficient or cost-effective diagnostics that are more readily accepted than the Company s products. The Company has ongoing, additional development to adapt its core technology to different formats, instruments and other delivery platforms that currently exist or may be developed. In particular, additional research and development will be required to adapt its core technology to high-speed, high-volume automated instruments typically used in large clinical laboratories or companies through which the Company may seek to expand the market for its products. There can be no assurance that the Company will be successful in adapting and further developing its core technology to meet such needs. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Osteomark test or future products based upon the Company s core technology. The failure to adapt the Company s core technology to different formats, instruments, and other delivery platforms, or otherwise to commercialize such core technology, would have a material adverse effect on the Company s business, financial condition, and results of operation.

Reliance on Collaborative Agreements and Certain Relationships

The Company has entered into collaborative, distribution or co-promotional agreements, arrangements, or programs with several partners, including, among others, Johnson & Johnson, Mochida, Procter & Gamble, Aventis Pharmaceuticals and Quest Diagnostics Incorporated. The level of each partner s involvement and support and the amount and timing of resources they will give or the amount of product they will purchase from the Company under these agreements, arrangements, or programs are not within the control of the Company and can significantly impact the Company s ability to achieve its objectives. There can be no assurance that these collaborators will perform their contractual or otherwise obligations as expected or that the Company will derive revenue from such arrangements. Moreover, the agreements or business could be terminated. The Company expects to rely on these and additional agreements, arrangements, or programs to develop and commercialize and sell its present and future products. There can be no assurance that the Company will be able to negotiate acceptable agreements in the future or that such new agreements or existing agreements will be successful. If any collaborator breaches or terminates its agreement, or fails to conduct its collaborative activities in a timely manner, the commercialization of existing and future products could be slowed down or blocked completely. Disputes may arise between the Company and its collaborators on a variety of matters, including financial or other obligations under the business relationships between the companies. These disputes may be both expensive and time consuming and may result in delays in the development and commercialization of the Company s products.

Limited Marketing and Distribution Experience

The Company has limited marketing and distribution experience. To market any of its products directly, the Company must develop and implement a substantial marketing and sales effort with technical expertise and supporting distribution capability. The Company intends to continue to market and sell its products in the U.S. through research and clinical laboratories, distributors, and business arrangements and sell its products in other markets through distributors and pharmaceutical companies. There can be no assurance that the Company will be able to establish effective marketing and distribution capabilities or that its collaborators will be successful in gaining market acceptance for the Company s products or that the Company will achieve or maintain significant market share for its products.

Limited Manufacturing Experience

The Company has, through an agreement with Metrika, developed an adaptation of its core technology for use in physicians offices, called the Osteomark NTx Point-of-Care device. Through December 2001, the Company has depended upon the efforts of Metrika for the production of the Osteomark NTx Point-of-Care device. In 2002, the Company expects to begin manufacturing the Osteomark NTx Point-of-Care device for sale itself, but will continue to rely on Metrika for supply of certain components. The Company has limited manufacturing experience with a product like the Osteomark NTx Point-of-Care device. Although the Company believes that its manufacturing facility will be capable of producing commercial-scale quantities of the Osteomark product, if the Company is unable to manufacture this and other products in a cost-effective manner, it will not become profitable. The Company is currently producing and testing certain critical components for the NTx Point-of-Care device. The NTx Point-of-Care device will not be available for sale from the Company s new facility until these critical components can be produced in significant quantities with consistent quality. The Company currently has purchase orders for the NTx Point-of-Care device from customers that had bought the device in the past when Metrika was manufacturing and supplying the NTx Point-of-Care device to Ostex. These orders are currently on back order until the Company produces NTx Point-of-Care devices that are available for sale. There can be no assurances given related to the Company s ability to successfully manufacture certain critical components for the NTx Point-of-Care device, or the device itself, or that the Company will be able to supply enough devices to meet the initial and future market demand for the device. Interruptions in the manufacturing process or the availability of raw materials could delay or prevent the commercial marketing of the Osteomark NTx Point-of-Care device, which could have a material adverse effect on the Company s results of operations.

Dependence on Licensed Patents and Proprietary Rights

The Company s success depends, in large part, on its current and future patent position relating to its core technology. The Company s patent position involves complex legal and factual questions. The Company is the exclusive licensee of certain patents within and outside of the U.S. relating to the Company s core technology. Claims made under patent applications may be denied or significantly narrowed, and issued patents may not provide significant commercial protection to the Company. There is no assurance that the Company s patents will not be successfully challenged or circumvented by others. The Company could incur substantial costs in proceedings before the U.S. Patent Office, including interference proceedings. These proceedings could also result in adverse decisions as to the patentability of the Company s licensed or assigned inventions. There can be no assurance that the Company s products do not or will not infringe on the patent or proprietary rights of others. The Company may be required to obtain additional licenses to the patents or other proprietary rights of others. The Company may also require licenses from the inventors of certain processes, technologies and assay formats in order to successfully market certain products. There can be no assurance that any such licenses would be made available on terms acceptable to the Company, if at all. If the Company needs and cannot or does not obtain such licenses, it could encounter delays in product introductions or may have to stop selling existing products while it attempts to circumvent such patents, assuming that is possible, or the development, manufacture, or sale of products requiring such licenses could be precluded. The Company believes there will continue to be significant litigation in the industry regarding patent and other intellectual property rights.

The Company is aware of competitors that are developing and selling products that may be covered by claims made in patents or patent applications of the Company. Because certain foreign patents are subject to third-party opposition following the date of grant of such patents, there can be no assurance that claims of the Company s foreign patents, once granted, will survive such opposition without cancellation or significant modification. Because U.S. applications are confidential until a patent issues, the Company cannot be assured that its patent claims have priority in the U.S. or will be entitled to patent protection.

The Company also relies on trade secrets and other unpatented proprietary technology. No assurance can be given that the Company can meaningfully protect its rights in such unpatented technology or that others will not independently develop substantially equivalent products and processes or otherwise gain access to the Company s technology. The Company seeks to protect its trade secrets and proprietary know-how, in

part, with confidentiality agreements with its employees and consultants. There can be no assurance that these agreements will not be breached, that the Company will have adequate remedies for any breach, or

that the Company s trade secrets will not otherwise become known or be independently developed by competitors.

The cost to the Company of any litigation or other proceedings relating to intellectual property rights, even if resolved in the Company s favor, could be substantial. Some of the Company s competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources.

Product Liability Claims in Excess of the Amount of Insurance Would Adversely Affect Financial Condition.

The testing, manufacturing, marketing and sale of the Company s products may subject us to product liability claims. The Company maintains coverage against product liability risks up to a $2 million aggregate limit. However, continuing insurance coverage may not be available at an acceptable cost, if at all. The Company may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to its reputation, withdrawal of clinical trial volunteers and loss of revenues. As a result, regardless of whether the Company is insured, a product liability claim or product recall may result in losses that could be material.

Limited Suppliers

The majority of the raw materials and purchased components used to manufacture the Company s products are readily available. However, certain of these materials, such as solid phase membranes and electronics modules for the Company s NTx Point-of-Care device, are from a sole supplier or a limited group of suppliers. There can be no assurance that the Company s reliance on these suppliers will not result in problems with product supply. Interruptions in the availability of products could have a material adverse effect on the Company s results of operations.

Uncertainty of Healthcare Reimbursement

The Company s ability to commercialize its products will depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from third-party payors, such as government health administration authorities, private health coverage insurers and other organizations. The status of the scope of healthcare programs worldwide is uncertain and there can be no assurance that adequate third-party coverage will be available for the Company to maintain price levels sufficient for realization of an appropriate return on its investment in product development. Third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. There can be no assurance that the Company s existing or any future products will provide sufficient value or be considered cost effective and that reimbursement to the consumer will be available or sufficient to allow the Company to sell its products on a competitive basis.

Volatility of Stock Price

The volatility of the Company s stock price has been significant since it first became publicly traded in January 1995. The stock market may experience significant price and volume fluctuations unrelated to the operating performance of particular companies. Factors such as any loss of key management, the results of the Company s clinical trials or those of its competitors, adverse regulatory actions or decisions, evidence regarding the safety or efficacy of the Company s products or those of its competitors, announcements of technological innovations or new products by the Company or its competitors, governmental regulation, developments with respect to patents or other proprietary rights, product or patent litigation or public concern as to the safety of products developed by the Company may have a volatile effect on the market price of the Company s stock. The realization of any of the risks described in this report, as well as other factors, could have a material adverse

impact on the market price of the Company s Common Stock and may result in loss of some or all of your investment.

In the past, securities class action litigation has often been brought against companies following periods of volatility in their stock prices. The Company may in the future be the target of similar litigation. Securities litigation could result in substantial costs and divert management s time and resources, which could cause the Company s business to suffer.

Item 1B. Executive Officers of the Registrant

The executive officers of the Company and their ages are as follows:

Name	Age	Position
Thomas A. Bologna	53	Chairman, President and Chief Executive Officer
Thomas F. Broderick	53	Vice President, Patent and General Counsel
J. Daniel Clemens	45	Vice President, Product Development
Michael C. Perry	57	Vice President, Sales and Marketing
Reed Simmons	49	Vice President, Operations

Johannes (Hans) van Houte	36	Vice President, Finance

There are no family relationships between any executive officers of the Company.

Thomas A. Bologna joined the Company in July 1997 as the President and Chief Executive Officer and as a member of the Board of Directors and in April 1999, he was appointed Chairman of the Board of Directors. From January 1996 to July 1997, Mr. Bologna was a principal in Healthcare Venture Associates, a consulting firm. From January 1994 to January 1996, Mr. Bologna was President and Chief Executive Officer for Scriptgen Pharmaceuticals, Inc., a biotechnology company with proprietary drug screening technology that is developing orally active drugs to regulate gene expression, and from July 1987 to January 1994, Mr. Bologna was Chairman of the Board of Directors, President and Chief Executive Officer of Gen-Probe Incorporated, a biotechnology company commercializing genetic-probe-based technology for diagnostic and therapeutic applications. Prior to Gen-Probe, Mr. Bologna held several senior level positions with Becton, Dickinson and Company and Warner-Lambert Company. At Becton, Dickinson and Company, he served as President of the Diagnostic Instrument Systems Division, President of the Johnston Laboratories Division, and Vice President and General Manager of the Hynson, Wescott & Dunning biotechnology unit. At Warner-Lambert Company, he served as a Vice President responsible for the marketing, sales and R&D functions, as well as the Asia/Pacific profit center for the Scientific Instrument Division. Mr. Bologna serves on the Board of Directors for LeonardoMD Corporation. Mr. Bologna received an M.B.A. and a B.S. from New York University.

Thomas F. Broderick was named the Vice President, Patent and General Counsel in November 1997. Mr. Broderick was Vice President, Intellectual Property from March 1997 to November 1997 and was Patent Counsel for the Company from April 1996 to March 1997. From 1989 to March 1996, Mr. Broderick was a partner at the patent law firm of Christensen, O Connor, Johnson & Kindness in Seattle, Washington.

J. Daniel Clemens was named the Vice President, Product Development in September 1998. Mr. Clemens was Director of Research & Development for the Company from May 1992 to September 1998 and Manager of Product Development from October 1990 to May 1992. Prior to joining the Company, Mr. Clemens was Senior Research & Development Scientist from February 1987 to October 1990 at Genetic Systems Corporation/Sanofi.

Michael C. Perry joined the Company in February 2000 as Vice President, Sales and Marketing. Prior to joining the Company, Mr. Perry was National Sales Manager for Sarstedt, Inc., a manufacturer of high quality plastic products for the clinical and research markets, from September 1996 to January 2000. Prior to Sarstedt, Mr. Perry was with Organon Teknika Corporation for over 20 years.

Reed Simmons joined the Company in 2002 as Vice President, Operations. Mr. Simmons has over 25 years of biomedical and biotechnology experience including manufacturing and operational management positions for divisions of pharmaceutical companies Smith-Kline Beckman and Bristol-Myers Squibb. From 1993 - 1999 Mr. Simmons was Vice President and General Manager of a U.S. operating division of Sanofi-Synthelabo S.A. Prior to that, Mr. Simmons worked for Genetic Systems Corporation and helped to develop and commercialize that company s first products.

Hans van Houte joined the Company in 2001. Mr. van Houte has worked in finance and accounting for biotech and healthcare related companies for the past ten years. Prior to joining Ostex, Mr. van Houte was Director of Finance at HealthTalk Interactive and the former Controller and Treasurer for Vertex Pharmaceuticals Incorporated.

Item 2. Properties

The Company s research laboratories, manufacturing operations, and administrative offices are located in Seattle, Washington. The Company leases approximately 46,000 square feet of space under three separate lease agreements that expire in 2002, 2005, and 2010 respectively. The Seattle facilities have adequate capacity for the Company s present needs.

Item 3. Legal Proceedings

Information regarding legal proceedings is contained in Item 8 of this Annual Report on Form 10-K in the section entitled Notes to Financial Statements, under Note 9 - Litigation.

Item 4. Submission of Matters to a Vote of Security Holders

Not applicable.

PART II

Item 5. Market for Registrant s Common Equity and Related Shareholder Matters

Market Price of Common Stock

The Company s Common Stock is traded on the Nasdaq National Market® under the symbol OSTX. The following table lists the high and low trading prices for the Company s Common Stock as reported on the Nasdaq National Market.

2001	High	Low
1st quarter	$ 1.94	$ 1.03
2nd quarter	1.95	1.06
3rd quarter	3.15	1.22
4th quarter	$ 3.35	$ 1.76

2000	High	Low
1st quarter	$ 9.56	$ 2.75
2nd quarter	3.63	1.66
3rd quarter	3.00	1.63
4th quarter	$ 2.38	$ 1.00

The closing price of the Common Stock on December 31, 2001 was $2.50.

Holders of Common Stock

As of March 14, 2002, there were 12,558,174 shares of Common Stock outstanding held of record by approximately 109 shareholders. The Company believes there are approximately 3,800 additional owners of Common Stock who own shares held in street name.

Dividend Policy

The Company has never paid cash dividends and has no present intention of paying dividends in the foreseeable future.

Common Stock Warrant

During the period covered by this report on Form 10-K, the Company issued warrants to one outside consultant for the purchase of 14,000 shares of common stock, with exercise prices ranging from $1.46 - $2.85, in exchange for services to be provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. These warrants were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that the transaction did not involve a public offering.

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is Mellon Investor Services, LLC, Ridgefield Park, New Jersey.

Item 6. **Selected Financial Data**

FISCAL YEAR ENDED DECEMBER 31,	2001	2000	1999	1998	1997
		(in thousands, except share amounts)			
REVENUES:					
Product sales and research testing services	$ 5,734	$ 5,552	$ 4,732	$ 3,047	$ 3,658
License fees and research and development payments					450
Total revenues	5,734	5,552	4,732	3,047	4,108
COST OF PRODUCTS SOLD	2,278	1,858	1,130	814	899
GROSS MARGIN ON PRODUCT SALES	3,456	3,694	3,602	2,233	3,209
(Percentage of revenue)	60%	67%	76%	73%	78%
OPERATING EXPENSES:					
POC facility start-up costs	872	80			
Research and development	1,834	1,611	1,734	2,901	4,470
Selling, general and administrative	3,932	4,568	3,831	8,122	8,031
Total operating expenses	6,638	6,259	5,565	11,023	12,501
Loss from operations	(3,182)	(2,565)	(1,963)	(8,790)	(9,292)
OTHER INCOME:					
Proceeds from legal settlement		152			6,200
Interest, net	83	396	393	695	828
Net Loss	$ (3,099)	$ (2,017)	$ (1,570)	$ (8,095)	$ (2,264)
Basic and diluted net loss per common and common equivalent share	$ (0.25)	$ (0.16)	$ (0.13)	$ (0.64)	$ (0.18)
Weighted average shares used in calculation of net loss per share	12,516	12,504	12,522	12,696	12,574

DECEMBER 31,	2001	2000	1999	1998	1997
			(in thousands)		
BALANCE SHEET DATA:					
Cash, cash equivalents and short-term investments	$ 3,827	$ 6,578	$ 8,400	$ 10,979	$ 18,965
Working capital	4,104	6,600	9,205	10,624	18,368
Total assets	9,635	12,311	12,297	15,065	24,112
Accumulated deficit	(38,909)	(35,810)	(33,793)	(32,223)	(24,128)
Total shareholders equity	$ 6,932	$ 9,906	$ 11,709	$ 13,488	$ 21,644

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

Results Of Operations

Years Ended December 31, 2001, 2000, 1999. The Company had total revenues of $5,734,000 for the year ending December 31, 2001, as compared to $5,552,000 and $4,732,000 for the years ended December 31, 2000 and 1999, respectively. Revenue is primarily comprised of sales of the Company s products which are recognized only upon shipment. The increase of $182,000 in 2001 compared to 2000 revenue is attributable to an increase in sales for the Osteomark NTx Point-of-Care Device. During 2001, the Company sold over 35,000 devices to Procter & Gamble and Aventis Pharmaceuticals, as compared to over 24,000 in 2000, to be used in marketing programs worldwide to test using the device with their osteoporosis drug, Actonel. The increase in revenue of $820,000 in 2000 compared to 1999 is attributable to higher volumes of serum kits, increased shipments of urine kits to Mochida, and the introduction of the Osteomark NTx Point-of-Care device.

The Company s cost of products sold totaled $2,278,000 for the year ended December 31, 2001, as compared to $1,858,000 and $1,130,000 for the same periods in 2000 and 1999, respectively. The gross margin rate on product sales for the year ended 2001 was 60% as compared to 67% in 2000 and 76% for 1999. The decrease in gross margin rate from 2000 to 2001 was due in part to increased sales of the NTx Point-of-Care device. In addition, there were certain inventory adjustments made in the first quarter of 2000, which resulted in a 91% margin in that quarter that affected the annual margin. The decrease in gross margin rate from 1999 to 2000 was primarily due to product mix regarding the launch of the NTx Point-of-Care device in 2000.

The Company s research and development expenditures totaled $1,834,000, $1,611,000, and $1,734,000 in 2001, 2000, and 1999, respectively. The $223,000 increase from 2000 to 2001 was driven by personnel costs and professional fees associated with the NTx Point-of-Care device including clinical trials related to seeking approval for CLIA Waiver and Rx Home-Use. The $123,000 decrease from 1999 to 2000 resulted from the conclusion of one of the research grants to the University of Washington.

Selling, general and administrative expenses totaled $3,932,000, $4,568,000, and $3,831,000 in 2001, 2000, and 1999, respectively. Expenses decreased by $636,000 in 2001 from 2000 primarily due to the reduction of the sales force and marketing related expenditures for the urine and serum kit products. The $737,000 increase in 2000 compared to 1999, was due primarily to higher wages, professional service fees, and marketing related expenditures related to launching the NTx Point-of-Care device.

The Company also incurred start-up costs for its new Point-of-Care facility that totaled $872,000 in 2001 as compared to $80,000 in 2000. In 2000, the Company decided to lease space on a long-term basis and build out its own facility to manufacture the NTx Point-of-Care device. The transfer of technology from Metrika, its third party vendor and initial manufacturer of the device, began towards the end of 2000 and the Company leased new space at the same time. The expense in 2001 relates to the facility operating costs, which include higher depreciation expense related to the build out of the new facility, labor and material costs to validate the facility, and production validation runs or pilot lots of the NTx Point-of-Care device. The Company expects it will continue to incur these costs in the first quarter of 2002 as production is increased and component parts are also manufactured at the Company s Point-of-Care manufacturing facility. Once that occurs, devices fully manufactured in the Company s facility will be available for sale and the cost of those devices will be expensed through cost of goods sold.

Other income totaled $83,000, $548,000, and $393,000 for the years ended December 31, 2001, 2000, and 1999, respectively. The $465,000 decrease in 2001 as compared to 2000 is a result of less interest income due to lower balances of cash and short-term investments, lower interest rates in 2001 versus 2000, and higher interest expense related to $2,316,000 in debt draw downs from Transamerica Business Credit Corporation for the Point-of-Care facility build-out, and in 2002, the Company recognized $152,000 of the one-time settlement fee by Osteometer Biotech A/S (Osteometer) related to the settlement of the lawsuit between Osteometer and the Company (see Note 9 - Litigation, to the accompanying financial statements). The increase from 1999 to 2000 was driven by the same $152,000 of the one-time settlement fee paid.

At December 31, 2001, the Company had tax net operating loss carryforwards of approximately $42,523,000, which will begin to expire in 2004. Income taxes are provided in the Statements of Operations as required by Statement of Financial Accounting Standards No. 109, Accounting For Income Taxes (SFAS No. 109). Under SFAS No. 109, deferred taxes are determined using an asset and liability approach. The Company has determined that the tax assets do not satisfy the recognition criteria set forth in SFAS No. 109. Accordingly, a valuation allowance has been recorded against the applicable deferred tax assets, and therefore no tax benefit has been recorded.

Net operating loss carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may be limited, in the event of certain cumulative changes in excess of 50% in ownership interests of significant shareholders over a three-year period.

Critical Accounting Policies

We have identified the most critical accounting policies used in the preparation of our financial statements by considering accounting policies that involve the most complex or subjective decisions or assessments. Our most critical accounting policies relate to revenue recognition, products returns and the carrying value of the investment in Metrika.

The Company s revenue recognition policies are based on the requirements of Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. Revenue is recorded when earned and for product sales upon shipment. Any payments received prior to revenue recognition are deferred.

Returns of product to date have been warranty related and insignificant; however, with the ramp up in our new manufacturing facility for the NTx Point-of-Care devices, there is a risk that returns in the future could increase. Should this occur, the Company s revenues could be impacted by an increase in the return provision.

The Company records its investment in Metrika at the lower of cost or market. Should market conditions result in a decline in the value of our investment to below our carrying value, the Company would have to record a loss resulting from the impairment of this investment.

Liquidity And Capital Resources

As of December 31, 2001, the Company had $3,827,000 in cash and cash equivalents and short-term investments, working capital of $4,104,000 and total shareholders equity of $6,932,000. During 2001, cash and cash equivalents and short-term investments decreased by $2,751,000, working capital decreased by $2,496,000, and shareholders equity decreased by $2,974,000. The decreases were primarily the result of the net loss incurred during 2001.

The Company used $2,995,000 of cash for operating activities in 2001. The Company used $582,000 in 2001 and $2,031,000 in 2000 for the purchase of leasehold improvements, manufacturing and office equipment, which were purchased primarily for the build out of the Company s

new manufacturing facility for production of the NTx Point-of-Care device. Inventory increased from $465,000 in 2000 to $994,000 in 2001 primarily due to the purchase in 2001 of component parts for the NTx Point-of-Care device. Inventories are stated at the lower of cost or market. In 2000, the Company entered into an agreement that provided up to $2,800,000 in debt financing for the new manufacturing facility and borrowed $1,228,000 during 2001 and $1,088,000 during 2000. As of December 31, 2001, outstanding borrowings under this agreement were $1,773,000. The Company has no further availability under this financing as of December 31, 2001. Also during 2001, the Company repurchased on the open market 14,000 shares of common stock at a total cost of $19,000 and issued 85,000 shares of common stock related to the exercise of stock options and warrants, receiving $59,000 in proceeds.

The following table summarizes the Company s contractual obligations and other commercial commitments as of December 31, 2001, and the effect such obligations and commitments are expected to have on liquidity for future periods. Long term debt payments include interest as well as principle.

Contractual obligations	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long-term debt	$ 2,125,000	$ 849,000	$ 1,276,000	$	$
Operating leases	3,020,000	669,000	1,855,000	208,000	288,000
Total cash obligations	$ 5,145,000	$ 1,518,000	$ 3,131,000	$ 208,000	$ 288,000

The Company s future capital requirements depend upon many factors, including the effectiveness of the Osteomark NTx Serum, Urine, and Point-of-Care commercialization, production and delivery activities and arrangements; continued scientific progress in its research and development programs; the costs involved in filing, prosecuting, and enforcing patent claims; the manufacturing needs for new and existing products; the time and costs involved in obtaining regulatory approvals, as well as other factors discussed in the section entitled Risk Factors above. Additional funds from equity or debt financing may be required especially as it relates to the manufacturing scale up of the NTx Point-of-Care device and uncertainty related to the timing of final production validation, market acceptance and demand for the product. There can be no assurance that such additional funds will be available on favorable terms, if at all. The Company may seek to raise additional capital if conditions in the public equity markets are favorable or through private placements, even if the Company does not have an immediate need for additional cash at that time. If additional financing is not available, the Company believes that its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales and interest income from short-term investments will be adequate to fund operations through at least the first quarter of 2003.

Other Factors That May Affect Operating Results

The Company s operating results may fluctuate due to a number of factors including, but not limited to, cost, volume and timing of product sales, pricing, market acceptance of the Company s products, changing economic conditions, actions of competitors, delays and increased costs of product and technology development, manufacturing performance, the Company s ability to develop and maintain collaborative arrangements, the outcome of litigation, and the effect of the Company s accounting policies and other risk factors detailed in this report and other Commission filings. All of the foregoing factors are difficult for the Company to predict and could materially and adversely affect the Company s business and operating results.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. The Company s exposure to market rate risk, as a result of changes in interest rates, relates primarily to its investment portfolio. At December 31, 2001, the Company held $1.3 million in cash and cash equivalents and $2.5 million in federal and government agency obligations. Although the Company holds both fixed and adjustable rate investments and each carry a certain degree of interest rate risk, the Company does not consider this risk to be. Additionally, at December 31, 2002 the Company had $1,773,000 of notes payable. While fluctuations in interest rates may affect the fair value of this debt, the Company s debt payments will not be effected due to fixed interest rates on this debt.

Currency risk. The Company conducts all financial transactions in U.S. currency. However, currency fluctuations may impact a foreign customer s ability to meet its payment obligations and/or future product pricing to that customer. Based upon the Company s credit authorization policy, current economic conditions in countries in which the Company does significant business, and the level of outstanding foreign receivables, the Company does not consider

this risk to be material.

Item 8. Financial Statements and Supplementary Data

Report of Independent Public Accountants

To the Shareholders of Ostex International, Inc.:

We have audited the accompanying balance sheets of Ostex International, Inc. (a Washington corporation) as of December 31, 2001 and 2000, and the related statements of operations, shareholders equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the 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 Ostex International, Inc. as of December 31, 2001 and 2000 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Seattle, Washington
January 31, 2002

OSTEX INTERNATIONAL, INC.

BALANCE SHEETS

December 31,	2001	2000
	(in thousands, except share and per share amounts)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,284	$ 1,348
Short-term investments	2,543	5,230
Trade receivables, net of allowance of $54 in 2001 and $55 in 2000	815	1,072
Inventory	994	465
Other current assets	33	122
Total current assets	5,669	8,237
Property, plant and equipment, net	3,272	3,413
Other assets	694	661
Total assets	$ 9,635	$ 12,311
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 279	$ 988
Customer deposits	156	
Accrued expenses	495	364
Current portion of note payable	635	285
Total current liabilities	1,565	1,637
Noncurrent Liabilities		
Note payable, net of current portion	1,138	768
Commitments and Contingencies (see Note 9)		
Shareholders Equity:		
Common stock, $.01 par value, 50,000,000 authorized;		
12,558,174 and 12,487,047 issued and outstanding at December 31, 2001 and 2000, respectively	126	125
Additional paid-in capital	45,709	45,651
Accumulated other comprehensive income (loss)	6	(60)
Accumulated deficit	(38,909)	(35,810)
Total shareholders equity	6,932	9,906
Total liabilities and shareholders equity	$ 9,635	$ 12,311

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

OSTEX INTERNATIONAL, INC.

STATEMENTS OF OPERATIONS

YEAR ENDED DECEMBER 31,	2001	2000	1999
	(in thousands, except per share amounts)		
REVENUE	$ 5,734	$ 5,552	$ 4,732
Cost of products sold	2,278	1,858	1,130
Gross margin	3,456	3,694	3,602
(Percentage of revenue)	60%	67%	76%
OPERATING EXPENSES:			
POC facility start-up costs	872	80	
Research and development	1,834	1,611	1,734
Selling, general and administrative	3,932	4,568	3,831
Total operating expenses	6,638	6,259	5,565
Loss from operations	(3,182)	(2,565)	(1,963)
OTHER INCOME:			
Proceeds from legal settlement		152	
Interest, net	83	396	393
Net loss	$ (3,099)	$ (2,017)	$ (1,570)
Basic and diluted net loss per common and common equivalent share	$ (0.25)	$ (0.16)	$ (0.13)
Weighted average shares used in calculation of net loss per share	12,516	12,504	12,522

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

OSTEX INTERNATIONAL, INC.

STATEMENTS OF CASH FLOWS

YEAR ENDED DECEMBER 31,	2001	2000	1999
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (3,099)	$ (2,017)	$ (1,570)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	721	496	553
Loss on disposal of property, plant and equipment	2	27	
Expense from issuance of warrants	19	105	134
Changes in current assets and current liabilities			
Trade receivables	257	(114)	(284)
Inventory	(529)	(214)	(4)
Other assets	56		
Accounts payable	(709)	710	(279)
Customer deposits	156		
Accrued expenses	131	169	(501)
Net cash used in operating activities	(2,995)	(838)	(1,951)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of short-term investments	(1,213)	(5,288)	(5,801)
Proceeds from sales and maturities of short-term investments	3,966	6,953	7,139
Purchase of property, plant and equipment	(582)	(2,031)	(76)
Net cash provided by (used in) investing activities	2,171	(366)	1,262
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of common stock and exercise of stock options	59	126	2
Stock repurchases	(19)	(74)	(286)
Proceeds from note payable	1,228	1,088	
Payments on note payable	(508)	(150)	(209)
Net cash provided by (used in) financing activities	760	990	(493)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(64)	(214)	(1,182)
CASH AND CASH EQUIVALENTS, beginning of period	1,348	1,562	2,744
CASH AND CASH EQUIVALENTS, end of period	$ 1,284	$ 1,348	$ 1,562
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Interest paid on notes payable	$ 212	$ 10	$ 28
SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITES:			

Warrants issued to lender	$		$	62	$

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

OSTEX INTERNATIONAL, INC.

STATEMENTS OF SHAREHOLDERS EQUITY

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	Comprehensive	Total Shareholders
	Shares	Amount	Capital	(Loss)	Deficit	Loss	Equity
				(in thousands)			
Balance, December 31, 1998	12,696	$ 127	$ 45,642	$ (58)	$ (32,223)		$ 13,488
Warrants issued to outside consultants			134				134
Stock options exercised	18		2				2
Stock repurchases	(245)	(2)	(284)				(286)
Comprehensive loss							
Unrealized loss on short-term investments				(59)		(59)	(59)
Net loss					(1,570)	(1,570)	(1,570)
Comprehensive loss						(1,629)	
Balance, December 31, 1999	12,469	$ 125	$ 45,494	$ (117)	$ (33,793)		$ 11,709
Warrants issued to outside consultants			105				105
Stock options exercised	61	1	125				126
Stock repurchases	(43)	(1)	(73)				(74)
Comprehensive loss							
Unrealized gain on short-term investments				57		57	57
Net loss					(2,017)	(2,017)	(2,017)
Comprehensive loss						(1,960)	
Balance, December 31, 2000	12,487	$ 125	$ 45,651	$ (60)	$ (35,810)		$ 9,906
Warrants issued to outside consultants			19				19
Stock options exercised	85	1	58				59
Stock repurchases	(14)		(19)				(19)
Comprehensive loss							
Unrealized gain on short-term investments				66		66	66
Net loss					(3,099)	(3,099)	(3,099)
Comprehensive loss						(3,033)	
Balance, December 31, 2001	12,558	$ 126	$ 45,709	$ 6	$ (38,909)		$ 6,932

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

Notes to Financial Statements

Note 1 - Organization And Summary Of Significant Accounting Policies

Organization

Ostex International, Inc. (the Company), a Washington corporation incorporated in May 1989, develops and commercializes products to make disease management a reality with osteoporosis being the first area of focus. The Company s products, the Osteomark NTx Serum and Urine kits and the Osteomark NTx Point-of-Care Device (the NTx Point-of-Care), incorporate breakthrough and patented technology for the management and prevention of osteoporosis. The Company markets the Osteomark NTx tests through distributors, medical laboratories, pharmaceutical and healthcare companies. The Company has incurred operating losses since its inception and has funded its operations primarily through existing cash and the sale of its urine and serum kits and its NTx Point-of-Care device. As the Company ramps up the manufacturing of the NTx Point-of-Care device, there can be no assurance that it will be able to produce enough devices to meet the initial demand or as to what the demand for this product will be in 2002 and beyond. The Company may require additional sources of capital in the future if the Company continues to generate operating losses throughout 2002.

Estimates And Uncertainties

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

Product sales are recognized when pervasive evidence of an arrangement exists, delivery has occurred, the fee if fixed and collectability is probable. Research testing fees are recognized when the services are substantially complete. License fees and research and development payments are recognized upon attainment of the agreed upon milestones. Cash payments received in advance of meeting the revenue recognition criteria are deferred and stated as customer deposits. Returns of product to date have been warranty related and insignificant.

Research And Development Expenses

Research and development costs are expensed as incurred.

Point-of-Care Facility Start-up Costs

Point-of-Care facility start-up costs are related to the operation and validation of the Company s new facility, tooling, and production. These costs are expensed as incurred.

Cash And Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. The carrying amount approximates fair value due to the short maturities of these investments.

Short-Term Investments

The Company considers all of its short-term investments to be available for sale, reporting them at fair market value with unrealized gains and losses included as a component of comprehensive income (loss) in shareholders equity. Realized gains and losses and declines in value of securities judged to be other than temporary are included in interest income. Contractual maturities range from one to 28 years.

Segments

Management has determined that the Company has one business segment the manufacturing and distribution of test products used in the treatment of osteoporosis.

Concentration Of Credit Risk

Trade receivables potentially subject the Company to credit risk. The Company extends credit to its customers based upon an evaluation of the customer s financial condition and credit history and generally does not require collateral. The Company historically has incurred minimal credit losses. In 2001, domestic product sales accounted for 65% of total revenue and product sales to foreign countries accounted for 35% of total revenue. Accounts receivable for the same year is comprised of 63% domestic and 37% foreign receivables.

The following table summarizes the number of customers that individually comprise greater than 10% of total revenues in each of the years listed and their aggregate percentage of the Company s total revenues:

	Number of Significant	Percentage of Total Revenues		
Year ended December 31,	Customers	A	B	C
1999	2	14%	13%	%
2000	3	10%	14%	10%
2001	3	16%	11%	11%

The following table summarizes the number of customers that individually comprise greater than 10% of net receivables and their aggregate percentage of the Company s total net receivables:

	Number of Significant	Percentage of Net Receivables		
December 31,	Customers	A	B	C
1999	2	18%	11%	%
2000	2	19%	%	14%
2001	2	30%	%	13%

Inventory

Inventory consists principally of raw materials and finished goods. Inventories are stated at the lower of cost (first-in, first-out) or market. Cost is computed using standard costs which approximate actual cost plus certain manufacturing overhead amounts.

Property, Plant And Equipment

Property, plant and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of their useful lives or the lease term. Estimated lives range from five to ten years. Depreciation and amortization expense during 2001, 2000, and 1999 was $721,000, $496,000, and $553,000, respectively. The Company assesses potential impairment of its long-lived assets when there is evidence that events or changes in circumstances have made recovery of the assets carrying value unlikely.

Comprehensive Income

The Company has adopted Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, which establishes standards for reporting and disclosure of comprehensive income (loss). Disclosure has been made for all years presented in the statements of shareholders equity.

Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares outstanding during the period. Diluted net loss per share excludes the impact of dilutive, potential common shares outstanding (consisting of stock options and warrants) as their effect would be antidilutive in all periods presented.

Recently Issued Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 141, Business Combinations (SFAS No. 141) and Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets (SFAS No. 142). SFAS No. 141 requires business combinations initiated after June 30, 2001, to be accounted for using the purchase method of accounting and broadens the criteria for recording intangible assets separate from goodwill. SFAS No. 142 requires the use of a no amortization approach to account for purchased goodwill and certain intangibles. The Company does not have any recorded goodwill or other intangibles.

In June 2001, the FASB issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations (SFAS No. 143) (effective for the Company on January 1, 2003). This statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company is in the process of evaluating the financial statement impact of the adoption of SFAS No. 143.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144) (effective for the Company on January 1, 2002). This statement supersedes Statement of Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of and Accounting Principles Board Opinion No. 30, Reporting the Results of Operations? Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions. The Company is in the process of evaluating the financial statement impact of SFAS No. 144.

Reclassification

Certain reclassifications have been made to prior year amounts to conform to the current presentation.

Note 2 - Short-Term Investments

The Company s short-term investments at December 31, 2001 and 2000 consisted of the following:

	2001	2000
Federal agency obligations	$ 1,580,000	$ 3,466,000
Government agency obligations	963,000	1,764,000
	$ 2,543,000	$ 5,230,000

Note 3 - Property, Plant And Equipment

Property, plant and equipment at December 31, 2001 and 2000 consisted of the following:

	2001	2000
Leasehold improvements	$ 4,058,000	$ 2,405,000
Laboratory and manufacturing equipment	1,909,000	1,431,000
Computers and office equipment	1,370,000	1,037,000
Construction-in-progress		1,898,000
	7,337,000	6,771,000
Accumulated depreciation and amortization	(4,065,000)	(3,358,000)
Net property, plant and equipment	$ 3,272,000	$ 3,413,000

Note 4 - Other Assets

Other assets primarily represent a $599,000 investment in preferred stock of Metrika, Inc. (Metrika). The investment is recorded in the accompanying financial statements at cost and represents an ownership interest of less than 5%. The Company periodically assesses the valuation of this asset based on historical financial data, valuations made during additional investment rounds, and future projections. Management currently believes that the investment is not impaired. However, given the nature of the business, there is a risk that the investment may become impaired in the future.

Note 5 - Note Payable

On October 2, 2000, the Company and Transamerica Business Credit Corporation (Transamerica) signed a letter of commitment whereby Transamerica will provide up to $2.8 million in debt financing for the Company s manufacturing expansion plan. Each draw down is on a separate note, secured by real property and equipment, payable in 36 monthly installments with a balloon payment at the end of the term. These notes have due dates ranging from November 2003 to January 2005. As of December 31, 2001, the Company has received $2,316,000 in proceeds under six separate note agreements, with a balance due of $1,773,000. The annual interest rate under the six notes is fixed at approximately 14.5%. The Company has no further availability under this financing as of December 31, 2001. The Company believes that the carrying value of the debt approximates the fair value of this debt.

Principal payments under the notes are as follows:

2002	$	635,000
2003		837,000
2004		276,000
2005		25,000
Total principal due on notes	$	1,773,000

Interest expense was $212,000 in 2001 and $10,000 in 2000.

Note 6 - Shareholders Equity

Stock Option Plans

The Company has three stock option plans: the Amended and Restated Stock Option Plan (the Old Plan), the 1994 Stock Option Plan (the 1994 Plan), both administered by the Compensation Committee of the Board of Directors, and the Directors Nonqualified Stock Option Plan (the Directors Plan), (collectively the Stock Option Plans). The Old Plan no longer permits additional stock option grants.

Shares of common stock reserved for issuance to the Company s employees and directors under the 1994 Plan and the Directors Plan are 3,000,000 and 600,000, respectively. Shares available for future grants under the 1994 Plan and the Directors Plan at December 31, 2001 are 598,000 and 230,000, respectively. These options generally vest ratably over three to four years. All options granted under the Stock Option Plans expire upon the earlier of 90 days after termination of employment or ten years from date of grant. Options are granted with exercise prices equal to or greater than fair market value at grant date.

Information relating to stock options outstanding and stock options exercisable at December 31, 2001 is as follows:

	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
RANGE OF EXERCISE PRICES	NUMBER OF SHARES	WEIGHTED AVERAGE REMAINING LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE
$ 0.08 - $ 1.90	1,009,722	8	$ 1.34	371,209	$ 1.18
$ 2.00 - $ 4.75	1,687,670	6	$ 2.87	1,369,158	$ 2.99
$ 5.00 - $ 17.13	57,612	2	$ 5.66	57,612	$ 5.66
	2,755,004	7	$ 2.43	1,797,979	$ 2.70

Information relating to stock options activity is as follows:

	2001		2000		1999	
	SHARES	WEIGHTED AVG. EXERCISE PRICE	SHARES	WEIGHTED AVG. EXERCISE PRICE	SHARES	WEIGHTED AVG. EXERCISE PRICE
Outstanding at beginning of period	2,524,910	$ 2.58	1,992,395	$ 2.68	1,836,087	$ 3.04
Granted	662,950	1.62	656,780	2.33	551,485	1.10
Exercised	(84,827)	0.70	(10,797)	2.45	(17,500)	0.11
Canceled	(328,029)	3.00	(113,468)	2.91	(377,677)	2.27
Outstanding at end of period	2,775,004	$ 2.37	2,524,910	$ 2.58	1,992,395	$ 2.68
Vested at end of period	1,797,979	$ 2.70	1,555,048	$ 2.83	1,159,074	$ 2.92
Weighted average fair value of options granted		$ 1.43		$ 2.06		$ 1.23

Options outstanding have weighted average remaining contractual lives of seven years at December 31, 2001 and 2000.

The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123). Accordingly, no compensation cost has been recognized for stock options issued at market value on the date of grant. Had compensation cost for the Company s Stock Option Plans been determined based on the fair value of the options at the grant date for awards in 2001, 2000, and 1999 consistent with the provisions of SFAS No. 123, the Company s net loss and net loss per common equivalent share would have changed to the pro forma amounts indicated below:

	2001	2000	1999
Net loss as reported	$ (3,099,000)	$ (2,017,000)	$ (1,570,000)
Net loss pro forma	$ (3,704,000)	$ (2,470,000)	$ (2,171,000)
Basic and diluted net loss per common and common equivalent share as reported	$ (0.25)	$ (0.16)	$ (0.13)
Basic and diluted net loss per common and common equivalent share pro forma	$ (0.30)	$ (0.20)	$ (0.17)

The fair value of each option grant is established on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for new grants in 2001: zero dividend yield; expected volatility of 135%; average risk-free interest rate of 3.5% and expected lives of five years. Assumptions for options granted in 2000 were: zero dividend yield; expected volatility of 134%; average risk-free interest rate of 5.5% and expected lives of five years. Assumptions for options granted in 1999 were: zero dividend yield; expected volatility of 129%; average risk-free interest rate of 6.0%; and expected lives of five years.

Common Stock Warrant

During 2001, the Company issued warrants to one outside consultant for the purchase of 14,000 shares of common stock, with exercise prices ranging from $1.46 - $2.85, in exchange for services to be provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. The Company recorded these warrants in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (EITF) Issue 98-16, which require that the fair value of the warrant be recognized as expense. Total expense recognized in 2001 related to these warrants was approximately $19,000.

During 2000, the Company issued warrants to two outside consultants for the purchase of 3,000 and 12,904 shares of common stock, each at an exercise price of $1.86, in exchange for services to be provided to the Company. Both warrants vest upon issuance, and expire five years and two years, respectively, from the grant date. The Company recorded these warrants in accordance with the provisions of SFAS No. 123 and

EITF Issue 98-16, which require that the fair value of the warrant be recognized as expense. Total expense recognized in 2000 related to these warrant was approximately $20,000.

Also during 2000, the Company issued a warrant to Transamerica for the purchase of 33,600 shares of common stock at an exercise price of $3.00 related to the debt financing agreement referenced in Note 5 above. These warrants are fully vested and expire in October 2005. The Company has provided for this warrant in accordance with the provisions of SFAS No. 123 and has recorded the fair value of the warrants as an asset to be amortized to interest expense.

During 1999, the Company issued a warrant to an outside consultant for the purchase of 100,000 shares of common stock at an exercise price of $2.00, in exchange for services to be provided to the Company. The warrant vests in twelve equal monthly installments beginning one month after the grant date, and expires three years from the grant date. The Company recorded this warrant in accordance with the provisions of SFAS No. 123 and EITF Issue 96-18, which require that the fair value of the warrant be recognized as expense, and that the fair value be remeasured at each balance sheet date (variable accounting). Total expense recognized in 2000 related to this warrant was approximately $23,000. Total expense recognized in 1999 was approximately $134,000. Also during 2000, 50,000 shares were exercised and issued, resulting in cash proceeds of approximately $100,000.

Note 7 - Licensing Agreements

Under the Company s license agreements with the Washington Research Foundation (the WRF), the Company has the worldwide exclusive right to commercialize technology developed from certain research conducted by the University of Washington (the UW). As consideration for the licenses acquired and for the attainment of certain milestones, the Company paid the WRF certain nonrefundable fees and issued common stock to the WRF and the UW. In addition, future cash payments and common stock grants may be due upon attainment of certain other milestones. All legal costs incurred by the WRF in connection with the filing, prosecution, and maintenance of certain defined patent rights are paid by the Company. The Company is obligated to pay the WRF royalties on net sales of any licensed products.

Note 8 - Related Party Transactions

Research Agreements

In the past, the Company has entered into research agreements with the UW, one of which was extended through December 31, 2001. Total expense was $150,000 during 2001, 2000, and 1999 and is included in research and development expense.

Manufacturing Agreement

The Company, through an agreement with Metrika, developed the NTx Point-of-Care device. Along with the agreement, the Company acquired preferred stock of Metrika (see Note 4). The Company paid approximately $1,276,000 and $677,000 in 2001 and 2000, respectively, to Metrika related to the development and production of NTx Point-of-Care devices. Metrika has been and continues to be a critical supplier of certain components of the NTx Point-of-Care device to the Company.

On May 10, 2000, the Company announced it had acquired the exclusive right from Metrika to manufacture the NTx Point-of-Care device. Under the agreement, Metrika receives a royalty based on the sales of the NTx Point-of-Care device. The Company started shipping product that was assembled at its new facility in the fourth quarter of 2001 and, in the first quarter of 2002, the Company anticipates shipping devices with highly specialized subcomponents that are also manufactured in its facility.

Note 9 - Commitments And Contingencies

Leases

The Company has entered into noncancelable operating leases for office space and certain equipment. Future minimum payments under these leases are as follows:

2002	$	669,000
2003		653,000
2004		645,000
2005		557,000
2006		104,000
Thereafter		392,000
Total	$	3,020,000

Total rent expense was approximately $442,000, $444,000, and $457,000 in 2001, 2000, and 1999, respectively.

Litigation

In December 2001, Osteometer Biotech A/S (Osteometer) and its licensee Roche Diagnostics GmbH sent the Company two notification letters concerning Osteometer s European Patent No. 0742902 which issued November 21, 2001. The patent claims synthetic NTx peptides in assays for bone resorption. The Company believes that its Osteomark products do not infringe upon the Osteometer patent and that the patent is invalid in light of prior art that was not taken into consideration by the issuing European Patent Office. In January 2002, the Company filed an action in the Court of Monza, Italy, seeking a pan-European declaration of noninfringement. Said action included a request to stay any such noninfringement determination pending the outcome of an opposition proceeding that the Company intends to initiate in the European Patent Office against this patent.

Effective August 1, 2000, the Company, Osteometer, Diagnostics Systems Laboratories (DSL), and the WRF, entered into an agreement settling a lawsuit brought against Osteometer and DSL for infringements of patents exclusively licensed by the WRF to the Company and directed to C-telopeptide markers of bone resorption. Under the settlement agreement, Osteometer may sell the CrossLaps™ ELISA urine kits in the United States until August 2002, paid the Company a lump sum settlement fee of approximately $200,000 for past sales and will pay royalties on future sales. Approximately $48,000 of the settlement fee was considered 2000 activity and was recorded under Revenues.

On November 19, 1999, Roche Diagnostics GmbH (Roche) filed a lawsuit against the Company in Belgium seeking to invalidate the Company s European patents as they cover the Belgium territory. The lawsuit also sought a declaration that Roche is not infringing on the Company s patents in all the European countries designated under the patents and where Roche markets or plans to market their Elecsys ß-Crosslaps Serum diagnostic test. In February 2000, this case was stayed indefinitely, pending the outcomes of opposition proceedings in the European Patent Office. The Company believes that this lawsuit will not lead to an award of damages against the Company.

Note 10 - Federal Income Taxes

Deferred taxes are determined using an asset and liability approach. The Company has incurred operating losses since inception and accordingly has determined that the net deferred tax assets do not satisfy recognition criteria. Therefore, a valuation allowance has been recorded against the net deferred tax assets and no tax benefit has been recorded in the accompanying statement of operations. The change in the valuation allowance during 2001, 2000, and 1999 was $1,141,000, $665,000, and $478,000, respectively. The Company s deferred tax assets (liabilities) are as follows:

	2001	2000
Net operating loss carryforward	$ 14,458,000	$ 13,511,000
Research and experimentation credits	806,000	713,000
Property, plant and equipment	408,000	326,000
Other	78,000	59,000
Gross deferred tax asset	15,750,000	14,609,000
Valuation allowance	(15,750,000)	(14,609,000)
Net deferred tax asset	$	$

At December 31, 2001, the Company had tax net operating loss carryforwards of approximately $42,523,000, which expire between 2004 and 2021.

Note 11 - Unaudited Quarterly Information

The following table sets forth certain unaudited quarterly statements of operations dated for the eight quarters ended December 31, 2001. In the opinion of management, this information has been prepared substantially on the same basis as the audited consolidated financial statements and all necessary adjustments, consisting only of normal recurring adjustments, have been included in the amounts stated below to present fairly the unaudited quarterly results of operations. The quarterly data should be read in conjunction with our audited consolidated financial statements and the notes thereto. The operating results for any quarter are not necessarily indicative of the operating results for any future period.

	Three-Month Periods Ended							
	Dec. 31, 2001	Sept. 30, 2001	June 30, 2001	March 31, 2001	Dec. 31, 2000	Sept. 30, 2000	June 30, 000	March 31, 2000
Revenue	$ 1,426,000	$ 1,286,000	$ 1,492,000	$ 1,529,000	$ 1,479,000	$ 1,619,000	$ 1,568,000	$ 887,000
Cost of products sold	585,000	487,000	590,000	614,000	509,000	628,000	619,000	78,000
Gross margin	841,000	799,000	902,000	915,000	970,000	991,000	949,000	809,000
(Percentage of revenue)	59%	62%	60%	60%	66%	61%	61%	91%
Operating Expenses:								
POC plant start-up costs	354,000	268,000	170,000	80,000	80,000			
Research and development	368,000	470,000	427,000	569,000	435,000	399,000	404,000	374,000
Selling, general and administrative	1,064,000	828,000	858,000	1,182,000	1,100,000	1,076,000	1,279,000	1,137,000
Total operating expenses	1,786,000	1,566,000	1,455,000	1,831,000	1,615,000	1,475,000	1,683,000	1,511,000
Loss from operations	(945,000)	(767,000)	(553,000)	(916,000)	(645,000)	(484,000)	(734,000)	(702,000)
Proceeds from legal settlement						152,000		
Interest, net	(58,000)	30,000	52,000	58,000	78,000	129,000	99,000	90,000
Net loss	$ (1,003,000)	$ (737,000)	$ (501,000)	$ (858,000)	$ (567,000)	$ (203,000)	$ (635,000)	$ (612,000)

Basic and diluted net loss per common and common equivelent share (1)	$ (0.08)	$ (0.06)	$ (0.04)	$ (0.07)	$ (0.05)	$ (0.02)	$ (0.05)	$ (0.05)
Weighted average shares used in calculation of net loss per share	12,553,000	12,540,000	12,484,000	12,485,000	12,508,000	12,529,000	12,504,000	12,472,000

(1) Earnings per share is computed independently for each of the periods presented. Therefore, the sum of the quarterly per share amounts will not necessarily equal the total amount for the year.

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

a. Directors

The information contained in the section entitled Election of Directors and Director Information of the Proxy Statement is incorporated herein by reference in response to this item.

b. Executive Officers of the Registrant

Information required by this item is contained in Part I of this Annual Report on Form 10-K in the section entitled Executive Officers of the Registrant.

c. Compliance With Section 16(a)

Information contained in the section entitled Section 16(a) Beneficial Ownership Reporting Compliance of the Proxy Statement is incorporated herein by reference in response to this item.

Item 11. Executive Compensation

The information contained in the section entitled Executive Compensation of the Proxy Statement is incorporated herein by reference in response to this item.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information contained in the section entitled Security Ownership of Certain Beneficial Owners and Management of the Proxy Statement is incorporated herein by reference in response to this item.

Item 13. Certain Relationships and Related Transactions

The information contained in the section entitled Compensation Committee Interlocks and Insider Participation of the Proxy Statement is incorporated herein by reference in response to this item.

PART IV

Item 14. Financial Statements, Financial Statement Schedules, Exhibits, and Reports on Form 8-K

a. Financial Statements, Financial Statement Schedules and Exhibits

(1) FINANCIAL STATEMENTS

The following financial statements are included in Item 8:

Balance Sheets - December 31, 2001 and 2000

Statements of Operations - Years ended December 31, 2001, 2000, and 1999

Statements of Cash Flows - Years ended December 31, 2001, 2000, and 1999

Statements of Shareholders Equity - Years ended December 31, 2001, 2000, and 1999

Notes to Financial Statements - December 31, 2001

(2) FINANCIAL STATEMENT SCHEDULES

Financial Statement Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto.

(3) Exhibit Index (see note (1))

EXHIBIT INDEX

Exhibit Number	Description	Notes
3.1	Articles of Incorporation, as amended, dated January 1997	(2)

3.2	Bylaws, as amended	(3)
4.1	Specimen Common Stock Certificate	(3)
10.1A	Amended and Restated Stock Option Plan*	(3)
10.1B	Amended and Restated 1994 Stock Option Plan*	(4)
10.1C	Amended and Restated Directors' Nonqualified Stock Option Plan*	(5)
10.5	Form of Indemnification Agreement with officers and directors*	(3)
10.7	Agreement with Thomas A. Bologna Executive Employment Agreement dated July 16, 1997*	(6)
	Agreements with Mochida Pharmaceutical Co., Ltd.	
10.12A	Research and Development Agreement dated August 1992	(3)
10.12B	Osteomark License Agreement Dated August 1992	(3)
10.12D	Second Amendment to Osteomark License Agreement dated December 24, 1997	(7)
	Agreements with the Washington Research Foundation	
10.13A	Restated Exclusive License Agreement effective June 19, 1992 (Urinary Assay for Measuring Bone Resorption)	(3)
10.13B	Amendment to Restated Exclusive License Agreement effective January 1, 1993	(3)
10.13C	Second Amendment effective June 2, 1994	(3)
10.14	Exclusive License Agreement dated February 10, 1994 (O-CSF)	(3)

Exhibit Number	Description	Notes
	Agreements with the University of Washington	
10.15A	Research Agreement dated July 1, 1996 (Molecular Markers of Connective Tissue Degradation)	(7)(8)
10.15B	Research Agreement dated October 1, 1996 (Role of O-CSF in Osteoclast Regulation)	(7)(8)
10.16A	Know-How Transfer and Consulting Agreement dated September 18, 1989 with David R. Eyre, Ph.D.*	(3)
10.16B	Extension and Amendment dated May 1, 1992*	(3)
	Lease Agreements	
10.27A	Lease Agreement dated October 2, 1995, with David A. Sabey and Sandra L. Sabey	(9)
10.27B	First Amendment of Lease dated October 15, 1996, with the City of Seattle, successor-in-interest to David A. Sabey and Sandra L. Sabey	(2)
	Agreements with Johnson & Johnson Clinical Diagnostics, Inc.	
10.28A	Distribution Agreement dated June 7, 1995	(10)
10.28B	Research, Development, License and Supply Agreement dated June 7, 1995	(10)
10.29	Clinical Laboratory Services License and Supply Agreement dated October 25, 1995, with SmithKline Beecham Clinical Laboratories, Inc.	(9)
10.35	Shareholder Rights Agreement dated January 21, 1997	(11)
10.37	Metrika Manufacturing and License Agreement dated March 10, 2000	(12)
10.38	Transamerica Business Credit Corporation Master Loan and Security Agreement dated October 23, 2000	(13)
23.1	Consent of Arthur Andersen LLP	(14)
99.1	Letter from Arthur Andersen	(14)

* Management contract or compensatory plan or agreement.

(1) Copies of exhibits may be obtained at prescribed rates from the Public Reference Section of the Commission at 450 5th Street NW, Room 1024, Washington, D.C. 20549, or through the Commission s Edgar system located on the internet at www.sec.gov.

(2) Incorporated herein by reference to exhibit of the same number filed with Form 10-K with the Commission for the year ended December 31, 1996.

(3) Incorporated herein by reference from Item 16(a) of Registrant s Form S-1 Registration Statement as declared effective January 24, 1995 (No. 33-86118).

(4) Incorporated herein by reference to Appendix B of the Registrant's Proxy Statement on schedule 14A filed on March 22, 2001.

(5) Incorporated herein by reference to Appendix B of the Registrant's Proxy Statement on schedule 14A filed on March 30, 2000.

(6) Incorporated herein by reference to exhibits of the same number filed with Form 10-K with the Commission for the year ended December 31, 1997.

(7) Confidential treatment requested. Exhibit omits information that has been filed separately with the Commission.

(8) Incorporated herein by reference to exhibits of the same number filed with Form 10-K with the Commission for the year ended December 31, 1996, and as amended with Form 10-K/A on October 17, 1997.

(9) Incorporated herein by reference to exhibit of the same number filed with Form 10-K with the Commission for the year ended December 31, 1995.

(10) Incorporated herein by reference to exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended June 30, 1995.

(11) Incorporated herein by reference to exhibit number 4.5 filed with Form 8-A with the Commission in January 1997.

(12) Incorporated herein by reference to exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended June 30, 2000. Confidential treatment has been granted or requested with respect to portions of this exhibit.

(13) Incorporated herein by reference to the exhibit of the same number filed with Form 10-K with the Commission for the year ended December 31, 2000.

(14) Included with this Form 10-K as exhibit of the same number.

(b) Reports on Form 8-K

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 28, 2002.

OSTEX INTERNATIONAL, INC.

By /s/ Thomas A. Bologna
Thomas A. Bologna
Chairman, President and Chief
Executive Officer and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Capacities	Date
/s/ Thomas A. Bologna Thomas A. Bologna	Chairman, President and Chief Executive Officer (principal executive officer and principal financial officer)	March 28, 2002
/s/ Thomas J. Cable Thomas J. Cable	Director	March 28, 2002
/s/ Elisabeth L. Evans Elisabeth L. Evans	Director	March 28, 2002
/s/ David R. Eyre David R. Eyre	Director	March 28, 2002
/s/ Fredric J. Feldman Fredric J. Feldman	Director	March 28, 2002
/s/ John H. Trimmer John H. Trimmer	Director	March 28, 2002