

OSTEK INTERNATIONAL INC /WA/
Form 10-K
March 24, 2003

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, 2002

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

OSTEK INTERNATIONAL, INC.

Exact Name of Registrant as Specified in Its Charter

State of Washington

State or Other Jurisdiction of Incorporation or Organization

91-1450247

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:

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

(none) Title of Class	(none) 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

No

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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

Yes

No

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant was approximately \$18,038,865 on March 12, 2003, based on the per-share closing price of \$1.80 on The Nasdaq National Market on that date. The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant was approximately \$13,726,111 on June 28, 2002, based on the per share closing price of \$1.37 on The Nasdaq National Market on that date.

The number of shares of Common Stock outstanding as of March 12, 2003 was 12,583,745.

OSTECH INTERNATIONAL, INC.

INDEX TO FORM 10-K

PART I

<u>ITEM 1</u>	<u>BUSINESS</u>
<u>ITEM 1A</u>	<u>RISK FACTORS</u>
<u>ITEM 2</u>	<u>PROPERTIES</u>
<u>ITEM 3</u>	<u>LEGAL PROCEEDINGS</u>
<u>ITEM 4</u>	<u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>

PART II

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

ITEM 6 SELECTED FINANCIAL DATA

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

ITEM 7A QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

ITEM 8 FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

PART III

ITEM 10 DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

ITEM 11 EXECUTIVE COMPENSATION

ITEM 12 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

ITEM 13 CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

ITEM 14 CONTROLS AND PROCEDURES

PART IV

ITEM 15 FINANCIAL STATEMENTS, FINANCIAL STATEMENT SCHEDULES, EXHIBITS, AND REPORTS ON FORM 8-K

SIGNATURES

CERTIFICATIONS

PART I

When used in this Report, the words may, will, believes, anticipates, expects, intends, estimates, predicts, and similar expressions qualify as forward-looking statements but are not the exclusive means of identifying such 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. Ostex 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 International, Inc. (Ostex), 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. Ostex' lead product, the Osteomark® NTx test, which is available in multiple formats, incorporates breakthrough and patented technology for the management of osteoporosis. Ostex has collaborative relationships with leading reference laboratories and distributors and markets its Osteomark NTx Point-of-Care device primarily to pharmaceutical companies to aid in the commercialization of its Osteomark technology.

Osteoporosis is a significant health problem. The National Osteoporosis Foundation (the NOF) updated its first prevalence report published in 1997 entitled America's Bone Health: The State of Osteoporosis and Low Bone Mass in our Nation. Based on 2000 Census data, the disease statistics indicate that 44 million U.S. women and men aged 50 and older have or are at high risk for developing osteoporosis due to low bone mass. Of these 44 million, over 10 million people, approximately 80 percent of them women, already have osteoporosis and an estimated 34 million have low bone mass density. By the year 2010, it is estimated that over 52 million American women and men in this same age category will be affected and, if current trends continue, the figure will climb to over 61 million by 2020. 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. Despite the serious human and economic consequences of these diseases (according to the NOF, the national direct expenditures for osteoporotic and associated fractures was \$17 billion in 2001), medical intervention usually commences only after pain, immobility, fractures, or other symptoms have appeared. Ostex expects the osteoporosis therapeutic market will continue to grow as the population ages.

Ostex 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 NTx 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 Wyeth's Premarin®, in postmenopausal women, which is intended for the prevention and treatment of osteoporosis. In addition, the Osteomark NTx test can aid clinicians in monitoring in postmenopausal women and those diagnosed with osteoporosis the effects of antiresorptive therapies, such as Merck & Co., Inc.'s Fosamax®, Eli Lilly and Company's Evista®, and Procter & Gamble Pharmaceuticals, Inc.'s and Aventis Pharmaceuticals, Inc.'s Actonel®, in a matter of three months versus one to two years with conventional technology.

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

Ostex has the worldwide exclusive right to commercialize technology developed from certain research conducted by the University of Washington under license agreements with the Washington Research Foundation. As consideration for the licenses acquired and for the attainment of certain milestones, Ostex paid the Washington Research Foundation certain nonrefundable fees and issued common stock to the

Washington Research Foundation and the University of Washington. All legal costs incurred by the Washington Research Foundation in connection with the filing, prosecution, and maintenance of certain defined patent rights are paid by Ostex. Ostex is obligated to pay the Washington Research Foundation royalties on net sales of any licensed products and also pays royalties to the Washington Research Foundation on milestones received from licensees of the products.

The first Osteomark test became commercially available in May 1995 as a urinary test in a microtiter plate format 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, Ostex received expanded claims for the urine microtiter 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 urine microtiter test claims were further expanded by allowing that 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.

Ostex's second Osteomark test is a serum microtiter plate 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. Ostex 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 Osteomark NTx Point-of-Care device became commercially available in October 1999 for use in the physician's office. Ostex and Metrika, Inc. developed a physician's office Point-of-Care Osteomark test device which 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, Ostex 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 NTx and 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. In August 2001, Ostex received Rx Home-Use clearance and CLIA Waiver status for its NTx Point-of-Care device from the 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 can purchase it at the pharmacy and use it in their own homes under the direction of their physicians.

Ostex manufactures its Osteomark NTx Urine and Serum kits in an Enzyme-linked Immunosorbent Assay format at its manufacturing facility in Seattle, Washington. After initial delays, Ostex completed validation lots for and began shipping NTx Point-of-Care devices in late May 2002 from its new point-of-care manufacturing facility, also located in Seattle.

Ostex began working with Procter & Gamble in 2000 to launch a test program in Germany to use the NTx Point-of-Care device with Actonel, Procter & Gamble's osteoporosis drug for the management of osteoporosis. This program initially was expanded by Procter & Gamble and its partner, Aventis Pharmaceuticals, and tested in a number of countries. Ostex could not deliver as many NTx Point-of-Care devices to Procter & Gamble and Aventis as anticipated in the second half of 2001 due to product supply difficulties. In addition, because of delays encountered with the start-up of its manufacturing facility, Ostex was unable to deliver NTx Point-of-Care devices to Procter & Gamble and Aventis during most of the first half of 2002. As a result, Procter & Gamble and Aventis cancelled a portion of their NTx Point-of-Care back orders or switched to the Osteomark NTx Urine test in the microtiter plate format. Ostex validated its manufacturing process late in the second quarter of 2002 and has shipped NTx Point-of-Care devices to Procter & Gamble and Aventis. Ostex has maintained a continuing dialogue with Procter & Gamble and Aventis and is working to rebuild their confidence in its manufacturing capabilities. Ostex is also working to expand sources of demand for its products and has shipped NTx Point-of-Care devices to other large pharmaceutical companies.

Ostex and Mochida Pharmaceutical Co., Ltd., 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 license agreement, Ostex granted Mochida exclusive marketing and distribution rights to certain products in Japan. In January 1998, Mochida launched the Osteomark NTx Urine test in a microtiter plate format 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, Labor and Welfare for the Osteomark test for selecting suitable drugs for the treatment of osteoporosis and monitoring efficacy of drug therapy for osteoporosis. In February 2002, Mochida exercised its option to license the serum test in Japan. The total license fee was \$750,000, \$500,000 of which Mochida paid to Ostex in March 2002, 30 days after the time it exercised the option to license, and \$250,000 of which Mochida paid to Ostex in August 2002, after Mochida received the official announcement of the Japanese reimbursement price from the Ministry of Health. Mochida obtained the Import Approval for Osteomark NTx Serum from the Japanese Ministry of Health, Labor and Welfare in July 2002 and launched the product for sale in November 2002.

Worldwide promotion of the Osteomark NTx Urine test is also supported by Johnson & Johnson Clinical Diagnostics, Inc. In 1995, Ostex 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 our bone resorption technology. Johnson & Johnson currently distributes in the United States and certain foreign countries the Osteomark NTx Urine test in the microtiter plate format manufactured by Ostex. Johnson & Johnson also offers the NTx urine test on its Vitros® automated analyzer, for which Ostex receives payments for materials supplied to Johnson & Johnson and royalties on Johnson & Johnson's sales. Under the Johnson & Johnson license agreement, Ostex has the right to license its technology for use on automated instruments to one other company in addition to Johnson & Johnson.

Ostex 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 20 million people in the United States alone. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. Further development of the Type II collagen degradation test will be needed 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, Ostex 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. Ostex 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 these tests in the future.

Ostex also has technology to enhance artificial joint recovery. Ostex is the exclusive licensee of U.S. Patents No. 6,190,412 and No. 6,508,838, directed to prosthetic devices having hydroxyapatite-coated bone attachment surfaces to which tartrate-resistant acid phosphatase (TRAP) is absorbed. Research supported by Ostex established that the human TRAP enzyme has a direct role as a local factor in the recruitment of osteoclasts from hematopoietic cells. Such research also established that recombinantly produced TRAP absorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. Ostex may seek collaborations to confirm whether or not 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 OSTEON® are registered United States trademarks of Ostex and the OSTEOMARK trademark is registered in 47 other countries. The collagen breakdown test technology is covered by 37 U.S. patents, 3 European patents, 6 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. These 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 Type I collagen patents will begin to expire in late 2007 for the U.S. and in 2010 for Europe and Japan. Ostex is also the exclusive worldwide licensee of Metrika's patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013.

Employees

As of March 12, 2003, Ostex had 47 full-time employees and 1 part-time employee. Ostex considers its relations with its employees to be good.

Proposed Merger with Inverness

On September 9, 2002, Ostex announced that it had entered into an agreement and plan of merger with Inverness Medical Innovations, Inc. and Geras Acquisition Corp., a wholly-owned subsidiary of Inverness. Under the terms of the agreement, Geras Acquisition Corp. will be merged with and into Ostex, Ostex will become a wholly owned subsidiary of Inverness, and each outstanding share of Ostex common stock will be converted into the right to receive common stock, par value \$.001 per share, of Inverness based on a conversion ratio that will be determined immediately prior to the closing of the merger. Under the merger agreement, as amended on February 18, 2003, the per share conversion ratio is designed to provide that an aggregate of approximately 1.9 million shares of Inverness common stock will be:

issued in exchange for all outstanding Ostex common stock; and

reserved for issuance upon exercise of the outstanding stock options and warrants to purchase Ostex common stock that will be assumed by Inverness in the merger.

The merger cannot be completed unless certain conditions are satisfied, including Inverness obtaining the consent of certain of its lenders and the approval by the affirmative vote of two-thirds of the outstanding shares of Ostex common stock. Ostex directors and their affiliates, who collectively own an aggregate of approximately 19.8% of the total outstanding common stock of Ostex, have entered into a voting agreement with Inverness, which provides that they will vote their shares in favor of the acquisition. Additionally, in connection with the acquisition, Inverness received an option to purchase up to 19.9% of Ostex common stock that will be exercisable under certain circumstances.

On January 2, 2003, Ostex and Inverness announced that Inverness had been unable to obtain the required consent of certain of its lenders to the merger. The amendment to the merger agreement, which, among other things, reduced the aggregate number of shares of Inverness common stock to be issued in the merger from 2.3 million shares to 1.9 million shares, is intended to increase the likelihood of Inverness receiving the consent of certain of its lenders. As reflected in the joint press release issued by Inverness and Ostex on February 19, 2003, Inverness advises that it has been working closely with its lenders to develop a proposal acceptable to its lenders and is optimistic that it will be able to satisfy its lenders requirements in a timely manner and obtain their consent to the merger. There can be no assurance, however, that Inverness lenders will give their consent to the proposed merger. Likewise, there can be no assurance that Ostex shareholders will approve the merger. Failure to complete the merger could have a material adverse effect on Ostex financial condition and results of operations. Ostex has provided additional information about some of these potential adverse effects under the captions Liquidity and Capital Resources and Additional Factors That May Affect Results below.

Inverness and Ostex have filed relevant documents concerning the merger with the Securities and Exchange (SEC), including a registration statement on Form S-4 and subsequently filed Reports and amendments. You should refer to these documents for further information about the proposed merger.

Item 1A. Risk Factors

Risks Related to the Proposed Merger with Inverness

Failure to complete the proposed merger with Inverness could negatively impact Ostex stock price and future business and operations.

If the merger is not completed for any reason, Ostex may be subject to a number of material risks, including the following:

Ostex may be required to pay Inverness a termination fee of \$1.8 million;

the stock option granted by Ostex to Inverness may become exercisable;

the price of Ostex common stock may decline to the extent that the current market price of Ostex common stock reflects an assumption that the merger will be completed;

Ostex must pay its accrued costs related to the merger, such as legal, accounting and financial advisory fees, even if the merger is not completed;

Ostex will need to repay all amounts that it borrowed under the loan agreement with Inverness by December 31, 2003 at the latest;

Ostex will need to seek immediate additional funding to meet its capital and other requirements, which funding may not be available when needed or may not be available on terms acceptable to Ostex; and

Ostex will be delisted from The Nasdaq National Market for failing to satisfy The Nasdaq National Market \$10 million minimum shareholders equity requirement, which delisting could adversely affect the liquidity and trading price of its common stock.

Edgar Filing: OSTEK INTERNATIONAL INC /WA/ - Form 10-K

In addition, Ostex customers may, in response to the announcement of the merger, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by Ostex customers would have a material adverse effect on Ostex business, regardless of whether or not the merger is ultimately completed. Similarly, current and prospective Ostex employees may experience uncertainty about their future role with Inverness until Inverness strategies with regard to Ostex are announced or executed. This uncertainty may adversely affect Ostex ability to attract and retain key management, marketing, technical, manufacturing, administrative, sales and other personnel.

The obligations of the parties to effect the merger are subject to a number of conditions, including obtaining consents of lenders of Inverness and approval by holders of Ostex common stock, and there can be no assurance that the merger will occur.

Ostex believes that the price of its common stock is based in large part on the price of Inverness common stock; the price of Inverness common stock may be affected by factors different than those affecting the price of Ostex common stock.

Upon completion of the merger with Inverness, the holders of Ostex common stock will become holders of Inverness common stock. In addition, prior to the merger and unless the merger agreement with Inverness is terminated, Ostex believes that the price of its common stock will be determined in part by the expectation that the merger will be completed and that Ostex shareholders will become shareholders of Inverness, and the price of Ostex common stock will be affected by the price of Inverness common stock. The business, strategy and financial condition of Inverness are different from those of Ostex. Inverness results of operations, as well as the price of Inverness common stock, will be affected by factors that may be different than those affecting Ostex results of operations and common stock price.

Risks Related to Ostex Business

Ostex has a history of losses and may not be able to continue as a going concern.

KPMG LLP, Ostex independent auditors, has included a going concern uncertainty paragraph in its audit report on Ostex financial statements for the year ended December 31, 2002, which states that Ostex recurring losses from operations and need to raise additional capital to meet its operating and debt requirements if the proposed merger with Inverness is unsuccessful, raise substantial doubt about Ostex ability to continue as a going concern.

Ostex has not been profitable for any year since its formation in 1989. Ostex had an accumulated deficit through December 31, 2002 of \$43,309,000. Ostex expects to incur additional costs as it continues with its existing operations, marketing and sales efforts for its products, and research and development activities. Ostex lead product, the Osteomark NTx Urine test, became commercially available in May 1995 in the United States, but sales to date have not been significant enough to generate net income. Ostex ability to achieve long-term profitability is dependent upon successfully manufacturing, marketing, and commercializing existing products. Ostex expects to continue to incur additional losses in the near-term future and Ostex is unable to predict when, if ever, it will achieve profitability. Ostex ability to continue as a going concern is dependant upon numerous factors, including its ability to obtain additional financing, its ability to increase its level of future revenues and its ability to reduce operating expenses.

Ostex cannot assure you that its Common Stock will continue to be listed on The Nasdaq National Market, and delisting could depress its stock price, limit shareholder liquidity and make it more difficult for Ostex to raise capital.

On November 22, 2002, Nasdaq notified Ostex that the Nasdaq Staff was reviewing the Ostex eligibility for continued listing on The Nasdaq National Market in light of Ostex failure to satisfy the \$10,000,000 minimum shareholders equity requirement set forth in Marketplace Rule 4450(a)(3). After reviewing information concerning the proposed merger with Inverness submitted by Ostex, Nasdaq granted Ostex an extension. Under the terms of the extension, if the merger with Inverness is not consummated by February 28, 2003 or Ostex does not apply for transfer to The Nasdaq SmallCap Market, Nasdaq will provide formal written notification that Ostex securities will be delisted. On March 18, 2003, Ostex received formal written notice of the Nasdaq Staff s determination that Ostex securities should be delisted from The Nasdaq National Market. On March 21, 2003, Ostex requested a hearing before a Nasdaq Listing Qualifications Panel to review the Staff delisting determination. At the hearing, Ostex intends to request continued listing on The Nasdaq National Market pending completion of the merger with Inverness. If Ostex appeal fails or if the merger is not consummated, Ostex may seek to list its Common Stock on The Nasdaq SmallCap Market. If Ostex does not qualify for listing on The Nasdaq SmallCap Market, its Common Stock would be listed on the over-the-counter bulletin board or another quotation system or exchange on which Ostex would qualify. If Ostex Common Stock is delisted, the delisting could have a material adverse effect on the trading price and liquidity of the stock, and shareholders ability to sell shares of Ostex stock would be severely limited. Among other things, if not listed on The Nasdaq National Market or The Nasdaq SmallCap Market, Ostex Common Stock may then constitute penny stock which would place increased regulatory burdens on brokers, making them less likely to make a market in Ostex stock. Loss of Ostex Nasdaq National Market status could also make it more difficult for Ostex to raise capital and would also complicate compliance with state blue sky laws.

The market acceptance and demand for Ostex products is uncertain.

Edgar Filing: OSTEON INTERNATIONAL INC /WA/ - Form 10-K

The Osteon NTx test, became commercially available in May 1995 in the United States, but sales to date have not been significant enough to generate net income. There can be no assurance that Osteon Osteon NTx tests will gain widespread acceptance from the medical community, clinical or hospital laboratories, pharmaceutical companies, physicians or patients as readily as other forms for testing or any newly developed test. There can be no assurance that Osteon will be able to develop significant market share for its products or maintain or increase its current market share. Osteon did not deliver as many NTx Point-of-Care devices to Procter & Gamble and Aventis Pharmaceuticals as anticipated in the second half of 2001 due to product supply difficulties. In addition, because of delays encountered with the start-up of Osteon point-of-care manufacturing facility, Osteon was unable to deliver NTx Point-of-Care devices to Procter & Gamble and Aventis during most of the first half of 2002. As a result, Procter & Gamble and Aventis cancelled a portion of their NTx Point-of-Care back orders or switched to Osteon Osteon NTx Urine test in the microtiter plate format.

Ostek point-of-care manufacturing facility was validated to produce a high volume of devices. The production capacity exceeds the production plan for devices in the near-term and may exceed the production plan for devices in the long-term. If this were to occur, the resulting excess capacity may have a negative impact to Ostek margins in future periods. The inability of Ostek to increase market acceptance and demand for its products could have a material, adverse effect on Ostek business, financial condition, and results of operations.

Ostek currently relies on a small number of customers, and the loss of a significant Ostek customer could harm Ostek business.

Ostek current operations are dependent upon a relatively small number of customers, which change from time to time. Ostek most significant customers during 2002 were Mochida Pharmaceutical Co., Ltd., Quest Diagnostics Incorporated, Covance Central Lab Services, Johnson & Johnson Clinical Diagnostics, Inc. and Fisher Scientific. These customers collectively accounted for approximately 56% of Ostek total product sales during the year. See discussion under the heading Concentration of Credit Risk in Note 1 to Financial Statements below for a summary of customers that comprised greater than 10% of Ostek total revenues in each of the last three fiscal years. Ostek generally does not have long-term purchase contracts with its customers, who order products on a purchase order basis. In certain circumstances, customer orders may be cancelled, changed or delayed on short notice. Because Ostek finished goods inventory has a limited shelf life, inventory amounts that are not sold within an appropriate time are charged against the cost of goods sold. There can be no assurance that Ostek current significant customers will continue to buy products at their current or increased levels. Ostek lost a number of orders from significant customers as a result of manufacturing delays encountered with the start-up of Ostek point-of-care manufacturing facility in late 2001 and early 2002. Loss of a significant Ostek customer or further reduction of the level of orders from a significant Ostek customer would have a material adverse effect on Ostek operating results.

Ostek is dependent on therapeutics developed by others.

Acceptance of and demand for Ostek products will be affected by physicians perceived needs to test for bone resorption for the purposes of the prevention, treatment and monitoring of osteoporosis. There are currently a limited number of therapies that are effective in preventing, treating and monitoring osteoporosis or other bone disorders. In the event new therapies do not receive regulatory approval or experience delayed market acceptance, or existing therapies are deemed not to be as effective or useful as originally suggested, Ostek could be adversely affected. Unfavorable publicity or studies concerning an Ostek product or therapeutic products for osteoporosis could also have an adverse effect on Ostek ability to obtain regulatory approvals or to achieve market acceptance.

Ostek has limited sales, marketing and distribution experience and resources.

Ostek has limited sales, marketing and distribution experience and resources. To market any of its products directly or indirectly, Ostek must develop and implement a substantial sales and marketing effort with technical expertise and supporting distribution capability. Ostek may need to increase its sales and marketing resources significantly in order for its products to gain relatively significant market acceptance. Ostek intends to continue to market and sell its products in the United States through research and clinical laboratories and distributors, establish relationships with a pharmaceutical company or companies, and to establish business arrangements to sell its products in other markets through distributors and a pharmaceutical company or companies. There can be no assurance that Ostek will be able to establish effective sales and marketing and distribution capabilities or that its collaborators will be successful in gaining market acceptance for Ostek products or that Ostek will achieve or maintain significant market share for its products.

Ostek has limited manufacturing experience.

Ostex has, through an agreement with Metrika, Inc., developed an adaptation of its core technology for use in physicians' offices, called the Osteonmark NTx Point-of-Care device. Until year-end 2001, Ostex depended upon the efforts of Metrika for the production of the NTx Point-of-Care device. In the second quarter of 2002, Ostex itself began manufacturing the NTx Point-of-Care device, but continues to rely on Metrika for supply of certain components. Ostex has limited manufacturing experience and technical

expertise with a product like the NTx Point-of-Care device. Failure by Ostex to manufacture the NTx Point-of-Care device and other products in significant quantities in a cost-effective manner could adversely affect Ostex results of operations. Because of delays encountered with the start-up of Ostex point-of-care manufacturing facility, Ostex was unable to deliver NTx Point-of-Care devices to customers during late 2001 and most of the first half of 2002. Any similar interruptions in the manufacturing process in the future could have a material adverse effect on Ostex results of operations.

Ostex is dependent on licensed patents and proprietary rights.

Ostex success is dependent in part on obtaining, maintaining and enforcing its patents and other proprietary rights and its ability to avoid and defend against allegations of infringing the proprietary rights of others. Patent law relating to the scope of claims in the biotechnology field in which Ostex operates is still evolving and, consequently, patent positions in Ostex industry may not be as strong as in other better-established fields. Accordingly, the United States Patent and Trademark Office, or PTO, and foreign patent offices may not issue patents from the patent applications owned by or licensed to Ostex. If issued, the patents may not give Ostex an advantage over competitors with similar technology.

Ostex is the exclusive licensee of 60 patents in North America, Europe, and Asia. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to Ostex patents if it attempts to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the PTO or a foreign patent office. It is possible that a competitor may successfully challenge Ostex patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to Ostex, third parties may be able to use Ostex patented invention without payment to Ostex. Moreover, it is possible that competitors may infringe Ostex patents or successfully avoid them through design innovation. To stop these activities, Ostex may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if Ostex is successful in stopping the violation of its patent rights. In addition, there is a risk that a court would decide that Ostex patents are not valid and that Ostex does not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of Ostex patents are upheld, a court would refuse to stop the other party on the ground that its activities do not infringe Ostex patents.

Further, once a patent has expired, the technology is no longer protected. Ostex Type I collagen patents will begin to expire in late 2007 for the United States and in 2010 for Europe and Japan. Ostex is the exclusive worldwide licensee of Metrika's patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013.

In addition to the intellectual property rights described above, Ostex relies on unpatented technology, trade secrets and confidential information. Therefore, others may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose Ostex technology. Ostex may not be able to effectively protect its rights in unpatented technology, trade secrets and confidential information. Ostex requires each of its employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with Ostex. However, these agreements may not provide effective protection of Ostex information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

Ostex patent rights could conflict with the patent rights of others.

Ostex competitors or others may have or acquire patent rights that they could enforce against Ostex. If they do so, Ostex may be required to alter its products, pay licensing fees or cease activities. If Ostex products conflict with patent rights of others, third parties could bring legal actions against Ostex claiming damages and seeking to enjoin manufacturing and marketing and sales of the affected products. If these legal actions are successful, in addition to any potential liability for damages, Ostex could be required to obtain a license in order to continue to manufacture or market the affected products. Ostex may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all.

In December 2001, Osteometer Biotech A/S, also known as Nordic Bioscience A/S, and its licensee Roche Diagnostics GmbH sent Ostex 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. Ostex 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, Ostex filed an action in the Court of Monza, Italy, seeking a pan-European declaration of noninfringement. This action included a request to stay any such noninfringement determination pending the outcome of an opposition proceeding that Ostex initiated on August 20, 2002, in the European Patent Office against this patent. By letter dated October 24, 2002, Nordic Bioscience A/S informed Ostex that it had filed infringement proceedings in July 2002 against Ostex before the District Court of Düsseldorf, Germany. Ostex was served notification on December 12, 2002 of the German proceeding. On January 9, 2003, Ostex filed a notification of appearance in Germany and indicated that it will contest the matter.

Ostex may be subject to significant costs of litigation relating to Ostex intellectual property.

The cost to Ostex of any litigation or other proceedings relating to intellectual property rights, even if resolved in Ostex favor, could be substantial. Some of Ostex competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If third parties file patent applications, or are issued patents claiming technology also claimed by Ostex in pending applications, Ostex may be required to participate in interference proceedings in the Patent Trademark Office, or opposition proceedings abroad, to determine priority of invention. Ostex may be required to participate in interference or opposition proceedings involving its issued patents and pending applications. Ostex may be required to cease using the technology or license rights from prevailing third parties as a result of an unfavorable outcome in an interference proceeding. Such a prevailing party may not offer Ostex a license on commercially acceptable terms.

Ostex is subject to lengthy regulatory processes and the uncertainty of regulatory approvals.

The manufacture and marketing and sales of Ostex products and research and development activities are subject to regulation for safety 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 Ostex. Significant difficulties or costs may be encountered by Ostex in its efforts to obtain approvals that could delay or preclude Ostex from marketing and selling its products. The FDA may request the development of additional data following original submissions, causing Ostex to incur further cost and delay. Additionally, the FDA may restrict the intended use of a submitted product as a condition for clearance.

The requirements governing the conduct of clinical studies, manufacturing and marketing and selling of Ostex 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

involve similar 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.

Ostex has completed an EC Declaration of Conformity, permitting the sale of its NTx Point-of-Care device in the European Union. Ostex other products sold in the European Union will be required to meet this regulation as well by December 31, 2003. Ostex is in the process of preparing an EC Declaration of Conformity for these products. For the products currently sold in Canada, Ostex is in the process of fulfilling the quality system requirements and submitting the quality system certificate required by Health Canada by November 1, 2003. If Ostex does not meet these deadlines, it will not be able to continue to sell these products in the respective markets.

Ostex is subject to extensive continuing government regulation.

The research, development, manufacturing, marketing and sales of Ostex products are subject to extensive continuing regulation by numerous governmental authorities in the United States and certain other countries, and Ostex, 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, 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. Ostex 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 Ostex operations. Ostex is unable to predict the extent or likelihood of adverse government regulation that might arise from future U.S. or foreign government action.

The market for Ostex products is subject to intense competition.

Competition from biotechnology companies, diagnostics companies, pharmaceutical companies, and research and academic institutions is intense and is based on price as well as product performance. Ostex main competitors are Osteometer Biotech A/S, also known as Nordic Bioscience A/S, and Quidel Corporation and licensees and distributors of their technologies and products. A number of tests and procedures for the detection of 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 diagnostics industry is subject to rapid technological change. Ostex competitors may succeed in developing products which are more effective or less expensive than those that have been or are being developed by Ostex or which would render Ostex core technology obsolete, uneconomical or non-competitive. Many of Ostex competitors have, or have access to substantially greater financial, technical and human resources than Ostex. In addition, many of these competitors have significantly greater experience and resources than Ostex in undertaking clinical trials and other regulatory approval procedures, as well as in marketing and sales 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.

Ostex is dependent on its core technology and may not be able to adapt this technology to different formats.

Ostex currently relies exclusively upon its core technology for the development of products associated with osteoporosis and other collagen-related diseases. Ostex' Type I collagen patents will begin to expire in late 2007 for the United States and in 2010 for Europe and Japan. Ostex is the exclusive worldwide licensee of Metrika's patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013. Competitors of Ostex may succeed in developing new or more efficient or cost effective tests that are more readily accepted than Ostex' products. Ostex may require additional development work to adapt its core technology to different, additional or more cost-effective 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 Ostex may seek to expand the market for its products. In addition, further research and development will be required to lower the cost of the NTx Point-of-Care device beyond volume considerations and to enhance its performance. Ostex may not be successful in adapting and further developing its core technology to meet such needs. Additionally, technological changes or medical advancements could diminish or eliminate the commercial viability of the Osteomark tests or future products based upon Ostex' core technology. The failure to adapt Ostex' core technology to different or more cost effective formats, instruments, and other delivery platforms, or otherwise to commercialize such core technology, could have a material adverse effect on Ostex' results of operations.

Ostex is reliant on collaborative agreements and other relationships.

Ostex has entered into collaborative, distribution or co-promotional agreements, arrangements, or programs with several partners, including, among others, Johnson & Johnson Clinical Diagnostics, Inc., Mochida Pharmaceutical Co., Ltd., Procter & Gamble, Aventis Pharmaceuticals and Quest Diagnostics Incorporated. The level of each collaborator's involvement and support and the amount and timing of resources it will give or the amount of product it will purchase from Ostex under these agreements, arrangements, or programs are not within the control of Ostex and can significantly impact Ostex' ability to achieve its objectives. There can be no assurance that these collaborators will perform their contractual obligations or intentions as expected or that Ostex will derive revenue from such arrangements. Moreover, the agreements or business could be terminated. Ostex expects to rely on these and additional agreements, arrangements, or programs to develop, commercialize, promote and sell its present and future products. Ostex may not be able to negotiate acceptable agreements in the future. Moreover, new agreements or existing agreements may not 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 Ostex and its collaborators on a variety of matters, including financial or other obligations under the business relationships and arrangements between the companies. These disputes may be both expensive and time consuming and may result in delays in the development and commercialization of Ostex' products.

Product liability claims with respect to Ostex' products in excess of the amount of insurance could adversely affect Ostex' financial condition.

The testing, manufacturing, marketing and sale of Ostex' products may subject Ostex to product liability claims. Ostex maintains coverage against product liability risks up to a \$2,000,000 aggregate limit. However, continuing insurance coverage may not be available at an acceptable cost, if at all. Ostex 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 Ostex is insured, a product liability claim or product recall may result in losses that could be material to Ostex.

Ostex has limited suppliers.

The majority of the raw materials, technologies and purchased components used to manufacture Ostex products are readily available. However, certain of these materials, technologies and related support such as solid phase membranes and electronics modules for Ostex NTx Point-of-Care device, are from a sole supplier or a limited group of suppliers. Metrika is the sole supplier of certain critical components for Ostex NTx Point-of-Care device and any issues with their ability to supply critical components could interrupt the supply of these components for the device. There can be no assurance that Ostex 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 Ostex results of operations.

The healthcare reimbursement for Ostex products is uncertain.

Ostex 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, and the amount of such reimbursement. 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 Ostex 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 Ostex 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 Ostex to sell its products on a competitive basis. The U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services issued its Final Rule for National Medicare Coverage in November 2001. The Rule established mandatory national Medicare coverage for the use of the Osteomark NTx Urine test. The implementation date for this coverage was January 1, 2003. However, because the Rule was negotiated based on earlier clinical studies with urine tests, the rulemaking did not extend to the Osteomark NTx Serum test. In the absence of a national coverage decision, Medicare contractors will have local discretion in deciding whether the Osteomark NTx Serum test is reimbursable as a medically necessary procedure for assessing and monitoring bone loss resorption.

Ostex has experienced volatility in its stock price

The volatility of Ostex 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 status of the merger between Ostex and Inverness, the potential delisting of Ostex Common Stock from The Nasdaq National Market, the results of Ostex clinical trials or those of its competitors, adverse regulatory actions or decisions, evidence regarding the safety or efficacy of Ostex products or those of its competitors, announcements of technological innovations or new products by Ostex 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 Ostex may have a volatile effect on the market price of Ostex 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 Ostex 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. Ostex 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 Ostex business to suffer.

Item 2. Properties

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

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

2002	High	Low
1 st quarter	\$ 3.15	\$ 2.00
2 nd quarter	2.50	1.37
3 rd quarter	2.10	1.04
4 th quarter	2.32	1.11

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

The closing price of the Common Stock on December 31, 2002 was \$1.76. The closing price of the Common Stock on March 12, 2003 was \$1.80.

On November 22, 2002, Nasdaq notified Ostex that the Nasdaq Staff was reviewing Ostex's eligibility for continued listing on The Nasdaq National Market in light of Ostex's failure to satisfy the \$10,000,000 minimum shareholders' equity requirement set forth in Marketplace Rule 4450(a)(3). After reviewing information concerning the proposed merger with Inverness submitted by Ostex, Nasdaq granted Ostex an extension. Under the terms of the extension, if the merger with Inverness is not consummated by February 28, 2003 or Ostex does not apply for transfer to The Nasdaq SmallCap Market, Nasdaq will provide formal written notification that Ostex's securities will be delisted. On March 18, 2003, Ostex received formal written notice of the Nasdaq Staff's determination that Ostex's securities should be delisted from The Nasdaq National Market. On March 21, 2003, Ostex requested a hearing before a Nasdaq Listing Qualifications Panel to review the Staff delisting determination. At the hearing, Ostex intends to request continued listing on The Nasdaq National Market pending completion of the merger with Inverness. If Ostex's appeal fails or if the merger is not consummated, Ostex may seek to list its Common Stock on The Nasdaq SmallCap Market. If Ostex does not qualify for listing on The Nasdaq SmallCap Market, its Common Stock would be listed on the over-the-counter bulletin board or another quotation system or exchange on which Ostex would qualify. If Ostex's Common Stock is delisted, the delisting could have a material adverse effect on the trading price and liquidity of the stock, and shareholders' ability to sell shares of Ostex stock would be severely limited. Among other things, if not listed on The Nasdaq National Market or The Nasdaq SmallCap Market,

Ostex Common Stock may then constitute penny stock which would place increased regulatory burdens on brokers, making them less likely to make a market in Ostex stock. Loss of Ostex Nasdaq National Market status could also make it more difficult for Ostex to raise capital and would also complicate compliance with state blue sky laws.

Holders of Common Stock

As of March 12, 2003, there were 12,583,745 shares of Common Stock outstanding held of record by approximately 121 shareholders.

Dividend Policy

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

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*(in thousands, except per share amounts)*

FISCAL YEAR ENDED DECEMBER 31,	2002	2001	2000	1999	1998
PRODUCT SALES AND OTHER REVENUE	\$ 5,428	\$ 5,734	\$ 5,552	\$ 4,732	\$ 3,047
COST OF PRODUCTS SOLD	2,484	2,278	1,858	1,130	814
GROSS PROFIT	2,944	3,456	3,694	3,602	2,233
(Percentage of revenue)	54%	60%	67%	76%	73%
OPERATING EXPENSES:					
POC facility start-up costs	569	872	80		
Research and development	1,757	1,834	1,611	1,734	2,901
Selling, general and administrative	4,156	3,932	4,568	3,831	8,122
Total operating expenses	6,482	6,638	6,259	5,565	11,023
Loss from operations	(3,538)	(3,182)	(2,565)	(1,963)	(8,790)
OTHER (EXPENSE) INCOME:					
Impairment of investment	(599)				
Proceeds from legal settlement			152		
Interest (expense) income, net	(188)	83	396	393	695
Total other (expense) income	(787)	83	548	393	695
Loss before income taxes	(4,325)	(3,099)	(2,017)	(1,570)	(8,095)
Income taxes	75				
Net loss	\$ (4,400)	\$ (3,099)	\$ (2,017)	\$ (1,570)	\$ (8,095)
Basic and diluted net loss per common and common equivalent share	\$ (0.35)	\$ (0.25)	\$ (0.16)	\$ (0.13)	\$ (0.64)
Weighted average shares used in calculation of net loss per share	12,571	12,516	12,504	12,522	12,696

(in thousands)

FISCAL YEAR ENDED DECEMBER 31,	2002	2001	2000	1999	1998
--------------------------------	------	------	------	------	------

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

BALANCE SHEET DATA:

Cash, cash equivalents and short-term investments	\$	1,330	\$	3,827	\$	6,578	\$	8,400	\$	10,979
Working capital		597		4,104		6,600		9,205		10,624
Total assets		6,838		9,635		12,311		12,297		15,065
Noncurrent liabilities		937		1,138		768				117
Accumulated deficit		(43,309)		(38,909)		(35,810)		(33,793)		(32,223)
Total shareholders' equity	\$	2,581	\$	6,932	\$	9,906	\$	11,709	\$	13,488

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

Results Of Operations

Years Ended December 31, 2002, 2001, 2000. Total revenues were \$5,428,000 for the year ended December 31, 2002 as compared to \$5,734,000 and \$5,552,000 for the years ended December 31, 2001 and 2000, respectively. Revenues in 2002 included \$62,000 related to Ostex' recognition of a portion of the \$750,000 payment received from Mochida in 2002 for the license of Ostex' NTx Serum test which is being amortized over the remaining term of the patent. Revenue is primarily comprised of sales of the Ostex' products that are recognized only upon shipment. The decrease in revenue of \$306,000 in 2002 as compared to 2001 was primarily due to lower shipments of Ostex' NTx Point-of-Care device, partially offset by the sales of the NTx Serum kits. The lower sales of the point-of-care device was due primarily to manufacturing delays in the first quarter of 2002 related to the validation of the point-of-care manufacturing facility. These delays caused Proctor & Gamble and Aventis to cancel a portion of their orders and, as a result, sales of point-of-care devices in 2002 were lower than in 2001. The increase of \$182,000 in 2001 revenue compared to 2000 revenue is attributable to an increase in sales for the Osteomark NTx Point-of-Care device.

Ostex' cost of products sold totaled \$2,484,000 for the year ended December 31, 2002, as compared to \$2,278,000 and \$1,858,000 for the same periods in 2001 and 2000, respectively. The gross margin on product sales for the year ended 2002 was 54% as compared to 60% and 67% in 2001 and 2000. The decrease in the gross margin from 2001 to 2002 was due to the excess capacity of the point-of-care manufacturing facility, which was validated to produce a high volume of devices. Point-of-care production capacity will continue to exceed the production plan for devices in the near-term future and may exceed the production plan for devices in the long-term. The resulting excess capacity will have a negative impact on Ostex' gross profit margins unless and until demand increases. The decrease in gross margin from 2000 to 2001 was due in part to increased sales of the NTx Point-of-Care device, which has a lower margin than the NTx Urine and Serum kits. 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.

Ostex also incurred start-up costs for its new point-of-care manufacturing facility that totaled \$569,000 in 2002 as compared to \$872,000 and \$80,000 in 2001 and 2000, respectively. This expense relates to the facility operating costs, labor and material costs to validate the facility, and production validation runs for pilot lots of the NTx Point-of-Care device prior to the production of sellable devices. The expense decreased by \$303,000 from 2001 to 2002 due to the successful validation of the facility in May of 2002. Ostex is now producing and shipping devices out of its own facility, and the cost of those devices is being expensed through cost of goods sold. Prior to manufacturing sellable devices on its own, Ostex purchased finished devices from Metrika.

Ostex' research and development expenditures totaled \$1,757,000, \$1,834,000, and \$1,611,000 in 2002, 2001, and 2000, respectively. The \$77,000 decrease from 2001 to 2002 was primarily related to personnel costs. 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.

Selling, general and administrative expenses totaled \$4,156,000, \$3,932,000, and \$4,568,000 in 2002, 2001, and 2000, respectively. Expenses increased by \$224,000 in 2002 over 2001 due to legal and investment banker fees and expenses in connection with the proposed merger of Ostex with Inverness, which merger related fees and expenses totaled approximately \$1,000,000 for the year 2002. The increase in expenses was

Edgar Filing: OSTEK INTERNATIONAL INC /WA/ - Form 10-K

partially offset by a business and occupancy tax refund in the third quarter of 2002, from the Washington Department of Revenue for research and development tax credits not taken in six prior years. In addition, sales and marketing had lower personnel costs and a lower level of expenditures in 2002 as compared 2001. 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 products.

Other expenses in 2002 includes an impairment of Ostex \$599,000 preferred stock investment in Metrika. In the fourth quarter, Ostex management determined that there had been an other than temporary decline in the value of Ostex investment in Metrika based on recent financial information obtained from Metrika, including

its cash balance, cash expenditure rate, and immediate need for financing. Management believes that these factors are a strong indicator that the fair value of Ostex preferred stock holdings in Metrika are substantially near zero and has adjusted the cost basis accordingly.

Interest (expense) income, net was (\$188,000) in 2002 as compared to interest income of \$83,000 and \$396,000 in 2001 and 2000, respectively. The \$271,000 decrease in 2002 as compared to 2001 and the \$313,000 decrease from 2000 as compared to 2001 resulted from less interest income from lower balances of cash and short-term investments and higher interest expense related to Ostex debt for both periods. Ostex borrowed \$2,316,000 from Transamerica Business Credit Corporation during 2000 and 2001 for the point-of-care facility build-out. Ostex started repaying the loans during 2001.

Proceeds from legal settlement were \$152,000 in 2000 and resulted from a one-time settlement fee paid by Osteometer Biotech A/S related to the settlement of the lawsuit between Osteometer and Ostex in 2000 (see Note 9 - Litigation, to the accompanying financial statements).

At December 31, 2002, Ostex had tax net operating loss carryforwards of approximately \$45,977,000, 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. Ostex has determined that the tax assets do not satisfy the realization 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. In 2002, Ostex recorded \$75,000 of foreign tax expense for the tax paid in Japan in connection with the lump sum payments received from Mochida under the Serum Osteomark License Agreement.

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.

Recently Issued Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations (SFAS No. 143), which provides the accounting requirements for retirement obligations associated with tangible long-lived assets. This statement requires entities to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred. The provisions of SFAS No. 143 are effective for fiscal years beginning after June 15, 2002. Ostex is currently assessing the impact of implementing this statement on our results of operations and financial position.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS No. 146). This statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). This statement requires that a liability for a cost associated with an exit or disposal activity be recognized at fair value when the liability is incurred. This statement will be effective for Ostex' 2003 fiscal year, and early adoption is permitted. The adoption of SFAS No. 146 is not expected to have a material impact on Ostex results of operations or financial position.

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

In November 2002, the FASB issued the FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, which elaborates on the disclosures to be made by a guarantor about its obligations under certain guarantees that it has issued, if any. OSTECH has reviewed the Interpretation and has concluded that it does not need to make any additional disclosures in this filing and does not expect this interpretation to have a material impact on its results of operations or financial position in 2003.

In December 2002, the FASB issued the Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement 123 (SFAS 148). SFAS 148 provides new transition alternatives for companies adopting the fair value method of accounting for stock-based compensation prescribed by SFAS 123 and changes certain disclosure requirements for companies electing to continue applying the APB 25 intrinsic value method. Ostex has no current plans to adopt the fair value method of accounting but has revised its disclosure accordingly.

Critical Accounting Policies

Ostex has identified the most critical accounting policies used in the preparation of its financial statements by considering accounting policies that involve the most complex or subjective decisions or assessments. Ostex most critical accounting policies relate to revenue recognition, products returns, the carrying value of the investment in Metrika, and the carrying value of Ostex property, plant and equipment for our manufacturing operations.

Ostex revenue recognition policies are based on the requirements of Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements. Revenue is recorded when earned, which for product sales occurs upon shipment. Any payments received prior to meeting the criteria for revenue recognition are deferred until such criteria are met. Research and development payments and license fees are recognized upon attainment of the agreed upon milestones and ratably over the term of the agreement, respectively. The 2002 license payments from Mochida, totaling \$750,000, related to the NTx Serum kit will be recognized ratably over the period Ostex is obligated to provide finished products as specified in the agreement.

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, our revenues could be impacted by an increase in the return provision.

Ostex has historically recorded its investment in Metrika at the lower of cost or market and periodically assessed the value of the investment and compared it to the cost basis to determine whether the investment is impaired. Ostex assessment of the valuation of this asset was based on historical financial data, assumed valuations of Metrika, relevant liquidation preferences made during additional investment rounds, future projections, Metrika's performance and the general changes in the U.S. equity markets. In the fourth quarter of 2002, Ostex management determined that there had been an other than temporary decline in the value of its investment in Metrika based on recent financial information obtained from Metrika including its cash balance, cash expenditure rate and immediate need for financing. Ostex believes that these factors are a strong indicator that the fair value of its preferred stock holdings in Metrika are substantially near zero and has adjusted the cost basis accordingly.

Ostex has adopted the provisions of the Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144) (effective for Ostex 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. Ostex has assessed its long-lived assets to see if any impairment should be recognized, paying particular attention to our NTx Point-of-Care device manufacturing assets. Ostex determined that these assets were not impaired at December 31, 2002. This assessment was conducted using Ostex most recent projections over the expected life of the underlying assets. The adoption of SFAS No. 144 did not have any effect on Ostex financial statements.

Liquidity And Capital Resources

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

As of December 31, 2002, OSTECH had \$1,330,000 in cash and cash equivalents, working capital of \$597,000 and total shareholders' equity of \$2,581,000. As a result of funding operating losses during 2002, cash and cash equivalents and short-term investments decreased by \$2,497,000, working capital decreased by \$3,507,000, and shareholders' equity decreased by \$4,351,000.

OSTECH used \$2,659,000 of cash for operating activities in 2002. OSTECH used \$271,000 in 2002 and \$582,000 in 2001 to purchase property, plant, and equipment. In 2002, these purchases were primarily for computer

upgrades and R&D equipment and in 2001 the purchases were for manufacturing and office equipment, primarily for the point-of-care manufacturing facility. Inventory increased to \$1,468,000 in 2002, up \$474,000 from 2001, primarily due to the manufacturing activities associated with producing and stocking finished NTx Point-of-Care devices and the purchase in 2002 of component parts for the device. Inventories are stated at the lower of cost or market. Also during 2002, Ostex issued 25,000 shares of common stock related to the exercise of stock options, receiving \$20,000 in proceeds.

In 2000, Ostex entered into an agreement with Transamerica Business Credit Corporation, which provided up to \$2,800,000 in debt financing for the new manufacturing facility. During 2000 and 2001, Ostex borrowed a total of \$2,316,000 under this agreement at an annual interest rate of approximately 14.5%. The indebtedness is evidenced by a series of notes and is secured by all equipment financed with the borrowed funds. There are no further funds available to Ostex under this financing arrangement. As of December 31, 2002, the principal balance remaining under the notes was \$1,138,000. Each note is payable in 36 monthly installments with a balloon payment at the end of the term. The notes have due dates ranging from November 2003 to January 2005.

On September 6, 2002, Ostex entered into an agreement to merge with Inverness Medical Innovations, Inc. The merger agreement was amended as of February 18, 2003 to, among other things, reduce the aggregate number of shares of Inverness common stock issuable in the merger. The transaction is expected to close in the second quarter of 2003. Inverness acquisition of Ostex is subject to certain closing conditions, including Inverness obtaining consent of certain of its lenders to the merger and approval of the merger by Ostex shareholders. Some of the closing conditions to the merger are outside the control of Ostex and Inverness, and there can be no assurance that the merger will occur.

Ostex has incurred substantial expenses in connection with the proposed merger. If the merger does not occur, Ostex currently expects to incur a total of approximately \$1.5 million to \$1.7 million in merger related expenses, excluding any termination fees, if applicable. These expenses would have a material adverse effect on the results of operations and financial condition of Ostex because Ostex will have not realized the expected benefits of the merger. As a result of the delay and the renegotiation of the merger agreement, Ostex will incur more expenses than originally anticipated due to additional legal, accounting and investment banking costs and the cost of extending the term of Ostex current directors and officers insurance coverage.

In connection with the merger agreement, as amended, Inverness and Ostex also entered into an amended and restated loan agreement. Under the loan agreement, Inverness has agreed to make, or arrange for one of its affiliates to make, loans of up to an aggregate of \$2,000,000 to Ostex. The annual interest rate of each loan is an amount equal to LIBOR for one-year loans as published in the Wall Street Journal on the date of each loan, plus four and one-half percent. Ostex borrowed \$334,000 under the loan agreement on October 10, 2002 at an interest rate of 6.27%, borrowed \$433,000 on November 12, 2002 at an interest rate of 6.04%, and borrowed \$233,000 on December 9, 2002 at an interest rate of 6.16%. As of December 31, 2002, the total amount borrowed under the Inverness loan agreement was \$1,000,000. Ostex is entitled to borrow the remaining \$1,000,000 under the loan agreement at any time on or after January 2, 2003, provided that certain conditions are met, in order to maintain sufficient cash, cash equivalents and short-term investments to fund six-months of its budgeted working capital needs. On January 9, 2003, Ostex borrowed an additional \$379,000 at an interest rate of 6.02%. On February 25, 2003, Ostex borrowed an additional \$246,158 at an interest rate of 5.90%.

The loans must be repaid at the earliest of:

the first business day after the effective time of the merger;

acceleration upon an event of default;

the termination of the merger agreement in specified circumstances related to Ostex breach of the terms of the merger agreement or stock option agreement or Ostex board's approval of an acquisition proposal or withdrawal of its approval or recommendation of the merger agreement;
or

December 31, 2003.

If, during the loan period, the merger agreement is terminated in circumstances that would not be an event of default under the loan agreement, Ostex may borrow a maximum of \$1,750,000 from Inverness under the loan agreement, assuming satisfaction of certain conditions. If the merger is not consummated and \$1,750,000 of the loan funds are received, Ostex believes it will be able to fund its operations through July 2003, based on current projections. Such loan liability, however, may have a material impact on the results of operations and financial condition of Ostex because Ostex will not have realized the expected benefits of the merger.

Until the merger becomes effective, and with some exceptions, Ostex is prohibited from entering into or soliciting, initiating or encouraging any inquiries or proposals that may lead to an acquisition proposal from any person other than Inverness. Ostex also agreed to pay a termination fee to Inverness of \$1.8 million if the merger agreement is terminated in specified circumstances, including circumstances in which Ostex takes any of these prohibited actions or fails to obtain the approval of its shareholders after a proposal from an eventual third party acquiror is received by Ostex or publicly announced. In addition, Ostex has granted Inverness an option to purchase up to 19.9% of Ostex outstanding shares of common stock at an exercise price of \$2.39 per share. Inverness may exercise this option upon the occurrence of specified events that ordinarily would be associated with an acquisition or potential acquisition of Ostex by a third party. If the option becomes exercisable in specified circumstances in connection with an acquisition proposal, Inverness may also cancel the option, or any portion of the option, in exchange for an amount of cash equal to the product of (a) the excess of the per share exercise price over the highest per share purchase price proposed to be paid pursuant to an acquisition proposal that caused, or would cause, the option to become exercisable, or the current average market price per share, if higher, multiplied by (b) the number of shares subject to the portion of the option that is canceled. These provisions could discourage other companies from trying to acquire Ostex even though those other companies might be willing to offer greater value to Ostex shareholders than Inverness has offered in the merger. The payment of the termination fee or cash upon an exercise of the stock option could also have a material adverse effect on Ostex financial condition.

If the proposed merger is not consummated, Ostex may seek to raise additional capital by sales of equity or debt securities in the public equity markets or through private placements. There can be no assurance that additional funds will be available on favorable terms, if at all. Ostex also may be required to delay, scale back or eliminate some or all of our marketing and sales and research and development programs, sell assets, license to third parties rights to commercialize products or technologies that it would otherwise seek to develop on its own, or seek bankruptcy protection. Ostex has agreed that, except as contemplated or permitted by the merger agreement or otherwise consented to by Inverness in writing, Ostex will, during the pendency of the merger and, if the loan is still in effect in certain circumstances after termination of the merger agreement, comply with restrictions relating to the operation of its business, including, but not limited to, acquiring or issuing any securities, incurring indebtedness for borrowed money, making any loans, advances or capital contributions, encumbering any of its assets, settling material litigation, making capital expenditures other than in the ordinary course of business and consistent with past practice and in an amount in excess of \$50,000, entering into any material agreement, and licensing, transferring or materially amending any of its intellectual property. These restrictions may limit severely Ostex ability to raise operating capital in a timely manner.

In addition, if the merger is not consummated, Ostex will not be able to satisfy ongoing listing requirements and there is at substantial risk that its Common Stock will be delisted from The Nasdaq National Market. Such delisting would most likely have a material adverse effect on the trading price and liquidity of Ostex securities and would further compound the difficulty of raising capital.

Ostex future capital requirements depend upon many factors, including the proposed merger with Inverness and the realization of the benefits expected from the proposed merger; effectiveness of the Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for Ostex products; continued scientific progress in research and development programs; the costs involved in filing, prosecuting, enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining regulatory approvals.

The following table summarizes our contractual obligations and other commercial commitments as of December 31, 2002, and the effect such obligations and commitments are expected to have on liquidity for future periods. Long-term debt payments are principal portions only.

Contractual obligations	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long-term debt	\$ 2,193,000	\$ 1,855,000	\$ 338,000	\$	\$
Operating leases	2,315,000	629,000	1,279,000	217,000	190,000
Total cash obligations	\$ 4,519,000	\$ 2,495,000	\$ 1,617,000	\$ 217,000	\$ 190,000

Ostex financial statements are presented on a going concern basis and assume that assets will be realized in the normal course of business. If Ostex is forced to liquidate its assets, Ostex may not recover the carrying amount of such assets.

KPMG LLP, Ostex independent auditors, has included a going concern uncertainty paragraph in its audit report on Ostex financial statements for the year ended December 31, 2002, which states that Ostex recurring losses from operations and need to raise additional capital to meet its operating and debt requirements if the proposed merger with Inverness is unsuccessful, raise substantial doubt about Ostex ability to continue as a going concern.

Other Factors That May Affect Operating Results

Ostex 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 Ostex products, changing economic conditions, actions of competitors, delays and increased costs of product and technology development, manufacturing performance, Ostex ability to develop and maintain collaborative arrangements, the outcome of litigation, the pending merger with Inverness and the associated costs, and the effect of Ostex accounting policies and other risk factors detailed in this report and other Securities and Exchange Commission filings. All of the foregoing factors are difficult for Ostex to predict and could materially and adversely affect our business and operating results.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. Ostex exposure to market rate risk, as a result of changes in interest rates, relates primarily to its investment portfolio. At December 31, 2002, Ostex held \$1,330,000 in cash and cash equivalents and no fixed or adjustable rate investments that would carry any significant degree of interest rate risk. Additionally, at December 31, 2002 Ostex had \$2,193,000 of notes payable. While fluctuations in interest rates may affect the fair value of this debt, Ostex debt payments will not be affected due to fixed interest rates on this debt.

Currency risk. Ostex 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 Ostex credit authorization policy, current economic conditions in countries in which Ostex does significant business,

and the level of outstanding foreign receivables, Ostex does not consider this risk to be material.

Item 8. Financial Statements and Supplementary Data

Report of Independent Public Accountants

INDEPENDENT AUDITORS' REPORT

To the Board of Directors and Shareholders:

We have audited the accompanying balance sheet of Ostex International, Inc. as of December 31, 2002 and the related statements of operations, shareholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. The accompanying financial statements of Ostex International, Inc. as of December 31, 2001 and 2000 and for the years then ended were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated January 31, 2002.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Ostex International, Inc. as of December 31, 2002, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and needs to raise significant additional capital to meet its operating and debt requirements if the proposed merger is unsuccessful. These factors raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Seattle, Washington
January 24, 2003

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

This audit report of Arthur Andersen LLP, Ostex' former independent public accountants, is a copy of the original report dated January 31, 2002 rendered by Arthur Andersen LLP on Ostex' financial statements included in Ostex' Form 10-K filed on March 29, 2002, and has not been reissued by Arthur Andersen LLP since that date. Ostex is including this copy of the Arthur Andersen LLP audit report pursuant to Rule 2-02(e) of Regulation S-X under the Securities Act of 1933.

OSTEK INTERNATIONAL, INC.

BALANCE SHEETS

(in thousands, except share and per share amounts)

December 31,	2002	2001
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 1,330	\$ 1,284
Short-term investments		2,543
Trade receivables, net of allowance of \$70 in 2002 and \$54 in 2001	944	815
Inventory	1,468	994
Other current assets	175	33
Total current assets	3,917	5,669
Property, plant and equipment, net	2,832	3,272
Other assets	89	694
Total assets	\$ 6,838	\$ 9,635
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 622	\$ 279
Customer deposits	99	156
Accrued liabilities	655	495
Current portion of deferred revenue	89	
Current portion of notes payable	1,855	635
Total current liabilities	3,320	1,565
Noncurrent Liabilities		
Deferred revenue, net of current portion	599	
Notes payable, net of current portion	338	1,138
Total noncurrent liabilities	937	1,138
Commitments and Contingencies		
Shareholders Equity:		
	126	126

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

Common stock, \$.01 par value, 50,000,000 authorized; 12,583,435 and 12,558,174 issued and outstanding at December 31, 2002 and 2001, respectively

Additional paid-in capital	45,764	45,709
Accumulated other comprehensive income		6
Accumulated deficit	(43,309)	(38,909)
Total shareholders' equity	2,581	6,932
Total liabilities and shareholders' equity	\$ 6,838	\$ 9,635

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

OSTECH INTERNATIONAL, INC.

STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

YEAR ENDED DECEMBER 31,	2002	2001	2000
REVENUE			
Product sales and other revenue	\$ 5,428	\$ 5,734	\$ 5,552
Cost of products sold	2,484	2,278	1,858
Gross profit	2,944	3,456	3,694
OPERATING EXPENSES:			
POC facility start-up costs	569	872	80
Research and development	1,757	1,834	1,611
Selling, general and administrative	4,156	3,932	4,568
Total operating expenses	6,482	6,638	6,259
Loss from operations	(3,538)	(3,182)	(2,565)
OTHER (EXPENSE) INCOME:			
Impairment of investment	(599)		
Proceeds from legal settlement			152
Interest income	61	295	433
Interest expense	(249)	(212)	(10)
Other expense			(27)
Total other (expense) income	(787)	83	548
Loss before income taxes	(4,325)	(3,099)	(2,017)
Income taxes	75		
Net loss	\$ (4,400)	\$ (3,099)	\$ (2,017)
Basic and diluted net loss per common and common equivalent share	\$ (0.35)	\$ (0.25)	\$ (0.16)
Weighted average shares used in calculation of net loss per share	12,571	12,516	12,504

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

OSTEK INTERNATIONAL, INC.

STATEMENTS OF SHAREHOLDERS EQUITY

(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Compre- hensive Loss	Total Shareholders Equity
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
Warrants issued to outside consultants			35				35
Stock options exercised	25		20				20
Comprehensive loss							
Reclassification adjustment for unrealized gains included in loss				(6)		(6)	(6)
Net loss					(4,400)	(4,400)	(4,400)

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

Comprehensive loss							(4,406)		
Balance, December 31,									
2002	12,583	\$	126	\$	45,764	\$	(43,309)	\$	2,581

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

OSTEK INTERNATIONAL, INC.

STATEMENTS OF CASH FLOWS

(In thousands)

YEAR ENDED DECEMBER 31,	2002	2001	2000
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (4,400)	\$ (3,099)	\$ (2,017)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	712	721	496
Loss on disposal of property, plant and equipment		2	27
Expense from issuance of warrants	35	19	105
Impairment of investment	599		
Changes in current assets and current liabilities			
Trade receivables	(129)	257	(114)
Inventory	(474)	(529)	(214)
Other current assets	(142)	56	
Accounts payable	343	(709)	710
Customer deposits	(57)	156	
Deferred revenue	688		
Accrued liabilities	160	131	169
Other assets	6		
Net cash used in operating activities	(2,659)	(2,995)	(838)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of short-term investments		(1,213)	(5,288)
Proceeds from sales and maturities of short-term investments	2,537	3,966	6,953
Purchase of property, plant and equipment	(272)	(582)	(2,031)
Net cash provided by (used in) investing activities	2,265	2,171	(366)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Net proceeds from issuance of common stock and exercise of stock options	20	59	126
Stock repurchases		(19)	(74)
Proceeds from note payable	1,000	1,228	1,088
Payments on note payable	(580)	(508)	(150)
Net cash provided by financing activities	440	760	990
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	46	(64)	(214)

CASH AND CASH EQUIVALENTS , beginning of period		1,284		1,348		1,562
CASH AND CASH EQUIVALENTS , end of period	\$	1,330	\$	1,284	\$	1,348
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:						
Interest paid on notes payable	\$	248	\$	212	\$	10
SUPPLEMENTAL DISCLOSURE OF NONCASH FINANCING ACTIVITIES:						
Warrants issued to lender	\$		\$		\$	62

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. (Ostex), 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. Ostex' lead product, the Osteomark® NTx test, which is available in multiple formats, incorporates breakthrough and patented technology for the management of osteoporosis. Ostex has collaborative relationships with leading reference laboratories and distributors and markets its Osteomark NTx Point-of-Care device primarily to pharmaceutical companies to aid in the commercialization of its Osteomark technology.

On September 9, 2002, Ostex announced that it had entered into an agreement and plan of merger whereby Ostex would be acquired by and become a wholly owned subsidiary of Inverness Medical Innovations, Inc. The agreement and plan of merger was amended in certain respects effective as of February 18, 2003. In connection with the merger agreement, as amended, Inverness and Ostex also entered into an amended and restated loan agreement. Under the loan agreement, Inverness has agreed to make, or arrange for one of its affiliates to make, loans of up to an aggregate of \$2,000,000 to Ostex. The loans must be repaid on the first business day after the effective time of the merger, upon an event of a default or a breach of the terms of the merger agreement by Ostex, or, in the case where the merger agreement is terminated and it is not an event of default under the loan agreement, on December 31, 2003.

Until the merger becomes effective, and with some exceptions, Ostex is prohibited from entering into or soliciting, initiating or encouraging any inquiries or proposals that may lead to an acquisition proposal from any person other than Inverness. Ostex also agreed to pay a termination fee to Inverness of \$1.8 million if the merger agreement is terminated in specified circumstances, including circumstances in which Ostex takes any of these prohibited actions or fails to obtain the approval of its shareholders after a proposal from an eventual third party acquiror is received by Ostex or publicly announced. In addition, Ostex has granted Inverness an option to purchase up to 19.9% of Ostex' outstanding shares of common stock at an exercise price of \$2.39 per share. Inverness may exercise this option upon the occurrence of specified events that ordinarily would be associated with an acquisition or potential acquisition of Ostex by a third party. If the option becomes exercisable in specified circumstances in connection with an acquisition proposal, Inverness may also cancel the option, or any portion of the option, in exchange for an amount of cash equal to the product of (a) the excess of the per share exercise price over the highest per share purchase price proposed to be paid pursuant to an acquisition proposal that caused, or would cause, the option to become exercisable, or the current average market price per share, if higher, multiplied by (b) the number of shares subject to the portion of the option that is canceled. These provisions could discourage other companies from trying to acquire Ostex even though those other companies might be willing to offer greater value to Ostex shareholders than Inverness has offered in the merger. The payment of the termination fee or cash upon an exercise of the stock option could also have a material adverse effect on Ostex' financial condition.

These financial statements have been prepared assuming that Ostex will continue as a going concern. Ostex' future capital requirements depend upon many factors, including the proposed merger with Inverness and the realization of the benefits expected from the proposed merger; effectiveness of its Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for Ostex products; continued scientific progress in research and development programs; the costs involved in filing, prosecuting, enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining regulatory approvals. Because of near-term cash requirements, if the merger is not consummated, Ostex will seek to raise additional capital through public or private sales of its equity or debt securities. There can be no assurance that additional funds will be available on favorable terms, if at all. In the circumstance that the merger is not consummated, Ostex could draw up to a maximum of \$1,750,000 in loan funds from Inverness (including funds drawn through December 31, 2002 and subject to satisfaction of certain conditions) under the loan agreement. Ostex believes that its existing available cash, the proceeds from the loan from Inverness, future license

and research revenues from existing collaboration agreements, and our current level of product sales will be adequate to fund operations through July 2003. If funding is insufficient at any time in the

future, Ostex may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; license to third parties rights to commercialize products or technologies that Ostex would otherwise seek to develop on its own; or seek bankruptcy protection.

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 is fixed and collection 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 or ratably over the term of the agreement. 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. Deferred revenue represents license payments received from Mochida for Ostex NTx Serum kit product which will be recognized ratably over the term of the period Ostex is obligated to provide finished products as specified in the agreement.

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 new facility, tooling, and production prior to the production of sellable devices. These costs were expensed as incurred.

Cash And Cash Equivalents

Ostex 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.

Segments

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

Concentration Of Credit Risk

Trade receivables potentially subject Ostex to credit risk. We extend credit to our customers based upon an evaluation of the customer's financial condition and credit history and we generally do not require collateral. Ostex historically has incurred minimal credit losses. In 2002, domestic product sales accounted for 60% of total revenue and product sales to customers in foreign countries accounted for 40% of total revenue. Sales to Japan accounted for 23% of total revenue. Accounts receivable for the same year is comprised of 62% domestic and 38% foreign receivables. In 2001, domestic product sales accounted for 65% of total revenue and product sales to customers in foreign countries accounted for 35% of total revenue with sales to Japan accounting for 10% of total revenue. Accounts receivable for 2001 was comprised of 63% domestic and 37% foreign receivables. In 2000, domestic product sales accounted for 70% of total revenue and product sales to customers in foreign countries accounted for 30% of total revenue with sales to Japan accounting for 10% of total revenue. All sales are denominated in U.S. dollars.

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 Ostex total revenues (an % means that for that year, the customers percentage went below 10%):

Year ended December 31,	Number of Significant Customers	Percentage of Total Revenues			
		A	B	C	D
2002	2	%	15%	23%	%
2001	3	16%	11%	10%	%
2000	3	%	14%	10%	10%

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

As of December 31,	Number of Significant Customers	Percentage of Net Receivables				
		A	B	C	D	E
2002	3	%	21%	17%	%	14%
2001	2	30%	%	13%	%	%

Trade Receivables

Trade receivables are stated at the net amount Ostex expects to collect for outstanding receivables after application of an allowance for doubtful accounts. Trade receivables are written-off when Ostex deems specific customer amounts to be uncollectible. The activity in the allowance for doubtful accounts consisted of additional provisions of \$16,000, \$0, and \$21,000 in 2002, 2001, and 2000, respectively, and write-offs of \$0, \$1,000, and \$0 in 2002, 2001 and 2000, respectively.

Warranty/Product Liability Accruals

Warranty and product liability accruals are established to provide for estimated future expenses as a result of construction and product defects. Ostex recorded expenses to increase the warranty accrual of \$10,000, \$10,000, and \$0 in 2002, 2001, and 2000, respectively. There were no warranty claims in 2002, 2001, and 2000. Liability estimates are determined based on management judgment considering such factors as historical experience, the likely current cost of corrective action, manufacturers and subcontractors participation in sharing the cost of corrective action, and consultations with third party experts such as engineers.

Inventory

Inventory consists principally of raw materials and work in process. Inventories are stated at the lower of cost (first-in, first-out) or market. Cost is computed using standard costs that approximate actual cost plus certain manufacturing overhead amounts. Our entire finished goods inventory has a limited shelf life and we regularly make estimates of inventory amounts which will not be sold within the appropriate time frame and charge off such amounts to cost of products sold.

The components of inventory are:

	December 31, 2002		December 31, 2001	
Raw materials	\$	971,000	\$	340,000
Work in process	\$	437,000	\$	585,000
Finished goods	\$	60,000	\$	69,000
Total inventory	\$	1,468,000	\$	994,000

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 2002, 2001, and 2000 was \$712,000, \$721,000, and \$496,000, respectively. We assess the potential impairment of our long-lived assets when there is evidence that events or changes in circumstances have made recovery of the assets carrying value unlikely. No such impairment charges have been recorded in the accompanying financial statements.

Fair Value of Financial Instruments

The carrying value of OSTECH financial instruments, including cash and cash equivalents, short-term investments, and trade receivables approximate fair value due to their short-term nature or variable interest rates. OSTECH also believes that the carrying value of debt approximates its fair value.

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. The number of stock options outstanding at December 31, 2002 was 2,684,597 and the number of warrants outstanding was 85,600. The number of stock options outstanding at December 31, 2001 was 2,755,004 and the number of warrants outstanding was 116,504. The number of stock options outstanding at December 31, 2000 was 2,524,910 and the number of warrants outstanding was 102,504. These were excluded from the loss per share calculation as their effect would be antidilutive.

Stock Option Plans

OSTECH has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123) and has applied that method in all years presented. Accordingly, no compensation cost has been recognized for stock options issued at market value on the date of grant. Had compensation cost for OSTECH Stock Option Plans been determined based on the fair value of the options at the grant date for awards in 2002, 2001, and 2000 consistent with the provisions of SFAS No. 123, OSTECH net loss and net loss per common equivalent share would have changed to the pro forma amounts indicated below:

	2002	2001	2000
Net loss as reported	\$ (4,400,000)	\$ (3,099,000)	\$ (2,017,000)
Stock based employee compensation - included in the determination of net loss as reported:			
Stock based employee compensation assuming application of fair value method to all awards:	544,000	605,000	453,000
Net loss pro forma	\$ (4,944,000)	\$ (3,704,000)	\$ (2,470,000)
Basic and diluted net loss per common and common equivalent share as reported	\$ (0.35)	\$ (0.25)	\$ (0.16)
Basic and diluted net loss per common and common equivalent share pro forma	\$ (0.39)	\$ (0.30)	\$ (0.20)

Recently Issued Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 143, Accounting for Asset Retirement Obligations (SFAS No. 143), which provides the accounting requirements for retirement obligations associated with tangible long-lived assets. This statement requires entities to record the fair value of a liability for an asset retirement obligation in the period in which it is incurred. The provisions of SFAS No. 143 are effective for fiscal years beginning after June 15, 2002. We are currently assessing the impact of implementing this statement on our results of operations and financial position.

In June 2002, the FASB issued Statement of Financial Accounting Standards No. 146, Accounting for Costs Associated with Exit or Disposal Activities (SFAS No. 146). This statement addresses financial accounting and reporting for costs associated with exit or disposal activities and

Edgar Filing: OSTEK INTERNATIONAL INC /WA/ - Form 10-K

nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). This statement requires that a liability for a cost associated with an exit or disposal activity be recognized at fair value when the liability is incurred. This statement will be effective for our 2003 fiscal year, and early adoption is permitted. The adoption of SFAS No. 146 is not expected to have a material impact on our results of operations or financial position.

In November 2002, the FASB issued the FASB Interpretation No. 45, Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others which elaborates on the disclosures to be made by a guarantor about its obligations under certain guarantees that it

has issued, if any. Ostex has reviewed the Interpretation and has concluded that it does not need to make any additional disclosures in this filing and does not expect his interpretation to have a material impact on its results of operations or financial position in 2003.

In December 2002, the FASB issued the Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure, an amendment of FASB Statement 123 (SFAS 148). SFAS 148 provides new transition alternatives for companies adopting the fair value method of accounting for stock-based compensation prescribed by SFAS 123 and changes certain disclosure requirements for companies electing to continue applying the APB 25 intrinsic value method. Ostex has no current plans to adopt the fair value method of accounting but has revised its disclosure accordingly.

Reclassification

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

Note 2 - Short-Term Investments

Ostex short-term investments at December 31, 2002 and 2001 consisted of the following:

	2002	2001
Federal agency obligations	\$	\$ 1,580,000
Government agency obligations	\$	963,000
	\$	\$ 2,543,000

Note 3 - Property, Plant And Equipment

Property, plant and equipment at December 31, 2002 and 2001 consisted of the following:

	2002	2001
Leasehold improvements	\$ 4,058,000	\$ 4,058,000
Laboratory and manufacturing equipment	2,072,000	1,909,000
Computers and office equipment	1,473,000	1,370,000
Construction-in-progress	5,000	
	7,608,000	7,337,000
Accumulated depreciation and amortization	(4,776,000)	(4,065,000)
Net property, plant and equipment	\$ 2,832,000	\$ 3,272,000

Note 4 - Impairment Of Investment In Metrika

At December 31, 2001, other assets primarily consisted of a \$599,000 investment in the preferred stock of Metrika. Ostex has historically recorded its investment in Metrika at the lower of cost or market and periodically assessed the value of the investment and compared it to the cost basis to determine whether it is impaired or not. Our assessment of the valuation of this asset was based on historical financial data, assumed valuations of Metrika, relevant liquidation preferences made during additional investment rounds, future projections, and Metrika's performance and the general changes in the U.S. equity markets. In the fourth quarter of 2002, management determined that there had been an other than temporary decline in the value of its investment in Metrika based on financial information obtained from Metrika including its cash balance, cash expenditure rate, and immediate need for financing. Management believes that these factors are a strong indicator that the fair value of its preferred stock holdings in Metrika is substantially near zero and has adjusted the cost basis accordingly.

Note 5 - Note Payable

On October 2, 2000, Ostex and Transamerica Business Credit Corporation (Transamerica) signed a letter of commitment whereby Transamerica provided debt financing for our manufacturing expansion plan. Each draw down was on a separate note, secured by 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, 2002, Ostex has received \$2,316,000 in proceeds under six separate note agreements, with a balance due of \$1,138,000. The annual interest rate under the six notes is fixed at approximately

14.5%. There is no further availability of funds under this financing. We believe that the carrying value of the debt approximates the fair value of this debt.

Ostex also entered into an amended and restated loan agreement with Inverness in connection with the merger agreement, as amended, between the two companies. Under the loan agreement, Inverness has agreed to make, or arrange for one of its affiliates to make, loans of up to an aggregate of \$2,000,000 to Ostex. The annual interest rate of each loan is an amount equal to LIBOR for one-year loans as published in the Wall Street Journal on the date of each loan, plus four and one-half percent. Ostex borrowed \$334,000 under the loan agreement on October 10, 2002 at an interest rate of 6.27%, borrowed \$433,000 on November 12, 2002 at an interest rate of 6.04%, and borrowed \$233,000 on December 9, 2002 at an interest rate of 6.16%. As of December 31, 2002, the total amount borrowed under the Inverness note was \$1,000,000. Ostex is entitled to borrow the remaining \$1,000,000 under the loan agreement at any time on or after January 2, 2003, provided that certain conditions are met, in order to maintain sufficient cash, cash equivalents and short-term investments to fund six-months of its budgeted working capital needs. On January 9, 2003, Ostex borrowed an additional \$379,000 at an interest rate of 6.02%. On February 25, 2003, Ostex borrowed an additional \$246,158 at an interest rate of 5.90%.

The loans from Inverness must be repaid at the earliest of:

- a. the first business day after the effective time of the merger;
- b. acceleration upon an event of default;
- c. the termination of the merger agreement in specified circumstances related to Ostex breach of the terms of the merger agreement or stock option agreement or Ostex board's approval of an acquisition proposal or withdrawal of its approval or recommendation of the merger agreement; or
- d. December 31, 2003.

If, during the loan period, the merger agreement is terminated in circumstances that would not be an event of default under the loan agreement, Ostex may borrow a maximum of only \$1,750,000 compared to the \$2,000,000 that would otherwise be available from Inverness under the loan agreement, assuming satisfaction of certain conditions. Ostex believes that the carrying value of the debt approximates the fair value of this debt due to its short-term nature.

As of December 31, 2002, the principal payments under all of Ostex notes are as follows:

2003	\$	1,855,000
------	----	-----------

2004	293,000
2005	37,000
2006	8,000
Total principal due on notes	\$ 2,193,000

Interest expense on all of Ostex notes combined was \$251,000 in 2002, \$212,000 in 2001, and \$10,000 in 2000.

Note 6 - Shareholders Equity

Stock Option Plans

Ostex 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 employees and directors under the 1994 Plan and the Directors Plan were 3,750,000 and 600,000, respectively. Shares available for future grants under the 1994 Plan and the Directors Plan at December 31, 2002 were 1,419,000 and 180,000, 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, 2002 is as follows:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE		
	NUMBER OF SHARES	WEIGHTED AVERAGE REMAINING LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE	
\$ 0.08 - \$ 1.90	951,500	7	\$ 1.35	577,245	\$ 1.28	
\$ 2.00 - \$ 4.75	1,688,970	6	\$ 2.84	1,409,606	\$ 2.93	
\$ 5.00 - \$ 17.13	44,487	1	\$ 5.85	44,487	\$ 5.85	
	2,684,957	6	\$ 2.36	2,031,338	\$ 2.53	

Information relating to stock option activity is as follows:

	2002		2001		2000	
	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	SHARES	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding at beginning of period	2,775,004	\$ 2.37	2,524,910	\$ 2.58	1,992,395	\$ 2.68
Granted	116,450	2.41	662,950	1.62	656,780	2.33
Exercised	(25,261)	0.80	(84,827)	0.70	(10,797)	2.45
Canceled	(181,236)	2.51	(328,029)	3.00	(113,468)	2.91
Outstanding at end of period	2,684,957	\$ 2.36	2,775,004	\$ 2.37	2,524,910	\$ 2.58
Exercisable at end of period	2,031,338	\$ 2.53	1,797,979	\$ 2.70	1,555,048	\$ 2.83
Weighted average fair value of options granted	\$ 1.84		\$ 1.43		\$ 2.06	

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 2002: zero dividend yield; expected volatility of 102%; average risk free rate of interest of 3.5% and expected lives of five years. Assumptions for options granted in 2001 were: 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.

Common Stock Warrants

During 2002, Ostex issued warrants to two outside consultants for the purchase of 38,000 shares of common stock, with exercise prices ranging from \$1.256 - \$2.53, in exchange for services provided to Ostex. The warrants vest upon issuance and expire two years from the date of grant. Ostex recorded these warrants in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force Issue 98-16, which require

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

that the fair value of the warrant be recognized as expense. Total expense recognized in 2002 related to these warrants was approximately \$35,000. The fair value of these warrant grants were established on the date of grant using the Black-Scholes option-pricing model with the following average assumptions: zero dividend yield; expected volatility of 97%; average risk free rate of interest of 1.5% and contractual lives of two years.

During 2001, Ostex 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 provided to Ostex. The warrants vest upon issuance and expire in two years from the date of grant. Total expense recognized in 2001 related to these warrants was approximately \$19,000.

During 2000, Ostex issued warrants to two outside consultants for the purchase of 6,000 and 12,904 shares of common stock, each at exercise prices ranging from \$1.73 - \$1.86, in exchange for services provided to

Ostex. Both warrants vest upon issuance and expire five years and two years, respectively, from the grant date. Total expense recognized in 2000 related to these warrants was approximately \$20,000.

Also during 2000, Ostex 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. This warrant is fully vested and expires in October 2005. Ostex has provided for this warrant in accordance with the provisions of SFAS No. 123 and has recorded the fair value of the warrant as an asset to be amortized to interest expense.

Note 7 - Licensing Agreements

Under Ostex license agreements with the Washington Research Foundation (WRF), Ostex has the worldwide exclusive right to commercialize technology developed from certain research conducted by the University of Washington (UW). As consideration for the licenses acquired and for the attainment of certain milestones, Ostex 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, by Ostex, 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 Ostex. Ostex must also pay the WRF royalties on net sales of licensed products from the WRF which are included in cost of goods sold.

On March 5, 2002, Ostex announced that it had entered into a Serum Osteomark License Agreement with its Japanese partner, Mochida Pharmaceutical Co. Ltd., under which Ostex will sell the Osteomark NTx Serum test, in the microtiter format, exclusively to Mochida for distribution in Japan. Under the terms of the agreement, Mochida paid Ostex \$750,000, \$500,000 of which was paid upfront as a nonrefundable license fee and \$250,000 of which was paid in August 2002. Mochida's payments were subject to a 10% Japanese withholding tax. Ostex recorded this \$75,000 tax expense in the third quarter of 2002. Ostex is recording license fee revenue under the Serum Osteomark License Agreement as earned ratably over the nine-year license period and recognized \$62,000 in 2002. Deferred revenue related to this agreement was \$688,000 at December 31, 2002. During the third quarter of 2002, Mochida began purchasing and paying for finished Osteomark NTx Serum kits manufactured by Ostex.

Note 8 - Related Party Transactions

Research Agreements

In the past, Ostex had entered into research agreements with the UW, one of which was extended through December 31, 2001 at which time the agreement was terminated. Ostex no longer has any agreements in place with the UW. Total expense related to these agreements was \$150,000 during 2001 and 2000 and is included in research and development expense for those periods.

Manufacturing Agreement

Ostex, through an agreement with Metrika, developed the NTx Point-of-Care device. Along with the agreement, Ostex acquired preferred stock of Metrika (see Note 4). Ostex paid approximately \$561,000, \$1,276,000 and \$677,000 in 2002, 2001 and 2000, respectively, to Metrika related to purchases of critical components for the development and production of the NTx Point-of-Care device. Metrika has been and continues to be a critical supplier of certain components of the NTx Point-of-Care device to Ostex. Ostex pays Metrika a royalty based on the sales of the NTx

Point-of-Care device. In the event of Metrika's inability to continue as a going concern, Ostex has contractual remedies that allow it access to tooling and third party suppliers for these critical components.

Note 9 - Commitments And Contingencies**Leases**

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

2003	\$	629,000
2004		629,000
2005		541,000
2006		109,000
2007		109,000
Thereafter		298,000
Total	\$	2,315,000

Total rent expense was approximately \$514,000, \$442,000, and \$444,000 in 2002, 2001, and 2000, respectively.

Litigation

In December 2001, Osteometer Biotech A/S, also known as Nordic Bioscience A/S, and its licensee Roche Diagnostics GmbH sent Ostex two notification letters concerning Osteometer's European Patent No. 0742902 which were issued November 21, 2001. The patent claims synthetic NTx peptides in assays for bone resorption. Ostex 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, Ostex filed an action in the Court of Monza, Italy, seeking a pan-European declaration of noninfringement. This action included a request to stay any such noninfringement determination pending the outcome of an opposition proceeding that Ostex initiated on August 20, 2002, in the European Patent Office against this patent. By letter dated October 24, 2002, Nordic Bioscience A/S informed Ostex that it had filed infringement proceedings in July 2002 against Ostex before the District Court of Düsseldorf, Germany. Ostex was served notification on December 12, 2002 of the German proceeding. On January 9, 2003, Ostex filed a notification of appearance in Germany and indicated that it will contest the matter. Ostex does not believe that these proceedings will have a material adverse effect on its financial position or results of operations.

Effective August 1, 2000, Ostex, 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 Ostex and directed to C-telopeptide markers of bone resorption. Under the settlement agreement, Osteometer could sell the CrossLaps™ ELISA urine kits in the United States until August 2002, paid Ostex a lump sum settlement fee of approximately \$200,000 for past sales and would 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 Ostex in Belgium seeking to invalidate Ostex's European patents as they cover the Belgium territory. The lawsuit also sought a declaration that Roche is not infringing on Ostex's patents in all the European countries designated under the patents and where Roche markets or plans to market their Elecsys β-Crosslaps Serum diagnostic test. In February 2000, this case was stayed indefinitely, pending the outcomes of opposition proceedings in the European Patent Office. Ostex believes that this lawsuit will not lead to an award of damages against Ostex.

Note 10 - Federal Income Taxes

There was no income tax benefit attributable to net operating losses for 2002, 2001 and 2000. The difference between taxes computed by applying the U.S. federal corporate tax rate of 34% and the actual income tax provision in 2002, 2001 and 2000 is primarily the result of establishing a full valuation allowance on Ostex deferred tax assets and, in 2002, relating to foreign taxes paid in connection with the Mochida agreement (see Note 7).

The tax effects of temporary differences and tax loss and credit carryforwards that give rise to significant portions of deferred tax assets at December 31 are comprised of the following:

	2002	2001
Net operating loss carryforward	\$ 15,632,000	\$ 14,458,000
Research and experimentation credits	816,000	806,000
Depreciation and amortization	547,000	408,000
Investment impairment	204,000	
Deferred revenue	234,000	
Other	78,000	78,000
Gross deferred tax asset	17,511,000	15,750,000
Less: Valuation allowance	(17,511,000)	(15,750,000)
Net deferred tax asset	\$	\$

The increase in the valuation allowance for deferred tax assets for 2002, 2001, and 2000 of **\$1,761,000**, **\$1,141,000** and **\$665,000**, respectively, was due primarily to the inability to utilize net operating losses and research and development credits.

At December 31, 2002, Ostex had net operating loss carryforwards of approximately **\$45,977,000** and unused research and development tax credits of approximately **\$816,000** available to offset future taxable income and income taxes, respectively, expiring from 2004 through 2022. Ostex ability to utilize net operating loss and credit carryforwards might be limited pursuant to the Internal Revenue Code, due to cumulative changes in stock ownership of Ostex in excess of 50%.

Note 11 - Unaudited Quarterly Information

The following table sets forth certain unaudited quarterly statements of operations for the eight quarters ended December 31, 2002. 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, 2002	Sept. 30, 2002	June 30, 2002	March 31, 2002	Dec. 31, 2001	Sept. 30, 2001	June 30, 2001	March 31, 2001
Revenue	\$ 1,278,000	\$ 1,655,000	\$ 1,572,000	\$ 923,000	\$ 1,426,000	\$ 1,286,000	\$ 1,492,000	\$ 1,529,000
Cost of products sold	660,000	805,000	726,000	293,000	585,000	487,000	590,000	614,000
Gross profit (Percentage of revenue)	618,000 48%	850,000 51%	846,000 54%	630,000 68%	841,000 62%	799,000 60%	902,000 60%	915,000 91%
Operating Expenses:								
POC facility start-up costs			138,000	431,000	354,000	268,000	170,000	80,000
Research and development	460,000	426,000	408,000	463,000	368,000	470,000	427,000	569,000
Selling, general and administrative	893,000	1,425,000	839,000	999,000	1,064,000	828,000	858,000	1,182,000
Total operating expenses	1,353,000	1,851,000	1,385,000	1,893,000	1,786,000	1,566,000	1,455,000	1,831,000
Loss from operations	(735,000)	(1,001,000)	(539,000)	(1,263,000)	(945,000)	(767,000)	(553,000)	(916,000)
Other (expense) income:								
Impairment of investment	(599,000)							
Interest income		9,000	19,000	35,000	19,000	90,000	91,000	94,000
Interest expense	(67,000)	(58,000)	(62,000)	(64,000)	(77,000)	(60,000)	(39,000)	(36,000)
Total other (expense) income	(666,000)	(49,000)	(43,000)	(29,000)	(58,000)	30,000	52,000	58,000
Loss before income taxes	\$ (1,401,000)	\$ (1,050,000)	\$ (582,000)	\$ (1,292,000)	\$ (1,003,000)	\$ (737,000)	\$ (501,000)	\$ (858,000)
Income taxes		75,000						
Net loss	\$ (1,401,000)	\$ (1,125,000)	\$ (582,000)	\$ (1,292,000)	\$ (1,003,000)	\$ (737,000)	\$ (501,000)	\$ (858,000)
Basic and diluted net loss per common and common equivalent share(1)								
	\$ (0.11)	\$ (0.09)	\$ (0.05)	\$ (0.10)	\$ (0.08)	\$ (0.06)	\$ (0.04)	\$ (0.07)
Weighted average shares used in calculation of net loss per share								
	12,582,000	12,581,000	12,562,000	12,558,000	12,553,000	12,540,000	12,484,000	12,485,000

(1) Loss 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

Previous Independent Accountant

Ostex dismissed Arthur Andersen LLP as its independent auditor on May 22, 2002. The decision to dismiss Arthur Andersen was recommended by the Audit Committee of the Ostex Board of Directors and approved by the Ostex Board of Directors.

During Ostex' two most recent fiscal years and through May 22, 2002, there were no disagreements with Arthur Andersen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure which, if not resolved to Arthur Andersen's satisfaction, would have caused Arthur Andersen to make reference to the subject matter in connection with its report on the Ostex financial statements for such years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K. Arthur Andersen's reports on the financial statements of Ostex for 2000 and 2001 did not contain any adverse opinions or disclaimers of opinions, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles.

Arthur Andersen furnished Ostex a letter dated June 10, 2002, stating that it agreed with the above statements. A copy of such letter was filed with the SEC as Exhibit 16 to Ostex' Form 8-K/A dated June 10, 2002. Ostex requested that Arthur Andersen provide a currently dated letter confirming its agreement with the above statements. Arthur Andersen has informed Ostex that, because of Arthur Andersen's current situation, it is unable to provide such letter.

New Independent Accountant

On May 22, 2002, Ostex engaged KPMG LLP as the firm of independent auditors to audit Ostex' financial statements for the fiscal year ending December 31, 2002. The decision to engage KPMG was recommended by the Ostex Audit Committee and approved by the Ostex Board of Directors. During the period from January 2000 to May 22, 2002, Ostex did not consult KPMG regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, that was an important factor Ostex considered in reaching a decision on an accounting, auditing, or financial reporting issue, or the type of audit opinion that might be rendered on Ostex' financial statements, or (ii) any matter that was the subject of either a disagreement or reportable event.

PART III

Item 10. Directors and Executive Officers of the Registrant

a. Directors of the Registrant

Edgar Filing: OSTEY INTERNATIONAL INC /WA/ - Form 10-K

Ostex Articles of Incorporation divide the Board of Directors into three classes, each class consisting, as nearly as possible, of one-third of the total number of directors. The members of each class are elected to serve for a three-year term and until the election and qualification of their successors. At each annual meeting of shareholders, one class of the Board of Directors is elected and directors in the other classes remain in office until their respective three-year terms expire. Under Ostex Amended Bylaws, the Board of Directors is to be comprised of no more than ten members and no fewer than three members, the exact number of which shall be set by the Board of Directors from time to time. The Board of Directors currently consists of six directors.

Class 1 Directors (terms expire 2003)

David R. Eyre, Ph.D., age 58, is a founder of Ostex and has been a director since Ostex formation in May 1989. His major research interests include collagen biochemistry, inborn skeletal diseases, cartilage pathology, biochemistry of the intervertebral disc, bone metabolism and osteoporosis. Since 1985, Dr. Eyre has served as the Burgess Professor of Orthopaedics at the University of Washington, where he is also an Adjunct Professor of Biochemistry and Oral Biology and a director of the Orthopaedic Research Laboratories. Dr. Eyre has previously served as a research scientist at Children's Hospital Medical Center in Boston, Massachusetts, and as a faculty member in the department of biological chemistry at Harvard Medical School. In addition, from 1973 to 1976, Dr. Eyre served on the permanent scientific staff of the Kennedy Institute of Rheumatology in

London, England, and as a Research Fellow at Massachusetts General Hospital and Harvard Medical School. Dr. Eyre has published numerous articles on the biochemistry of connective tissue. Dr. Eyre earned his Ph.D. and B.S. in biochemistry from the University of Leeds, England.

Fredric J. Feldman, Ph.D., age 63, has been a director with Ostex since April 1997 and currently serves on the Audit Committee of the Board of Directors. Dr. Feldman has served as the President of FJF Associates since 1992, a firm providing management and investment consulting services to venture capital and emerging growth companies in the health care industry. From 1995 to 1996 and from 1999 to 2000, Dr. Feldman has served and is serving as Chief Executive Officer of Biex, Inc., a biotechnology company; from 1992 to 1995, Dr. Feldman served as the Chairman of the Board of Directors and Chief Executive Officer of Oncogenetics, Inc., a genetic cancer diagnostic company; and from 1988 to 1992, he was President and Chief Executive Officer of Microgenic Corporation, a biotechnology diagnostic company. Dr. Feldman serves on the Board of Directors of Orthologic Corp. and SangStat Medical Corp. Dr. Feldman received a Ph.D. and M.S. in chemistry from the University of Maryland and a B.S. in chemistry from Brooklyn College of City University of New York.

Class 2 Directors (terms expire 2005)

Thomas J. Cable, age 63, has been a director of Ostex since 1989 and currently serves on the Compensation Committee of the Board of Directors. Mr. Cable was co-founder and partner of Cable & Howse Ventures, Inc., a venture management company founded in 1979. Mr. Cable was also co-founder and, from 1982 to 1985, a partner in Cable Howse & Ragen, a Seattle investment banking and brokerage firm now known as Ragen MacKenzie Group Incorporated. Mr. Cable is a founder and current Chairman of the Washington Research Foundation and serves on the Board of Directors of Therus Corporation, Omeros Medical Systems, Inc., and Stellar One Corporation. Mr. Cable received an M.B.A. from Stanford University and a B.A. from Harvard College.

John H. Trimmer, age 50, has been a director of Ostex since June 1997 and currently serves on the Audit and Compensation Committees of the Board of Directors. Mr. Trimmer presently serves as President and Chief Executive Officer of CallTower, Inc., a telecommunications company. From 1992 to 1994, Mr. Trimmer served as Chairman, President and Chief Executive Officer of National Diagnostic Systems, Inc., a managed care company focused on the management of clinically appropriate diagnostic imaging services; from 1985 to 1989 as President and Chief Operating Officer of American Biodyne, Inc., a managed care company focused on the delivery and management of clinically appropriate mental health services; and from 1984 to 1985 as President of TMS, Inc., a private management consulting firm providing services to health care venture businesses. Mr. Trimmer also held positions with American Medical Systems, Inc., Hospital Business, and Booz, Allen & Hamilton. Mr. Trimmer received an M.B.A. from the University of Chicago and a B.A. from Harvard University.

Class 3 Directors (terms expire 2004)

Thomas A. Bologna, age 54, joined Ostex 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.

Elisabeth L. Evans, M.D., age 55, has been a director of Ostex since June 1997 and currently serves on the Audit Committee of the Board of Directors. Since 1987, Dr. Evans has been in private practice in obstetrics and gynecology at Overlake Obstetricians and Gynecologists, and from 1997 to 2000 served as Chief of Medical Staff at Overlake Hospital Medical Center. Dr. Evans previously served as Section Chief, Department of Obstetrics and Gynecology at Overlake Hospital Medical Center, a Staff Physician, Department of Obstetrics and Gynecology, Kaiser Permanente, Portland, Oregon; as the Senior Staff and Division Head, Department of Gynecology and Obstetrics, Henry Ford Hospital, Detroit, Michigan; and as a Clinical Instructor at the University of Michigan Medical Center, Ann Arbor, Michigan. Dr. Evans received an M.D. from the University of Washington School of Medicine and a B.A. from Wellesley College.

b. Executive Officers of the Registrant

Thomas A. Bologna, age 54, joined Ostex 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, age 54, 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 Ostex 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, age 46, was named the Vice President, Product Development and Operations in February 2003. Mr. Clemens was Vice President, Product Development for Ostex from September 1998 to February 2003, Director of Research & Development from May 1992 to September 1998, and Manager of Product Development from October 1990 to May 1992. Prior to joining Ostex, Mr. Clemens was Senior Research & Development Scientist from February 1987 to October 1990 at Genetic Systems Corporation/Sanofi.

Michael C. Perry, age 58, joined Ostex in February 2000 as Vice President, Sales. Prior to joining Ostex, 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.

Effective February 28, 2003, Johannes (Hans) van Houte, resigned as Vice President, Finance of Ostex International, Inc. to accept a position with another company. Mr. van Houte joined Ostex in 2001 and served as Ostex principal accounting and financial officer. Thomas A. Bologna, the Chairman, President and Chief Executive Officer of Ostex, will serve as Ostex principal accounting and financial officer until the earlier of the consummation or termination of Ostex agreement to merge with Inverness. At the time of his resignation, Mr. van Houte provided Ostex a certification representing that (i) he is not aware of any significant deficiencies or material weaknesses in the design or operation of Ostex internal controls that could adversely affect Ostex ability to record, process, summarize and report financial data, (ii) he is not aware of any fraud, whether or not material, that involves management or other employees who have a significant role in Ostex internal controls, and (iii) he reviewed the financial statements and other information to be included in this Annual Report on Form 10-K and, based on his knowledge, such financial statements and other

financial information fairly present in all material respects the financial condition, results of operations and cash flows of Ostex as of and for the periods presented.

Reed W. Simmons, who served as Vice President, Operations of Ostex, resigned effective February 14, 2003.

There are no family relationships between any executive officers of Ostex.

c. Compliance With Section 16(a)

Section 16(a) of the Securities Exchange Act of 1934 requires Ostex officers and directors, and persons who own more than 10% of the Common Stock, to file reports of ownership and change in ownership with the SEC. Officers, directors and greater than 10% shareholders are required by SEC regulations to furnish Ostex with copies of all Section 16(a) reports that they file.

To Ostex knowledge, based solely on its review of the copies of such reports furnished to the Company and written representations that no other reports were required, all Section 16(a) filing requirements applicable to its officers, directors and greater than 10% shareholders were satisfied during the fiscal year ended December 31, 2002.

Item 11. Executive Compensation

The following table sets forth certain information regarding compensation awarded to, earned by, or paid to Ostex Chief Executive Officer and each of Ostex four most highly compensated executive officers (other than the Chief Executive Officer) who earned more than \$100,000 in 2002 (the Named Executive Officers), during the years ended December 31, 2002, 2001 and 2000.

SUMMARY COMPENSATION TABLE

Name and Principal position	Year	Annual Compensation			Long Term Compensation	
		Salary (\$)	Bonus (\$)	Other annual compensation (\$)	Awards Securities Underlying Options (#)	All other compensation (\$)
Thomas A. Bologna, Chairman, President & Chief Executive Officer	2002	391,000	0	37,406(1)	0	52,993(2)
	2001	373,000	0	28,000	300,000	40,409
	2000	345,000	60,000	25,000	258,000	36,000
Thomas F. Broderick, Vice President, Patent & General Counsel & Secretary	2002	202,000	0	0	0	0
	2001	194,000	0	0	20,000	0
	2000	184,000	11,000	0	60,000	0
Michael C. Perry, Vice President, Sales	2002	134,000	0	0	0	0
	2001	127,000	0	0	23,000	0
	2000	109,000	6,000	0	48,000	25,000 (3)
Reed W. Simmons, Vice President, Operations (4)	2002	130,000	0	0	50,000	0
	2001					
	2000					
Hans van Houte, Vice President, Finance (5)	2002	121,000	0	0	0	0
	2001	50,000	0	0	41,000	0
	2000					

-
- (1) Represents gross up to compensate for income taxes with respect to living and traveling expenses.
- (2) Represents living and traveling expenses and insurance premiums paid on behalf of Mr. Bologna..
- (3) Represents relocation expenses paid to or on behalf of Mr. Perry.
- (4) Mr. Simmons joined Ostex in 2002. He resigned as Vice President, Operations effective February 14, 2003.

- (5) Mr. van Houte joined Ostex in 2001. He resigned as Vice President, Finance effective February 28, 2003.

Option Grants in 2002

The following table sets forth certain information regarding stock options granted to the Named Executive Officers during the year ended December 31, 2002.

Name	Individual Grants					Potential realizable value at assumed annual rates of stock price appreciation for option term(4)	
	Number of securities underlying options granted	Percentage of total options granted to employees(1)	Exercise price per share(2)	Expiration Date(3)			
					5%	10%	
Reed W. Simmons	50,000(5)	42.94%	\$ 2.63	1/2/2012	\$ 82,700	\$ 209,577	

(1) Based on a total of 116,450 shares subject to options granted to employees during 2002.

(2) The exercise price equals the fair market value on the date of grant based on the closing price of the Common Stock as reported on The Nasdaq National Market.

(3) Options have terms of ten years from the date of grant and become exercisable generally over a period of four years. Upon the occurrence of certain business transactions, including a change in control of Ostex, the exercisability of the options is accelerated.

(4) Assumes all options are exercised at the end of their respective 10-year terms. The dollar amounts under these columns are the result of calculations at the 5% and 10% rates required by applicable regulations of the SEC and, therefore, are not intended to forecast possible future appreciation, if any, of the Common Stock price. Actual gains, if any, on stock option exercises depend on the future performance of the Common Stock and overall stock market conditions, as well as the option holders' continued employment through the vesting period. The amount reflected in this table may not necessarily be achieved.

(5) Relates to a stock option granted upon the commencement of employment in January 2002.

Aggregate Option Exercises and Year-End Option Values for 2002

The following table sets forth certain information regarding the exercise of stock options by Ostex; Named Executive Officers during the last fiscal year and the value of the Named Executive Officers' unexercised options as of December 31, 2002. No options were exercised by the Named Executive Officers during the year ended December 31, 2002.

Number of shares underlying unexercised options at fiscal

Value of unexercised in-the-money options at fiscal

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

Name	year end		year end(1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Thomas A. Bologna	1,225,250	322,750	\$ 211,683	\$ 85,717
Thomas F. Broderick	225,729	34,271	\$ 24,379	\$ 3,271
Michael C. Perry	43,021	27,979	\$ 2,424	\$ 3,536
Reed W. Simmons	0	50,000	\$ 0	\$ 0
Hans van Houte	14,548	26,452	\$ 5,888	\$ 3,536

(1) Based on the \$1.76 closing price of Ostex Common Stock on December 31, 2002, as reported by The Nasdaq National Market, minus the per-share exercise price, multiplied by the number of shares underlying the option.

Compensation Committee Interlocks and Insider Participation

During 2002, Osteon Compensation Committee consisted of Messrs. Cable and Trimmer, both of whom are nonemployee directors. To Osteon knowledge, no member of the Compensation Committee has a relationship that would constitute an interlocking relationship with executive officers or directors of another entity.

Mr. Cable is Chairman of the Board of Trustees of the Washington Research Foundation (the WRF), a not-for-profit licensing agency dedicated to the transfer to the private sector of technology developed at the University of Washington. During the year ended December 31, 2002, Osteon incurred \$247,000 in royalty expense for OSTEOMARK® kit revenue in accordance with Osteon worldwide exclusive license agreements with the WRF for the bone resorption test and osteoclast colony stimulating factor technologies.

Report of the Compensation Committee of the Board of Directors on Executive Compensation

The Compensation Committee of the Board of Directors (the Committee) is responsible for determining the compensation of the executive officers of Osteon. During 2002, the Committee was comprised of two directors who are not employees of Osteon. In making its determinations, the Committee relies on input from compensation consultants and industry surveys and reviews appropriate decisions with all nonemployee directors, who constitute a majority of the full Board of Directors.

Executive Compensation Policy. Osteon executive compensation program reflects the policy that executives rewards should be structured to closely align their interests with those of the shareholders. The program emphasizes stock-based incentives, and extends these concepts beyond the executive officer population to all of Osteon full-time employees in the interest of motivation, teamwork, and fairness. Osteon executive compensation programs are designed to attract and retain experienced and well-qualified executive officers who will enhance the performance of Osteon and build shareholder value. Osteon executive compensation program generally includes three components: base salary, bonuses and stock options.

In setting the compensation level for executive officers, the Committee is guided by the following considerations:

Compensation levels should be competitive with compensation generally being paid to executives in the biotechnology and diagnostic industries to ensure Osteon ability to attract and retain superior executives;

A significant portion of executive officer compensation should be paid in the form of equity-based incentives to link closely shareholder and executive interests and to encourage stock ownership by executive officers; and

Each individual executive officer s compensation should reflect the performance of Osteon as a whole and the individual performance of the executive officer.

Base Salary. An executive officer's base salary is determined by Ostex' overall performance, the responsibility of the particular position, and an assessment of the person's performance against individual responsibilities and objectives, including, where appropriate, the impact of such performance on the business results of Ostex. The Committee also may consider nonfinancial indicators including, but not limited to, strategic developments for which an executive officer has responsibility, intangible elements of managerial performance and levels of compensation to maintain competitive levels with similar companies in the biotechnology and diagnostic industries. The companies surveyed for compensation levels include some of the companies in the Nasdaq Pharmaceutical Index included in the performance graph below. Generally, unless special circumstances apply, the Committee sets executive salaries at or near the midpoint of the range indicated by the surveys, depending on the applicable experience level of the executive officer and subject to minimum salaries established in an employment agreement with the executive. See

Employment, Termination and Change In Control Agreements of this Report for further information. Executive officer salaries are reviewed annually and adjusted each January based on the above factors and taking into consideration industry compensation based on a survey report published by Radford and Associates, an independent consulting group.

Bonus. Executive officers of Ostex, including the Chief Executive Officer, are eligible for annual bonuses. The amount, if any, of each executive officer's bonus is determined by the Committee based on the Committee's subjective assessment of a variety of factors, including Ostex' overall performance, Ostex' financial ability to pay bonuses, and the executive officer's individual performance and contributions to Ostex. In 2002, at

the recommendation of Ostex Chief Executive Officer, no executive bonuses were awarded for 2002 performance.

Stock Options. Ostex grants a stock option in connection with an executive's initial employment with the Company. In making such grants the Committee evaluates the long-term incentive packages offered to Ostex executives in relation to the long-term incentive packages offered by other biotechnology and diagnostic companies that the Committee considers to be in Ostex peer group. These option grants reflect the Committee's policy of encouraging long-term performance and promoting executive retention while further aligning management's and shareholders' interests in the performance of Ostex Common Stock. Through 1996, it was Ostex policy to grant stock options annually to executives and other employees. Ostex ended this policy in 1997 but may, from time to time, grant stock options to executives other than in connection with their initial employment.

Compensation of the Chief Executive Officer. Mr. Bologna's employment with Ostex began in July 1997. The Compensation Committee set Mr. Bologna's compensation to be competitive with base salaries paid to other executives in the biotechnology industry with similar responsibilities and seniority. In 2002, Mr. Bologna's annual base salary was increased to \$391,000.

Compliance With Internal Revenue Code Section 162(m). Section 162(m) of the Internal Revenue Code generally disallows a tax deduction to publicly held companies for annual compensation in excess of \$1 million earned by the chief executive officer or any of the other four most highly compensated officers. The deduction limit does not apply, however, to performance-based compensation that satisfies certain requirements. The Committee's policy is generally to provide executive compensation that is fully deductible by Ostex for income tax purposes. No executive officer of Ostex earned or is expected to earn compensation in excess of \$1 million in 2002 that would not qualify as performance-based compensation. Ostex stock option program is qualified as performance-based for future option grants.

Compensation Committee of the Board of Directors

Thomas J. Cable, Chairman
John H. Trimmer

Stock Performance Graph

The following graph compares the cumulative total return on Ostex Common Stock during the period from December 31, 1997 to December 31, 2002 to the Nasdaq US Stock Market Index and the Nasdaq Pharmaceutical Index. The graph assumes \$100 invested on January 1, 1998 in Ostex Common Stock, the Nasdaq US Stock Market and the Nasdaq Pharmaceutical Index, with all dividends reinvested. Ostex used the Nasdaq Pharmaceutical Index this year in lieu of the JP Morgan H&Q Healthcare Index used in prior years because Ostex was advised that the JP Morgan H&Q Healthcare Index is no longer available. The stock performance shown on the graph is historical and not necessarily indicative of future price performance.

	12/97	6/98	12/98	6/99	12/99	6/00	12/00	6/01	12/01	6/02	12/02
Ostex International, Inc.	\$ 100.00	57.14	15.48	50.00	114.29	83.33	47.62	68.61	95.24	52.19	67.05
Nasdaq U.S. Stock Market Index	\$ 100.00	123.53	152.49	186.62	285.18	284.15	174.55	153.23	137.34	106.50	96.30
Nasdaq Pharmaceutical Index	\$ 100.00	103.08	133.58	158.99	272.47	371.93	334.38	309.92	284.00	176.61	174.64

Employment, Termination and Change in Control Agreements

Employment Agreement with the Chief Executive Officer. In July 1997, Mr. Bologna entered into an employment agreement with Ostex that provides for an initial annual base salary of \$275,000 and the grant of a stock option for 700,000 shares of Common Stock vesting over four years. The base salary will be increased effective on the first anniversary of employment by not less than 10% of the initial base salary and, thereafter, further increases to the base salary will be determined by the Board of Directors. In addition, the employment agreement authorized a \$50,000 bonus for Mr. Bologna for services rendered through December 1997, of which \$25,000 was to be paid upon execution of the agreement and \$25,000 was to be paid in January 1998.

Ostex has obtained term life insurance on Mr. Bologna, which provides for payment to Mr. Bologna's family in the event of his death of an amount equal to his annual base salary. During the term of Mr. Bologna's employment, Ostex will also reimburse Mr. Bologna for or pay directly the reasonable expense of (i) recurring travel from Washington State to California and (ii) expenses associated with living in Washington. To the extent the reimbursement for living expenses or direct payment is treated as taxable income, Mr. Bologna is entitled to a gross up to compensate for any and all income taxes that Mr. Bologna may be required to pay with respect to such reimbursement and gross up.

The employment agreement is terminable at will by either party. In the event that the Board of Directors terminates Mr. Bologna's employment without cause, Mr. Bologna will be entitled to all accrued compensation and Company benefits as well as the then existing base salary Mr. Bologna would have received if his employment had continued for 12 months from the date of termination. If such termination occurs without cause in connection with or at any time following a change in control (as defined in Ostex's 1994 Amended and Restated Stock Option Plan), Mr. Bologna shall be entitled to a lump sum payment equal to two years' base salary, plus a bonus of 30% of such amount and continuation of benefits for a period of 24 months following such termination.

Change In Control Agreements. Pursuant to the Ostex Amended and Restated Stock Option Plan (the "Old Plan"), the Ostex Amended and Restated 1994 Stock Option Plan (the "1994 Plan") and the Ostex Amended and Restated Directors Nonqualified Stock Option Plan (the "Directors Plan"), in the event of a change in control of Ostex, any outstanding option granted under either plan will become fully vested and immediately exercisable. A "change in control" is defined under both plans as (i) the acquisition by any person (other than a shareholder on the date of the plan, Ostex or a subsidiary or employee benefit plan of Ostex) of beneficial ownership of 50% or more of the voting power of Ostex outstanding securities or (ii) the occurrence of a transaction requiring shareholder approval and involving the sale of all or substantially all of the assets of Ostex or the merger of Ostex with or into another corporation. In addition, upon the liquidation or dissolution of Ostex, all outstanding options will terminate; provided, however, that prior to such liquidation or dissolution, an option holder has the right to exercise his or her options in whole or in part whether or not the vesting requirements set forth in the option agreement have been satisfied.

Compensation of Directors

Ostex pays a retainer of \$1,875 to each director on a quarterly basis and an additional \$1,000 for each Board of Directors meeting attended and \$500 for each committee meeting attended. Each director is reimbursed actual travel expenses for attendance at regular Board of Directors and committee meetings. Additionally, Ostex's nonemployee directors participate in the Directors Plan. Upon election or appointment to the Board of Directors, nonemployee directors receive a one-time stock option grant to purchase 25,000 shares of Common Stock under the Directors Plan. In addition, each nonemployee director who is in office the day following an annual meeting of shareholders of Ostex (at which meeting such director was re-elected or continued in office) and who has been in office for at least five months prior to such annual meeting, receives an option to purchase 10,000 shares of Common Stock.

Options granted under the Directors Plan vest in equal annual installments over a three-year period with the first vesting event occurring on the one-year anniversary of the grant date. Options will be accelerated and vest immediately if a director is terminated by reason of death or disability. Options granted under the Directors Plan have a term of ten years from the date of grant. Vested options may be exercised for 90 days after a director's termination as a director of Ostex for any reason other than death or disability, and one year after termination upon death or disability unless the option expires according to its terms prior to the end of the 90 day or one year post-termination exercise period, as the case may be. The exercise price of options granted under the Directors Plan is the fair market value of the Common Stock on the date of grant. Upon exercise, the exercise price may be paid immediately in cash, by delivering to Ostex shares of Common Stock previously held by such director, by having shares withheld from the amount of shares of Common Stock to be received by the director, or by delivering an irrevocable subscription agreement obligating the director to take and pay for the shares of Common Stock to be purchased within one year of the date of exercise.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of Ostex Common Stock as of December 31, 2002, by (i) each person who is known by Ostex to own beneficially more than 5% of the Common Stock; (ii) each director and nominee for director; (iii) Ostex Chief Executive Officer and each of its four most highly compensated executive officers (other than Ostex Chief Executive Officer) who earned more than \$100,000 in 2002; and (iv) all directors and executive officers of Ostex as a group.

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

The term "beneficial ownership" includes shares over which the indicated beneficial owner exercises voting and/or investment power. The rules of the SEC also deem common stock subject to options or warrants currently exercisable, or exercisable within 60 days, to be outstanding for the purposes of computing the percentage of ownership of the person holding the options or warrants, but they do not deem that stock to be outstanding for the purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each of the individuals listed below is c/o Ostex International, Inc., 2203 Airport Way South, Suite 400, Seattle, Washington 98134.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership (1)	Percent of Class (2)
Inverness Medical Innovations, Inc. (3) 51 Sawyer Road, Suite 200 Waltham, MA 02453	3,989,320	31.7%
CH Partners IV Limited Partnership (3) 1615 72 nd Ave. SE Mercer Island, WA 98040	977,070	7.76%
Wisconsin Investment Board (4) P.O. Box 7842 Madison, WI 53707	829,000	6.59%
Mochida Pharmaceutical, Co., Ltd. Y.S. Building 9 San-Eicho, Shinjuku-ku Tokyo 160, Japan	736,842	5.86%
Thomas A. Bologna (3),(5)	1,278,417	9.24%
Thomas J. Cable (3),(6)	1,088,570	8.59%
Elisabeth L. Evans, M.D. (3),(7)	58,083	*
David R. Eyre, Ph.D. (3),(8)	1,507,500	11.92%
Fredric J. Feldman, Ph.D. (3),(7)	57,000	*
John H. Trimmer (3),(9)	55,000	*
Thomas F. Broderick (10)	293,688	2.29%

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

Michael C. Perry (9)	45,979	*
Reed W. Simmons (11)	13,542	*
Hans van Houte (12)	16,167	*
All directors and executive officers as a group (eight people) (13)	4,384,237	30.38%

* Less than 1 %

-
- (1) Unless otherwise indicated in the footnotes to this table, each of the shareholders named in this table has sole voting and investment power with respect to the, shares of Common Stock shown as beneficially owned.
- (2) Percentage beneficially owned is calculated based on 12,583,435 shares of Common Stock outstanding as of December 31, 2002, together with any applicable options and warrants for each shareholder.
- (3) Based on publicly available information filed with the SEC on Schedule 13D filed on September 16, 2002, as amended by Schedule 13D/A filed on February 19, 2003. Inverness reported sole voting power with respect to certain matters and no dispositive power over all shares of Ostex common stock beneficially owned by CH Partners IV Limited Partnership, Thomas A. Bologna, Thomas J. Cable, Elisabeth L. Evans, MD, David R. Eyre, Ph.D., Fredric J. Feldman, Ph.D., and John H. Trimmer (collectively, the Shareholders). Inverness has the power to vote these shares pursuant to the Voting Agreement, as amended, between Inverness and the Shareholders, in connection with the proposed merger of Ostex into a wholly owned subsidiary of Inverness. Additionally, Inverness may be deemed to beneficially own, and have sole voting and dispositive power of, 2,504,103 shares of common stock (calculated based on Ostex shares outstanding as of December 31, 2002) under a Stock Option Agreement dated as of September 6, 2002, entered into by Inverness and Ostex in connection with the merger. Because Inverness ability to acquire Ostex common stock pursuant to the Stock Option Agreement is subject to certain material contingencies, Inverness has expressly disclaimed beneficial ownership of the shares of Ostex common stock subject to the Stock Option Agreement. Including the shares of Ostex common stock subject to the Stock Option Agreement (of which shares Inverness disclaims beneficial ownership), Inverness may be deemed to beneficially own approximately 6,493,423 shares of Ostex common stock, constituting approximately 51.6% of the total issued and outstanding shares of Ostex common stock on December 31, 2002. See additional discussion under the Section entitled Changes in Control-Proposed Merger with Inverness below.
- (4) Based on publicly available information filed with the SEC on Amendment No. 6 to Schedule 13G on February 13, 2003.
- (5) Includes 6,000 shares held in trust for the benefit of one of Mr. Bologna s children. In addition, the number of shares includes 1,251,417 shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (6) Includes 977,070 shares held by CH Partners IV Limited Partnership (CH IV), a venture capital fund of which Mr. Cable is a general partner. Under federal securities laws, Mr. Cable may be deemed to own beneficially all the shares held by CH IV. In addition, the number of shares includes 90,000 shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (7) Includes 55,000 shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (8) Includes 560,000 shares held in trust for the benefit of Dr. Eyre s children and 65,000 shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (9) Represents shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (10) Includes 229,688 shares subject to stock options that are exercisable within 60 days of December 31, 2002.
- (11) Resigned as Vice President, Operations effective February 14, 2003. Represents shares issuable pursuant to vested options exercisable within 90 days of the date of Mr. Simmons resignation.

(12) Resigned as Vice President, Finance effective February 28, 2003. Represents shares issuable pursuant to vested options exercisable within 90 days of the date of Mr. van Houte's resignation.

(13) Includes 1,847,084 shares subject to stock options that are exercisable within 60 days of December 31, 2002.

Changes in Control Proposed Merger with Inverness

On September 9, 2002, Ostex announced that it had entered into an agreement and plan of merger with Inverness Medical Innovations, Inc. and Geras Acquisition Corp., a wholly-owned subsidiary of Inverness. Certain terms of the merger agreement were amended as of February 18, 2003. Under the terms of the merger agreement, as amended on February 18, 2003, Geras Acquisition Corp. will be merged with and into Ostex, Ostex will become a wholly owned subsidiary of Inverness, and each outstanding share of Ostex Common Stock will be converted into the right to receive common stock, par value \$.001 per share, of Inverness based on a conversion ratio that will be determined immediately prior to the closing of the merger. The per share conversion ratio is designed to provide that an aggregate of approximately 1.9 million shares of Inverness common stock will be issued in exchange for all outstanding Ostex Common Stock and reserved for issuance upon exercise of the outstanding stock options and warrants to be assumed by Inverness in the merger.

The merger cannot be completed unless certain conditions are satisfied, including Inverness obtaining the consent of certain of its lenders to the merger and Ostex receiving approval of the merger by the affirmative vote of two-thirds of the outstanding shares of Ostex Common Stock. Ostex directors and their affiliates, who collectively own an aggregate of approximately 19.8% of the total outstanding Common Stock of Ostex, have entered into a voting agreement, as amended, with Inverness, which provides that they will vote, and granted Inverness an irrevocable proxy and power of attorney to vote all of his, her or its shares of Ostex Common Stock:

in favor of the adoption of the merger agreement and the approval of the merger and other transactions contemplated by the merger agreement;

against any acquisition proposal (as defined in the merger agreement) and any action that could reasonably be expected to impact, interfere with, delay, postpone or materially adversely affect completion of the transactions contemplated by the merger agreement; and

in favor of any other matter reasonably necessary for the completion of the transactions contemplated by the merger agreement.

In the voting agreement, each of Ostex directors and their affiliates also agreed not to dispose of or encumber his, her or its shares of Ostex Common Stock and not to enter into any other voting agreement or arrangement or grant any other proxy or power of attorney with respect to his, her or its shares of Ostex Common Stock. The voting agreement terminates immediately upon the earlier of the effective time of the merger or the termination of the merger agreement in accordance with its terms.

Until the merger becomes effective, and with some exceptions, Ostex is prohibited from entering into or soliciting, initiating or encouraging any inquiries or proposals that may lead to an acquisition proposal from any person other than Inverness. Ostex also agreed to pay a termination fee to Inverness of \$1.8 million if the merger agreement is terminated in specified circumstances, including circumstances in which Ostex takes any of these prohibited actions or fails to obtain the approval of its shareholders after a proposal from an eventual third party acquirer is received by Ostex or publicly announced. In addition, Ostex has granted Inverness an option to purchase up to 19.9% of Ostex outstanding shares of common stock at an exercise price of \$2.39 per share. Inverness may exercise this option upon the occurrence of specified events that ordinarily would be associated with an acquisition or potential acquisition of Ostex by a third party. If the option becomes exercisable in specified circumstances in connection with an acquisition proposal, Inverness may also cancel the option, or any portion of the option, in exchange for an amount of cash equal to the product of (a) the excess of the per share exercise price over the highest per share purchase price proposed to be paid pursuant to an acquisition proposal that caused, or would cause, the option to become exercisable, or the current average market price per share, if higher, multiplied by (b) the number of shares subject to the portion of the option that is canceled.

Equity Compensation Plan Information

The following table provides certain information about Ostex equity compensation plans in effect as of the end of fiscal year 2002, including the Ostex Amended and Restated Stock Option Plan (the "Old Plan"), the Ostex Amended and Restated 1994 Stock Option Plan (the "1994 Plan") and Ostex Amended and Restated Nonqualified Stock Option Plan (the "Directors Plan").

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted- Average Exercise Price of Outstanding Options, Warrants and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity Compensation Plans Approved by Shareholders (1)	2,635,970	\$ 2.33	1,598,520
Equity Compensation Plans Not Approved by Shareholders (2)	134,587	\$ 2.97	0
Total	2,770,557	\$ 2.36	1,598,520

(1) Includes the 1994 Plan and Directors Plan.

(2) Includes the Old Plan and warrants granted to consultants.

Item 13. Certain Relationships and Related Transactions

In connection with the merger agreement, as amended, among Inverness Medical Innovations, Inc., Ostex and a wholly owned subsidiary of Inverness, Inverness and Ostex entered into an a loan agreement dated September 6, 2002, which was amended and restated as of February 18, 2003. Under the loan agreement (as amended and restated), Inverness has agreed to make, or arrange for one of its affiliates to make, loans of up to an aggregate of \$2,000,000 to Ostex. The annual interest rate of each loan is an amount equal to LIBOR for one-year loans as published in the Wall Street Journal on the date of each loan, plus four and one-half percent. Ostex borrowed \$334,000 under the loan agreement on October 10, 2002 at an interest rate of 6.27%, borrowed \$433,000 on November 12, 2002 at an interest rate of 6.04%, and borrowed \$233,000 on December 9, 2002 at an interest rate of 6.16%. As of December 31, 2002, the total amount borrowed under the Inverness loan agreement was \$1,000,000. Ostex is entitled to borrow the remaining \$1,000,000 under the loan agreement at any time on or after January 2, 2003, provided that certain conditions are met, in order to maintain sufficient cash, cash equivalents and short-term investments to fund six-months of its budgeted working capital needs. On January 9, 2003, Ostex borrowed an additional \$379,000, at an interest rate of 6.02% and on February 25, 2003, borrowed an additional \$246,159, at an interest rate of 5.90%.

The loans must be repaid at the earliest of:

the first business day after the effective time of the merger;

acceleration upon an event of default;

the termination of the merger agreement in specified circumstances related to Ostex breach of the terms of the merger agreement or stock option agreement or Ostex board s approval of an acquisition proposal or withdrawal of its approval or recommendation of the merger agreement; or

December 31, 2003.

If, during the loan period, the merger agreement is terminated in circumstances that would not be an event of default under the loan agreement, Ostex may borrow a maximum of \$1,750,000 from Inverness under the loan agreement, assuming satisfaction of certain conditions.

Thomas A. Bologna, Ostex Chairman, President and Chief Executive Officer, entered into an employment agreement with Ostex dated as of July 16, 1997. Under the agreement, if Mr. Bologna's employment is terminated without cause after the merger with Inverness, Mr. Bologna is entitled to a lump sum payment equal to two years' base salary, plus a bonus of 30% of such lump sum, and continuation of benefits for a period of 24 months following his termination. Mr. Bologna's current base salary is \$412,000 and the current term of the employment agreement, as amended, extends through July 15, 2006.

On September 6, 2002, Mr. Bologna entered into a consulting agreement with Geras Acquisition Corp., a wholly owned subsidiary of Inverness. The consulting agreement provides that, immediately following the effective time of the merger, Ostex will terminate Mr. Bologna's employment without cause and Mr. Bologna will be entitled to the termination payments described above. In addition, immediately following the effective time of the merger, Ostex will retain Mr. Bologna as a consultant for a term of one year under the consulting agreement. Ostex will pay Mr. Bologna a fee of \$16,833 per month during this term, which fee is subject to adjustment. This agreement also provides that Mr. Bologna will be reimbursed for reasonable costs and expenses incurred in performing the consulting services, and legal expenses up to \$5,000 incurred in preparation of the agreement.

Thomas J. Cable, a director of Ostex, is Chairman of the Board of Trustees of the Washington Research Foundation (the "WRF"), a not-for-profit licensing agency dedicated to the transfer to the private sector of technology developed at the University of Washington. During the year ended December 31, 2002, Ostex incurred \$247,000 in royalty expense for OSTEOMARK® kit revenue in accordance with Ostex' worldwide exclusive license agreements with the WRF for the bone resorption test and osteoclast colony stimulating factor technologies.

Item 14. Controls and Procedures

Within the 90-day period prior to the filing of this report, an evaluation was carried out under the supervision and with the participation of Ostex management, including its Chief Executive Officer and its Vice President, Finance (prior to his resignation on February 28, 2003), of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-14(c) under the Securities Exchange Act of 1934). Based upon that evaluation, Ostex management concluded that the design and operation of these disclosure controls and procedures were effective. No significant changes were made in Ostex' internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation.

PART IV

Item 15. 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, 2002 and 2001

Statements of Operations - Years ended December 31, 2002, 2001, and 2000

Statements of Cash Flows - Years ended December 31, 2002, 2001 and 2000

Statements of Shareholders' Equity - Years ended December 31, 2002, 2001, and 2000

Notes to Financial Statements - December 31, 2002

(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) below)

EXHIBIT INDEX

Exhibit Number	Description	Notes
---------------------------	--------------------	--------------

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

<u>Agreements with Inverness Medical Innovations, Inc.</u>		
2.1	Agreement and Plan of Merger dated as of September 6, 2002	(15)
2.1A	Amendment to Agreement and Plan of Merger dated as of February 18, 2003	(17)
2.2	Voting Agreement dated as of September 6, 2002	(15)
2.2A	Letter Agreement dated as of February 18, 2003, amending the Voting Agreement	(17)
2.3	Stock Option Agreement dated as of September 6, 2002	(15)
2.3A	Second Amended and Restated Loan Agreement dated as of February 18, 2003	(17)
3.1	Articles of Incorporation, as amended, dated January 1997	(2)
3.2	Bylaws, as restated	(16)
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)
<u>Agreements with Thomas A. Bologna</u>		
10.7	Executive Employment Agreement dated July 16, 1997*	(6)
10.7A	Amendment Agreement dated February 10, 1998*	(16)
10.7B	Amendment No. 2 to Employment Agreement dated January 16, 2002*	(16)
10.7C	Amendment No. 3 to Employment Agreement dated July 9, 2002*	(16)

Edgar Filing: OSTEEX INTERNATIONAL INC /WA/ - Form 10-K

	<u>Agreements with Mochida Pharmaceutical Co., Ltd.</u>	
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	(6) (7)
10.12E	Serum Osteomark License Agreement	(14)
	<u>Agreements with the Washington Research Foundation</u>	
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)
10.14A	Amendment to Exclusive License Agreement effective September 5, 2002	(16)
	<u>Agreements with the University of Washington</u>	
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)
	<u>Agreements with David R. Eyre, Ph.D.</u>	
10.16A	Know-How Transfer and Consulting Agreement dated September 18, 1989*	(3)
10.16B	Extension and Amendment dated May 1, 1992*	(3)
	<u>Lease Agreements</u>	
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)
	<u>Agreements with Johnson & Johnson Clinical Diagnostics, Inc.</u>	
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, as amended on February 18, 2003	(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)
16	Letter of Arthur Andersen dated June 10, 2002**	(18)
23	Consent of KPMG LLP	(19)
99.1	Certification of Periodic Report	(19)

* Management contract or compensatory plan or agreement.

** Ostex requested that Arthur Andersen provide a currently dated letter in accordance with Item 601(b)(16) of Regulation S-K. Arthur Andersen has informed Ostex that, because of Arthur Andersen's current situation, it is unable to provide such letter.

(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, as amended by Form 8-A/A filed on February 21, 2003.
- (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) Incorporated herein by reference to the exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended March 31, 2001.
- (15) Incorporated herein by reference to the exhibit of the same number filed with Form 8-K dated September 10, 2002 with the Commission.
- (16) Incorporated herein by reference to exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended September 30, 2002.
- (17) Incorporated herein by reference to exhibit of the same number filed with Form 8-K dated February 20, 2003 with the Commission.
- (18) Incorporated by referenced to exhibit of the same number filed with Form 8-K/A dated June 10, 2002 with the Commission
- (19) 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 21, 2003.

OSTEK INTERNATIONAL, INC.

By /s/ Thomas A. Bologna
 Thomas A. Bologna
 Chairman, President and Chief Executive Officer
 and Director
 (principal executive officer and principal
 financial and accounting officer)

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	March 21, 2003
/s/ Thomas J. Cable Thomas J. Cable	Director	March 21, 2003
/s/ Elisabeth L. Evans Elisabeth L. Evans	Director	March 21, 2003
/s/ David R. Eyre David R. Eyre	Director	March 21, 2003
/s/ Fredric J. Feldman Fredric J. Feldman	Director	March 21, 2003
/s/ John H. Trimmer John H. Trimmer	Director	March 21, 2003

CERTIFICATIONS

I, Thomas A. Bologna, certify that:

1. I have reviewed this annual report on Form 10-K of Ostex International, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this annual report is being prepared;

 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the Evaluation Date); and

 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on my evaluation as of the Evaluation Date;

5. I have disclosed, based on my most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: OSTECH INTERNATIONAL INC /WA/ - Form 10-K

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of my most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 21, 2003

/s/ Thomas A. Bologna
Thomas A. Bologna
Chairman, President and Chief Executive Officer
(sole principal executive officer and sole principal financial and
accounting officer)