OSTEX INTERNATIONAL INC /WA/
Form 10-Q
November 15, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

ý **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 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

OSTEX INTERNATIONAL, INC.

Name of Registrant as Specified in Its Charter

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

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

[n/a]
Former name, address and fiscal year, if changed since last report

Yes ý

Indicate by checkmark 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. No o

The number of shares of the Registrant s common stock outstanding as of November 12, 2002 was 12,583,435.

OSTEX INTERNATIONAL, INC.

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PART I - FINANCIAL INFORMATION

PART I - FINANCIAL INFORMATION

Item 1. - Financial Statements

OSTEX INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

(Unaudited)

	September 30, 2002	December 31, 2001
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 295,000	$ 1,284,000
Short-term investments	741,000	2,543,000
Trade receivables, net of allowance of $68,000 in 2002 and $54,000 in 2001	1,326,000	815,000
Inventory	1,466,000	994,000
Other current assets	201,000	33,000
Total Current Assets	4,029,000	5,669,000
Property, Plant and Equipment, net	2,994,000	3,272,000
Other Assets	708,000	694,000
Total Assets	$ 7,731,000	$ 9,635,000
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 1,014,000	$ 279,000
Customer deposits	110,000	156,000
Accrued liabilities	553,000	495,000
Current portion of notes payable	717,000	635,000
Total Current Liabilities	2,394,000	1,565,000
Noncurrent Liabilities:		
Deferred revenue	709,000	
Notes payable, net of current portion	646,000	1,138,000
Total Noncurrent Liabilities	1,355,000	1,138,000
Commitments and Contingencies		
Shareholders Equity:		
Common stock, $.01 par value, 50,000,000 authorized; 12,581,216 and 12,558,174 issued and outstanding at September 30, 2002 and December 31, 2001 respectively	126,000	126,000
Additional paid-in capital	45,764,000	45,709,000

Accumulated other comprehensive income		1,000		6,000
Accumulated deficit		(41,909,000)		(38,909,000)
Total Shareholders Equity		3,982,000		6,932,000
Total Liabilities and Shareholders Equity	$	7,731,000	$	9,635,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarter Ended		Year to Date	
	September 30, 2002	**September 30, 2001**	**September 30, 2002**	**September 30, 2001**
Product sales and other revenue	$ 1,655,000	$ 1,286,000	$ 4,150,000	$ 4,307,000
Cost of products sold	805,000	487,000	1,824,000	1,691,000
Gross profit	850,000	799,000	2,326,000	2,616,000
Operating Expenses:				
POC facility start-up costs		268,000	569,000	518,000
Research and development	426,000	470,000	1,297,000	1,466,000
Selling, general and administrative	1,425,000	828,000	3,263,000	2,868,000
Total operating expenses	1,851,000	1,566,000	5,129,000	4,852,000
Loss from operations	(1,001,000)	(767,000)	(2,803,000)	(2,236,000)
Interest (expense) income, net	(49,000)	30,000	(122,000)	140,000
Net loss before taxes	(1,050,000)	(737,000)	(2,925,000)	(2,096,000)
Taxes	75,000		75,000	
Net loss	$ (1,125,000)	$ (737,000)	$ (3,000,000)	$ (2,096,000)
Basic and diluted net loss per common share	$ (0.09)	$ (0.06)	$ (0.24)	$ (0.17)
Weighted average shares used in calculation of net loss per share	12,581,000	12,540,000	12,567,000	12,503,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Year to Date	
	Sept. 30, 2002	**Sept. 30, 2001**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (3,000,000)	$ (2,096,000)
Adjustments to reconcile net loss to net cash used in operating activities -		
Depreciation and amortization	529,000	463,000
Expense from issuance of warrants	38,000	7,000
Loss on disposal of property, plant, and equipment		2,000
Changes in current assets and current liabilities -		
Trade receivables	(511,000)	225,000
Inventory	(472,000)	(693,000)
Other assets	(182,000)	(92,000)
Accounts payable	735,000	(307,000)
Customer deposits	(46,000)	
Deferred revenue	709,000	
Accrued expenses	58,000	(53,000)
Net cash used in operating activities	(2,142,000)	(2,544,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of short-term investments		(1,213,000)
Proceeds from sales and maturities of short-term investments	1,797,000	2,698,000
Purchases of property, plant and equipment	(251,000)	(455,000)
Net cash provided by investing activities	1,546,000	1,030,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from the issuance of common stock	17,000	49,000
Repurchase of common stock		(19,000)
Proceeds from notes payable		1,059,000
Payments on notes payable	(410,000)	(361,000)
Net cash (used by) provided by financing activities	(393,000)	728,000
NET DECREASE IN CASH AND EQUIVALENTS	(989,000)	(786,000)
CASH AND CASH EQUIVALENTS, beginning of period	1,284,000	1,348,000
CASH AND CASH EQUIVALENTS, end of period	$ 295,000	$ 562,000

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

OSTEX INTERNATIONAL, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Basis of Presentation

The unaudited condensed financial statements include the accounts of Ostex International, Inc., a Washington corporation. These financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. for interim financial reporting and pursuant to the rules and regulations of the Securities and Exchange Commission. While these statements reflect all normal recurring adjustments that are, in the opinion of management, necessary for fair presentation of the results of the interim periods, they do not include all of the information and notes required by accounting principles generally accepted in the U.S. for complete financial statements. For further information, refer to the financial statements and notes thereto included in the Company s Annual Report filed on Form 10-K for the year ended December 31, 2001.

On September 9, 2002, the Company 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. (See Note 13 below). In connection with the merger agreement, Inverness and Ostex also entered into a loan agreement, which was subsequently amended and restated. 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 September 30, 2003.

The Company s future capital requirements depend upon many factors, including the Company s 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 the Company s 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 the Company s near-term cash requirements, if the merger is not consummated, the Company may 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. If the merger is not consummated and Ostex receives a maximum of $1,750,000 in loan funds available in this circumstance (subject to satisfaction of certain conditions) under the loan agreement, the Company believes that its existing available cash, the proceeds from the loan from Inverness, its future license and research revenues from existing collaboration agreements, its current level of product sales and its interest income from short-term investments will be adequate to fund operations through the third quarter of 2003, at which time repayment of the loan from Inverness will be required. If funding is insufficient at any time in the future, the Company may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; or license to third parties rights to commercialize products or technologies that the Company would otherwise seek to develop on its own.

Certain amounts in prior periods financial statements have been reclassified to conform to the current year presentation.

2. Earnings Per Share

As presented, basic and diluted loss per share are equal since common equivalent shares are excluded from the calculation of diluted earnings per share because their effects are antidilutive to the Company s net losses. The calculation of dilutive shares excludes approximately 2,811,000 and 3,177,000 of stock options and warrants outstanding as of September 30, 2002 and September 30, 2001, respectively, because of their antidilutive effect.

3. 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.

4. Concentration of Credit Risk

Trade receivables potentially subject the Company to credit risk. The Company extends credit to its customers based upon an evaluation of the customer s financial condition and credit history and generally does not require collateral. The Company historically has incurred minimal credit losses. For the three-month period ended September 30, 2002, domestic product sales accounted for 44% of total revenue and product sales to customers located in foreign countries accounted for 56% of total revenue. For the nine-month period ended September 30, 2002, domestic product sales accounted for 57% of total revenue and foreign product sales accounted for 43% of total revenue. For both periods, Mochida Pharmaceuticals and Quest Diagnostics each accounted for over 10% of total revenue and Mochida accounted for over 10% of total accounts receivable.

5. 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 which approximate actual cost plus certain manufacturing overhead amounts. The Company s entire finished goods inventory has a limited shelf life and the Company regularly makes estimates of inventory amounts which will not be sold within the appropriate time frame and charges off to cost of products sold such amounts.

The components of inventory are:

	December 31, 2001	September 30, 2002
Raw materials	$ 340,000	$ 505,000
Work in process	$ 585,000	$ 792,000
Finished goods	$ 69,000	$ 169,000
Total inventory	$ 994,000	$ 1,466,000

6. Comprehensive Income (Loss)

The components of comprehensive income (loss) for the three-month periods and the nine-month periods ended September 30, 2002 and 2001, are as follows:

	Quarter ended September 30, 2002	Quarter ended September 30, 2001	Year to date September 30, 2002	Year to date September 30, 2001
Net Loss	$ (1,125,000)	$ (737,000)	$ (3,000,000)	$ (2,096,000)
Unrealized gain/(loss) on short-term investments	(1,000)	18,000	(5,000)	53,000
Total comprehensive loss	$ (1,126,000)	$ (719,000)	$ (3,005,000)	$ (2,043,000)

7. Point-of-Care Manufacturing Facility Start-up Costs

Point-of-care manufacturing facility start-up costs are related to the operation and validation of the Company s new facility, tooling, and production. These costs are expensed as incurred. The Company successfully validated its point-of-care manufacturing facility in the second quarter of 2002 and does not expect to incur any additional costs associated with start-up activities going forward.

8. Other Assets

Other assets primarily represent a $599,000 investment in the preferred stock of Metrika, Inc.. The investment is recorded in the accompanying financial statements at cost and represents an ownership interest of less than 2%. The Company periodically assesses the valuation of this asset based on historical financial data, assumed valuations of Metrika, relevant liquidation preferences made during additional investment rounds, future projections, and Metrika s performance. The value of the Company s Metrika investment may also fluctuate with general changes in the U.S. equity markets. Management has considered these factors and believes that there has not been a decline in the market value of Ostex investment in Metrika below the cost basis of that investment at the end of this reporting period and therefore it is not impaired. However, given the nature of Metrika s business, there is a risk that the investment may become impaired in the near term future as a result of adverse changes in any of the factors noted above or Metrika s inability to build its business. The investment in Metrika represents approximately 7% of Ostex total assets. Any future impairment to this investment could be material to the Company s results of operations and financial position.

9. Common Stock Warrants

For the nine months ended September 30, 2002, the Company issued warrants to two outside consultants for the purchase of 38,000 shares of common stock, with exercise prices ranging from $1.25 - $2.53, in exchange for services to be provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. These warrants were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that the transaction did not involve a public offering. Total expense recognized in 2002 for these warrants was $38,000 which was estimated using the Black Scholes model.

10. Recent 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 provision of SFAS No. 143 is effective for fiscal years beginning after June 15, 2002. The Company is currently assessing the impact of this statement on its results of operations, financial position and cash flows.

In August 2001, the FASB issued Statement of Financial Accounting Standards No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No. 144) (effective for the Company on January 1, 2002). This statement supersedes Statement of Financial Accounting Standards No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of . The Company adopted the provisions of SFAS No. 144 on January 1, 2002. The adoption of SFAS No. 144 did not have a material effect on our financial statements.

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 our 2003 fiscal year, and early adoption is permitted. The adoption of SFAS No. 146 is not expected to have a material impact on the Company s consolidated results of operations, financial position or cash flows.

11. Legal Proceedings

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 has not yet been served in the German proceeding.

12. Mochida License Agreement

On March 5, 2002, the Company announced that it had entered into a Serum Osteomark License Agreement with its Japanese partner, Mochida Pharmaceutical Co. Ltd., under which the Company 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 must pay the Company $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. The Company recorded this $75,000 tax expense in the third quarter of 2002. During the third quarter of 2002, Mochida began purchasing and paying for finished Osteomark NTx Serum kits manufactured by the Company. The Company is recording license fee revenue under the Serum Osteomark License Agreement as earned ratably over the nine-year license period. Deferred revenue related to this agreement was $709,000 at September 30, 2002.

13. Proposed Merger with Inverness Medical Innovations, Inc.

On September 9, 2002, the Company announced that it had signed a definitive merger agreement with Inverness Medical Innovations, Inc. The aggregate number of shares of Inverness common stock to be issued in the merger in exchange for Ostex outstanding shares and to be reserved for the options and warrants to be assumed by Inverness is approximately 2.3 million shares, with each share of Ostex common stock expected to convert into approximately 0.1494 shares of Inverness common stock. The transaction is expected to close late in the fourth quarter of 2002 or in the first quarter of 2003. Inverness acquisition of Ostex is subject to certain closing conditions, including receipt of certain consents and the approval of Ostex shareholders. Certain shareholders of Ostex who hold an aggregate of approximately 19.8% of the outstanding Ostex common stock 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 under certain circumstances.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Quarterly Report on Form 10-Q contains forward-looking statements that reflect the Company s current views with respect to future events and financial performance. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results or the timing of certain events to differ materially from historical results or those anticipated. Words used herein such as may, will, believes, anticipates, expects, intends, estimates, predicts, and similar expressions are intended to qualify as forward-looking statements but are not th exclusive means of identifying such statements. In evaluating forward-looking statements, you should specifically consider various factors described below in the section entitled Additional Factors That May Affect Results. These factors may cause the Company s actual results to differ materially from any forward-looking statement.

Although the Company believes the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, product demand, performance or achievements. You should not place undue reliance on the Company s forward-looking statements, which apply only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and Annual Report on Form 10-K.

Overview

The Company develops and commercializes products to make disease management a reality, with osteoporosis being the first area of focus. The Company s lead product, the OSTEOMARK NTx test, which is available in multiple test formats, incorporates breakthrough and patented technology for the management and prevention of osteoporosis. The Company has formed collaborative relationships with leading reference laboratories, distributors, and pharmaceutical companies to aid in the commercialization of its Osteomark technology.

Osteoporosis is a significant health problem. Recently, 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. The Company expects the osteoporosis therapeutic market will continue to grow as the population ages.

The Company is the exclusive licensee of the Osteomark technology, known clinically as the NTx test, which is available in multiple formats that can aid in healthcare decision-making at early menopause and beyond.

The Osteomark 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 Company s 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.

The Company 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, the Company 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 the Company. The Company is obligated to pay the Washington Research Foundation royalties on net sales of any licensed products. The Company also pays royalties to the Washington Research Foundation on milestones received from licensees of the products.

The Company s 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, the Company 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.

The Company 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. The Company believes that the use of a serum NTx test provides a number of advantages to centralized testing laboratories, including the elimination of the requirement to normalize NTx values to creatinine concentration.

The Osteomark NTx Point-of-Care device became commercially available in October 1999 for use in the physician s office. The Company 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, the Company announced it had acquired the exclusive right from Metrika to manufacture the Osteomark NTx Point-of-Care device, as well as the exclusive worldwide license to manufacture, market and sell this device for the measurement of 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, the Company 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.

The Company 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, the Company 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.

The Company 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 did 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 the Company s manufacturing facility, the Company 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. The Company validated its manufacturing process late in the second quarter of 2002 and has shipped NTx Point-of-Care devices to Aventis. The Company has maintained a continuing dialogue with Procter & Gamble and Aventis and is working to rebuild their confidence in the Company s manufacturing capabilities. The Company is also working to expand sources of demand for its products.

The Company 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, the Company granted Mochida exclusive marketing and distribution rights to certain products in Japan. In January 1998, Mochida launched the Osteomark test in Japan for the management of patients with hyperparathyroidism and for patients with metastatic bone tumors. In December 1999, Mochida received an additional regulatory indication from the Japanese Ministry of Health, 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 the Company in March 2002, 30 days after the time it exercised the option to license, and $250,000 of which Mochida paid to the Company in August 2002, after Mochida received the official announcement of the Japanese reimbursement price from the Ministry of Health.

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

The Company has technology for measuring Type II and Type III collagen degradation. Type II collagen is a primary constituent of joint cartilage. Osteoarthritis, a degenerative disease of joint cartilage, affects over 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 Company s 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, the Company believes that the Type II collagen degradation test will aid in the clinical management of osteoarthritis patients. Type III collagen is a significant constituent of blood vessels such as coronary arteries. Measuring degradation of this type of collagen may be useful in identifying cardiovascular disease. The Company has no immediate plans to commercialize tests for Type II or Type III collagen degradation, but has patents in these areas if it decides to commercialize tests for Type II and III in the future.

The Company also has technology to enhance artificial joint recovery. The Company is the exclusive licensee of U.S. Patent No. 6,190,412, directed to prosthetic devices having hydroxyapatite-coated bone attachment surfaces

to which tartrate-resistant acid phosphatase (TRAP) is absorbed. Research supported by the Company established that the human TRAP enzyme has a direct role as a local factor in the recruitment of osteoclasts from hematopoietic cells. Also that recombinantly produced TRAP absorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. The Company may seek collaborations to confirm 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 OSTEX are registered United States trademarks of the Company. The Company has also registered its OSTEOMARK trademark in 46 other countries. The Company s collagen breakdown test technology is covered by 36 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. The Company s patents are variously directed to Type I collagen breakdown products, including NTx, CTx, and deoxypyridinoline, as well as related breakdown products of Type II and Type III collagen. The Company s Type I collagen patents will begin to expire in late 2007 for the US and in 2010 for Europe and Japan. The Company 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.

Pending Merger with Inverness

On September 9, 2002, the Company 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. The per share conversion ratio is designed to provide that an aggregate of approximately 2.3 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 receipt of certain consents 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. Failure to complete the merger could have a material adverse effect on Ostex financial condition and results of operations. The Company 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. You should refer to these documents for further information about the proposed merger.

Results of Operations for the Three Months Ended September 30, 2002 and September 30, 2001

Total revenues were $1,655,000 for the quarter ended September 30, 2002, compared to $1,286,000 for the quarter ended September 30, 2001. The increase in revenues for the quarter was primarily due to higher sales of the Company s NTx Urine and Serum kits, offset by lower sales of the Company s NTx Point-of-Care device, as compared to the same period in 2001. Sales of urine kits were particularly strong for the Company s Japanese

partner, Mochida. Mochida also began purchasing the Company s serum kit in the quarter ended September 30, 2002.

The Company recorded a net loss of $1,125,000 ($0.09 per share) for the quarter ended September 30, 2002 compared to a net loss of $737,000 ($0.06 per share) for the quarter ended September 30, 2001. The increase in loss was primarily due to higher general and administrative expenses of $775,000 associated with the legal and investment banker fees related to the proposed merger with Inverness. The Company also recorded a $75,000 tax expense in the third quarter of 2002 for Japanese withholding taxes related to payments received from Mochida under its Serum Osteomark License Agreement.

Total cost of products sold was $805,000 for the quarter ended September 30, 2002, compared to $487,000 for the quarter ended September 30, 2001. The increase in 2002 over 2001 was primarily due to higher product sales of the NTx Urine and Serum kits and the excess capacity of the Company s point-of-care manufacturing facility, which is being expensed through cost of goods sold. The Company s production capacity exceeded the actual production of point-of-care devices in the third quarter and the resulting excess capacity had a negative impact to the Company s margins for the quarter. This excess capacity, and resulting lower margins as a percentage of revenue, will continue until demand for the point-of-care device increases.

The Company s research and development expenditures totaled $426,000 for the quarter ended September 30, 2002, compared to $470,000 for the quarter ended September 30, 2001. The decrease in 2002 as compared to 2001 is related to slightly lower personnel related expenditures. Selling, general and administrative expenses totaled $1,425,000 for the quarter ended September 30, 2002, compared to $828,000 for the quarter ended September 30, 2001. The increase in 2002 is due to higher legal and investment banking fees of approximately $775,000 incurred in connection with the proposed merger with Inverness. The higher fees were offset somewhat by a $140,000 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.

Net interest expense totaled $49,000 for the quarter ended September 30, 2002, compared to net interest income of $30,000 for the quarter ended September 30, 2001. In 2002, the Company earned lower interest income due to lower balances of cash and short-term investments as compared with the same period in 2001.

Results of Operations for the Nine Months Ended September 30, 2002 and September 30, 2001

Total revenues were $4,150,000 for the nine-month period ended September 30, 2002, compared to $4,307,000 for the nine-month period ended September 30, 2001. The $157,000 decrease was the result of lower sales of the Company s NTx Point-of-Care device offset somewhat by higher sales of the NTx Serum kits on a year to date basis. 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 to date in 2002 have suffered when compared to the same period in 2001.

For the nine months ended September 30, 2002, the Company recorded a net loss of $3,000,000 ($0.24 per share) relative to a net loss of $2,096,000 ($0.17 per share) for the corresponding period last year.

Total cost of products sold was $1,824,000 for the nine-month period ended September 30, 2002, compared to $1,691,000 for the nine-month period ended September 30, 2001. The $133,000 increase in 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 to the Company s gross profit margins until demand increases.

The Company s research and development expenditures totaled $1,297,000 for the nine-month period ended September 30, 2002, compared to $1,466,000 for the nine-month period ended September 30, 2001. The $169,000 decrease was due to slightly lower personnel and consulting related expenses. Selling, general and administrative expenses totaled $3,263,000 for the nine-month period ended September 30, 2002, compared to $2,868,000 for the

nine-month period ended September 30, 2001. The increase in 2002 is due to legal and investment banker fees and expenses of approximately $775,000 in connection with the proposed merger of Ostex with Inverness. This increase was 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 year to date in 2002 as compared to the same period in 2001.

Net interest expense totaled $122,000 for the nine-month period ended September 30, 2002, compared to net interest income of $140,000 for the nine-month period ended September 30, 2001. In 2002, the Company earned lower interest income due to lower balances of cash and short-term investments as compared to the same period in 2001.

Liquidity and Capital Resources

As of September 30, 2002, the Company had cash and cash equivalents and short-term investments of $1,036,000, working capital of $1,635,000 and total shareholders equity of $3,982,000. As a result of funding operating losses during the nine months ended September 30, 2002, cash, cash equivalents and short-term investments decreased by $2,791,000, accounts receivable, inventory and other current assets increased by $1,151,000, working capital decreased by $2,469,000 and shareholders equity decreased by $2,950,000. During the nine-month period ended September 30, 2002, the Company purchased $251,000 of manufacturing and office equipment, and reduced notes payable by $410,000.

The Company s future capital requirements depend upon many factors, including the Company s 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 the Company s 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.

On September 6, 2002, Ostex entered into an agreement to merge with Inverness Medical Innovations, Inc. The transaction is expected to close late in the fourth quarter of 2002 or in the first quarter of 2003. Inverness acquisition of Ostex is subject to certain closing conditions, including receipt of certain consents and the approval of 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 approximately $1.2 million to $1.4 million in merger related expenses, excluding any termination fees, if applicable. These expenses may 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.

In connection with the merger agreement, 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. The interest rate for that loan is 6.27%. Ostex borrowed an additional $433,000 on November 12, 2002, at an interest rate of 6.04%. Ostex is entitled to borrow an additional $233,000 on December 9, 2002. Ostex may 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.

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;

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the termination of the merger agreement in specified circumstances related to Ostex breach of the terms of 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

September 30, 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 Ostex receives $1,750,000 of the loan funds, the Company believes that it will be able to fund its operations through the third quarter of 2003, at which time the loan repayment will be due. Such loan liability, however, may have a material impact on the results of operations and financial condition of Ostex because the Company 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, the Company 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. The Company also may be required to delay, scale back or eliminate some or all of its marketing and sales and research and development programs, sell assets, or license to third parties rights to commercialize products or technologies that the Company would otherwise seek to develop on its own. 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 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 is at substantial risk of being 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. If the merger is not consummated and Ostex receives a maximum $1,750,000 in loan funds available in this circumstance (subject to satisfaction of certain conditions) under the loan agreement, the Company believes that its current cash, the proceeds from the loan from Inverness, its future license and research revenues from existing collaboration agreements, its current level of product sales and its interest income from short-term investments will be adequate to fund operations through the third quarter of 2003, at which time the loan must be repaid. If funding is insufficient at any time in the future, the Company may be required to:

delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; or license to third parties rights to commercialize products or technologies that the Company would otherwise seek to develop on its own.

The Company s financial statements are presented on a going concern basis and assume that assets will be realized in the normal course of business. If the Company is forced to liquidate its assets, it may not recover the carrying amount of such assets. See discussion under Additional Factors that May Affect Results below.

Critical Accounting Policies

The Company s critical accounting policies used in the preparation of the financial statements relate to revenue recognition and the carrying value of its investment in Metrika. The reader is advised to refer to the Company s Form 10-K for the period ending December 31, 2001 for a more complete discussion of all of the critical accounting policies.

Additional Factors That May Affect Results

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 September 30, 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 likely be subject to delisting from the Nasdaq National Market, which delisting could adversely affect the liquidity and trading price of its common stock.

Under Nasdaq s listing maintenance standards, if Ostex shareholders equity is less than $10,000,000, Nasdaq may choose to notify it that Nasdaq is delisting its common stock from the Nasdaq National Market. Ostex received notice from Nasdaq that if Ostex shareholders equity reflected in Ostex first periodic report due after November 1, 2002 does not comply with Nasdaq s minimum shareholders equity requirement of $10,000,000, Nasdaq may send formal notification regarding the commencement of delisting procedures. As a result, there is a substantial risk that Ostex common stock may be delisted from trading on the Nasdaq National Market. If Ostex common stock is delisted, the delisting would most likely have a material adverse effect on the trading price and liquidity of Ostex common stock and shareholders ability to sell shares of Ostex common stock would be severely limited.

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 could have a material adverse effect on

Failure to complete the proposed merger with Inverness could negatively impact Ostex stock price and fu ure busi

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 that 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.

Ostex believes that the price of its common stock is based in large part on the price of Inverness common stock; the

Risks Related to Ostex Business

Ostex has a history of losses.

Ostex has not been profitable for any year since its formation in 1989. Ostex had an accumulated deficit through September 30, 2002 of $41,909,000. 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. These matters may raise substantial doubt about Ostex ability to continue as a going concern. 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.

The market acceptance and demand for Ostex products is uncertain.

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. There can be no assurance that Ostex Osteomark 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 Ostex will be able to develop significant market share for its products or maintain or increase its current market share. Ostex did not deliver as many NTx Point-of-Care devices to Procter & Gamble or 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 Ostex point-of-care 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 Ostex Osteomark NTx Urine test in the microtiter plate format.

Ostex 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 Ostex

margins in future periods. The inability of Ostex to increase market acceptance and demand for its products could have a material, adverse effect on Ostex business, financial condition, and results of operations.

The loss of a significant Ostex customer could harm Ostex business.

Ostex current operations are dependent upon a relatively small number of customers, which change from time to time. Ostex most significant customers during the first nine months of 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 60% of Ostex total sales during that period. Ostex 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. There can be no assurance that Ostex current significant customers will continue to buy products at their current or increased levels. Ostex lost a number of orders from significant customers as a result of manufacturing delays encountered with the start-up of Ostex point-of-care manufacturing facility in late 2001 and early 2002. Loss of a significant Ostex customer or further reduction of the level of orders from a significant Ostex customer could have a material adverse effect on Ostex operating results.

Ostex is dependent on therapeutics developed by others.

Acceptance of and demand for Ostex 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, Ostex could be adversely affected. Unfavorable publicity concerning an Ostex product or therapeutic products for osteoporosis could also have an adverse effect on Ostex ability to obtain regulatory approvals or to achieve market acceptance.

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

Ostex has limited sales, marketing and distribution experience and resources. To market any of its products directly or indirectly, Ostex must develop and implement a substantial sales and marketing effort with technical expertise and supporting distribution capability. Ostex may need to increase its sales and marketing resources significantly in order for its products to gain relatively significant market acceptance. Ostex 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 Ostex will be able to establish effective sales and marketing and distribution capabilities or that its collaborators will be successful in gaining market acceptance for Ostex products or that Ostex will achieve or maintain significant market share for its products.

Ostex 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 Osteomark 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 58 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 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 PTO, 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. In addition, 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. 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. 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. The Company s exposure to market rate risk, as a result of changes in interest rates, relates primarily to the Company s investment portfolio. At September 30, 2002, the Company held $295,000 in cash and cash equivalents and $741,000 in Federal and Government agency obligations, and corporate and municipal bonds. Although the Company holds both fixed and adjustable rate investments and each carry a certain degree of interest rate risk, the Company does not consider this risk to be material to the accompanying financial statements.

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

Item 4. 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 our Chief Executive Officer and our Vice President, Finance (Ostex chief financial officer), 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, the Chief Executive Officer and the Vice President, Finance 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 II OTHER INFORMATION

Item 1. Legal Proceedings

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 has not yet been served in the German proceeding.

Item 2. Changes in Securities

During the nine-month period ended September 30, 2002**,** the Company issued warrants to two outside consultants for the purchase of 38,000 shares of common stock, with exercise prices ranging from $1.25 - $2.53, in exchange for services to be provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. These warrants were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that the transaction did not involve a public offering. Total expense recognized in 2002 for these warrants was $38,000.

In connection with the execution of the merger agreement, Ostex granted Inverness an option to purchase up to approximately 19.9% of the outstanding shares of Ostex common stock at a price of $2.39 per share. The option is only exercisable upon the occurrence of specified events that ordinarily would be associated with the acquisition or potential acquisition of Ostex by a third party. The option is intended to increase the likelihood that the merger will be completed. Aspects of the stock option agreement may have the effect of discouraging persons who might now or at any time be interested in acquiring all or a significant interest in Ostex before closing the merger. 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 paid or proposed to be paid pursuant to an acquisition proposal that caused 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 cancelled. The grant of this option is exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that such grant did not involve a public offering.

Item 6. **Exhibits and Reports on Form 8-K**

(a) **Exhibits (see note 1)**

EXHIBIT INDEX

Exhibit Number `	Description	Notes
	Agreements with Inverness Medical Innovations, Inc.	
2.1	Agreement and Plan of Merger dated as of September 6, 2002	(15)
2.2.	Voting Agreement dated as of September 6, 2002	(15)
2.3	Stock Option Agreement dated as of September 6, 2002	(15)
2.4A	Amended and Restated Loan Agreement dated October 10, 2002	(16)
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)
	Agreements with Thomas A. Bologna	
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)
	Agreements with Mochida Pharmaceutical Co., Ltd.	
10.12A	Research and Development Agreement dated August 1992	(3)
10.12B	Osteomark License Agreement Dated August 1992	(3)
10.12D	Second Amendment to Osteomark License Agreement dated December 24, 1997	(7)
10.12E	Serum Osteomark License Agreement	(14)
	Agreements with the Washington Research Foundation	
10.13A	Restated Exclusive License Agreement effective June 19, 1992 (Urinary Assay for Measuring Bone Resorption)	(3)
10.13B	Amendment to Restated Exclusive License Agreement effective January 1, 1993	
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)
	Agreements with the University of Washington	
10.15A	Research Agreement dated July 1, 1996 (Molecular Markers of Connective Tissue Degradation)	(7)(8)
10.15B	Research Agreement dated October 1, 1996 (Role of O-CSF in OsteoclastRegulation)	(7)(8)
	Agreements with David R. Eyre, Ph.D.	
10.16A	Know-How Transfer and Consulting Agreement dated September 18, 1989*	(3)
10.16B	Extension and Amendment dated May 1, 1992*	(3)
	Lease Agreements	
10.27A	Lease Agreement dated October 2, 1995, with David A. Sabey and Sandra L. Sabey	(9)
10.27B	First Amendment of Lease dated October 15, 1996, with the City of Seattle, successor-in-interest to David A. Sabey and Sandra L. Sabey	(2)
	Agreements with Johnson & Johnson Clinical Diagnostics, Inc.	
10.28A	Distribution Agreement dated June 7, 1995	(10)
10.28B	Research, Development, License and Supply Agreement dated June 7, 1995	(10)
10.29	Clinical Laboratory Services License and Supply Agreement dated October 25, 1995, with SmithKline Beecham Clinical Laboratories, Inc.	(9)
10.35	Shareholder Rights Agreement dated January 21, 1997, as amended on September 5, 2002	(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)
99.1	Certification of Periodic Report by CEO	(16)
99.2	Certification of Periodic Report by CFO	(16)

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* Management contract or compensatory plan or agreement.

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

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

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

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

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

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

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

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

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

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

(11) Incorporated herein by reference to exhibit number 4.5 filed with Form 8-A with the Commission in January 1997, as amended by Form 8-A/A filed on September 19, 2002.

(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**) Included with this Form 10-Q as exhibit of the same number.

(b) **Reports on Form 8-K**

On September 10, 2002 the Company filed with the SEC a Current Report on Form 8-K reporting that Ostex had entered into an Agreement and Plan of Merger with Inverness Medical Innovations, Inc. and Geras Acquisition Corp., a wholly-owned subsidiary of Inverness.

SIGNATURES

Pursuant to the requirements 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.

OSTEX INTERNATIONAL, INC.

DATED: November 14, 2002	By:	/s/ Thomas A. Bologna Thomas A. Bologna Chairman, President and Chief Executive Officer
DATED: November 14, 2002	By:	/s/ Hans van Houte Hans van Houte Vice President, Finance (Principal financial and accounting officer)

CERTIFICATIONS

I, Thomas A. Bologna, certify that:

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

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we 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 us by others within those entities, particularly during the period in which this quarterly 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 quarterly report (the Evaluation Date); and

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

5. The registrant s other certifying officer and I have disclosed, based on our 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

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. The registrant s other certifying officer and I have indicated in this quarterly 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 our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

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

CERTIFICATIONS

I, Hans van Houte, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Ostex International, Inc.:

2. Based on my knowledge, this quarterly 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 quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly 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 quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we 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 us by others within those entities, particularly during the period in which this quarterly 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 quarterly report (the Evaluation Date); and

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

5. The registrant s other certifying officer and I have disclosed, based on our 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

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. The registrant s other certifying officer and I have indicated in this quarterly 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 our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ Hans van Houte
Hans van Houte
Vice President, Finance