OSTEX INTERNATIONAL INC /WA/
Form 10-Q
May 14, 2003

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 March 31, 2003

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

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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.	Yes ý No o
Indicate by checkmark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).	Yes o No ý

The number of shares of the Registrant s common stock outstanding as of May 5, 2003 was 12,599,912.

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)

	March 31, 2003	December 31, 2002
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,256,000	$ 1,330,000
Trade receivables, net of allowance of $70,000 in 2003 and $68,000 in 2002	1,015,000	944,000
Inventory	1,361,000	1,468,000
Other current assets	202,000	175,000
Total current assets	3,834,000	3,917,000
Property, plant and equipment, net	2,659,000	2,832,000
Other assets	120,000	89,000
Total assets	$ 6,613,000	$ 6,838,000
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 736,000	$ 622,000
Customer deposits	47,000	99,000
Accrued liabilities	579,000	655,000
Current portion of deferred revenue	87,000	89,000
Current portion of notes payable	2,467,000	1,855,000
Total current liabilities	3,916,000	3,320,000
Noncurrent Liabilities:		
Deferred revenue , net of current portion	579,000	599,000
Notes payable, net of current portion	175,000	338,000
Total noncurrent liabilities	754,000	937,000
Commitments and Contingencies		
Shareholders Equity:		
Common stock, $.01 par value, 50,000,000 authorized; 12,583,745 and 12,583,435 issued and outstanding at March 31, 2003 and December 31, 2002, respectively	126,000	126,000

Additional paid-in capital		45,764,000		45,764,000
Accumulated deficit		(43,947,000)		(43,309,000)
Total shareholders equity		1,943,000		2,581,000
Total Liabilities and Shareholders Equity	$	6,613,000	$	6,838,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarter Ended	
	March 31, 2003	**March 31, 2002**
Product sales and other revenue	$ 1,651,000	$ 923,000
Cost of products sold	772,000	293,000
Gross profit	879,000	630,000
Operating Expenses:		
POC facility start-up costs		431,000
Research and development	367,000	463,000
Selling, general and administrative	1,078,000	999,000
Total operating expenses	1,445,000	1,893,000
Loss from operations	(566,000)	(1,263,000)
Interest expense, net	(72,000)	(29,000)
Net loss	(638,000)	(1,292,000)
Basic and diluted net loss per common share	$ (0.05)	$ (0.10)
Weighted average shares used in calculation of net loss per share	12,584,000	12,558,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Year to Date	
	March 31, 2003	**March 31, 2002**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (638,000)	$ (1,292,000)
Adjustments to reconcile net loss to net cash used in operating activities -		
Depreciation and amortization	174,000	173,000
Changes in current assets and current liabilities -		
Trade receivables	(71,000)	363,000
Inventory	107,000	(330,000)
Other current assets	(27,000)	(184,000)
Accounts payable	114,000	335,000
Customer deposits	52,000	99,000
Deferred revenue	(22,000)	445,000
Accrued liabilities	(76,000)	(41,000)
Other assets	(31,000)	
Net cash used in operating activities	$ (522,000)	$ (432,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sales and maturities of short-term investments		622,000
Purchases of property, plant and equipment	(1,000)	(104,000)
Net cash provided by investing activities	(1,000)	518,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	625,000	
Payments on notes payable	(176,000)	(156,000)
Net cash provided by (used by) financing activities	449,000	(156,000)
NET DECREASE IN CASH AND EQUIVALENTS	(74,000)	(70,000)
CASH AND CASH EQUIVALENTS, beginning of period	1,330,000	1,284,000
CASH AND CASH EQUIVALENTS, end of period	$ 1,256,000	$ 1,214,000

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 Ostex Annual Report filed on Form 10-K for the year ended December 31, 2002.

On September 9, 2002, Ostex announced that it had entered into an agreement and plan of merger whereby Ostex would be acquired by and become a wholly owned subsidiary of Inverness Medical Innovations, Inc. The agreement and plan of merger was amended in certain respects effective as of February 18, 2003. (See Note 11 below). In connection with the merger agreement, as amended, Inverness and Ostex also entered into an amended and restated loan agreement. Under the loan agreement, Inverness has agreed to make, or arrange for one of its affiliates to make, loans of up to an aggregate of $2,000,000 to Ostex. As of March 31, 2003, $1,625,000 had been borrowed under the loan agreement. The loans must be repaid on the first business day after the effective time of the merger, upon an event of a default or a breach of the terms of the merger agreement by Ostex, or, in the case where the merger agreement is terminated and it is not an event of default under the loan agreement, on December 31, 2003.

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

Ostex future capital requirements depend upon many factors, including Ostex proposed merger with Inverness and the realization of the benefits expected from the proposed merger; effectiveness of its Osteomark® NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for Ostex products; continued scientific progress in research and development programs; the costs involved in filing, prosecuting, enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining regulatory approvals. Because of near-term cash requirements, if the merger is not consummated, Ostex will seek to raise additional capital through public or private sales of its equity or debt securities. There can be no assurance that additional funds will be available on favorable terms, if at all. If the merger is not consummated, Ostex believes that its

existing available cash, the $2,000,000 received under the loan from Inverness, its future license and research

revenues from existing collaboration agreements, and its current level of product sales will be adequate to fund operations through August 2003. If funding is insufficient at any time in the future, Ostex may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; scale back or eliminate some or all of its manufacturing operations; sell assets; license to third parties rights to commercialize products or technologies that the Company would otherwise seek to develop on its own; or seek bankruptcy protection.

These financial statements have been prepared assuming that Ostex will continue as a going concern. In their report dated January 24, 2003 on the financial statements as of December 31, 2002 and for the year then ended, Ostex independent auditors expressed substantial doubt about our ability to continue as a going concern.

Ostex has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS No. 123) and has applied that method in the three-month periods presented. Accordingly, no compensation cost has been recognized for stock options issued at market value on the date of grant. Had compensation cost for Ostex Stock Option Plans been determined based on the fair value of the options at the grant date for awards in the quarters ended March 31, 2003 and March 31, 2002 consistent with the provisions of SFAS No. 123, Ostex net loss and net loss per common equivalent share would have changed to the pro forma amounts indicated below:

	March 31, 2003	March 31, 2002
Net loss as reported	$ (638,000)	$ (1,292,000)
Stock based employee compensation - included in the determination of net loss as reported		
Stock based employee compensation assuming application of fair value method to all awards	99,000	133,000
Net loss pro forma	$ (737,000)	$ (1,425,000)
Basic and diluted net loss per common and common equivalent share as reported	$ (0.05)	$ (0.10)
Basic and diluted net loss per common and common equivalent share pro forma	$ (0.06)	$ (0.11)

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 Ostex net losses. The calculation of dilutive shares excludes approximately 2,696,266 and 2,878,000 of stock options and warrants outstanding as of March 31, 2003 and March 31, 2002, respectively, because of their antidilutive effect.

3. Revenue Recognition

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 or deferred revenue. Deferred revenue represents license payments received from Mochida for Ostex NTx Serum kit product which will be recognized ratably over the term of the period Ostex is obligated to provide finished products as specified in the agreement. Returns of product to date have been warranty related and insignificant.

4. Concentration of Credit Risk

Trade receivables potentially subject Ostex to credit risk. Ostex 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 March 31, 2003, domestic product sales accounted for 49% of total revenue and product sales to customers located in foreign countries accounted for 51% of total revenue. Mochida Pharmaceuticals, Quest Diagnostics and Johnson & Johnson each accounted for over 10% of total revenue and Mochida accounted for over 10% of total accounts receivable. For the three-month period ended March 31, 2002, domestic product sales accounted for 72% of total revenue and product sales to customers located in foreign countries accounted for 28% of total revenue. Mochida Pharmaceuticals and Quest Diagnostics each accounted for over 10% of total revenue and 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. Ostex entire finished goods inventory has a limited shelf life and Ostex 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:

	March 31, 2003	December 31, 2002
Raw materials	$ 903,000	$ 971,000
Work in process	$ 390,000	$ 437,000
Finished goods	$ 68,000	$ 60,000
Total inventory	$ 1,361,000	$ 1,468,000

6. Comprehensive Income (Loss)

There were no other elements of comprehensive loss in the three-month periods ended March 31, 2003 and March 31, 2002.

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 Ostex point-of-care manufacturing facility, tooling, and production prior to the production of sellable devices. Ostex successfully validated its point-of-care manufacturing facility in the second quarter of 2002. These costs were expensed as incurred and totaled $431,000 for the quarter ended March 31, 2002.

8. 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. SFAS No. 143 became effective for Ostex on January 1, 2003. The adoption of SFAS 143 did not have any significant impact on Ostex' financial statements.

9. 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 was served notification on December 12, 2002 of the German proceeding. On January 9, 2003, Ostex filed a notification of appearance in Germany and indicated that it will contest the matter. Ostex does not believe that these proceedings will have a material adverse effect on its financial position or results of operations.

10. Mochida License Agreement

On March 5, 2002, Ostex announced that it had entered into a Serum Osteomark License Agreement with its Japanese partner, Mochida Pharmaceutical Co. Ltd., under which Ostex will sell the Osteomark NTx Serum test, in the microtiter format, exclusively to

Mochida for distribution in Japan. Under the terms of the agreement, Mochida paid Ostex $750,000, $500,000 of which was paid upfront as a nonrefundable license fee and $250,000 of which was paid in August 2002. Mochida s payments were subject to a 10% Japanese withholding tax. Ostex recorded this $75,000 tax expense in the third quarter of 2002. During the third quarter of 2002, Mochida began purchasing and paying for finished Osteomark NTx Serum kits manufactured by Ostex. Ostex 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 $666,000 at March 31, 2003 and $22,000 and $5,000 were recorded in product sales and other revenue during the first quarters of 2003 and 2002, respectively.

11. Proposed Merger with Inverness Medical Innovations, Inc.

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

issued in exchange for all outstanding Ostex common stock; and

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

The merger cannot be completed unless certain conditions are satisfied, including Inverness obtaining the final consent of certain of its lenders and the approval by the affirmative vote of two-thirds of the outstanding shares of Ostex common stock. Ostex directors and their affiliates, who collectively own an aggregate of approximately 19.6% of the total outstanding common stock of Ostex, have entered into a voting agreement with Inverness, which provides that they will vote their shares in favor of the acquisition. Additionally, in connection with the acquisition, Inverness received an option to purchase up to 19.9% of Ostex common stock that will be exercisable under certain circumstances.

On January 2, 2003, Ostex and Inverness announced that Inverness had been unable to obtain the required consent of certain of its lenders to the merger. The amendment to the merger agreement, which, among other things, reduced the aggregate number of shares of Inverness common stock to be issued in the merger from 2.3 million shares to 1.9 million shares, is intended to increase the likelihood of Inverness receiving the consent of certain of its lenders. On April 17, 2003, Inverness obtained the written consent of its lenders to the proposed transaction, subject to the condition that the merger be completed by June 30, 2003 and other conditions relating to the addition of Ostex as a party to the credit facility, the lenders obtaining a security interest in Ostex assets, the delivery of various certificates and updating schedules, the amount of Inverness fees and expenses in connection with the proposed transaction and the repayment of Ostex indebtedness with the completion of the merger. A special meeting of shareholders of Ostex will be held on June 20, 2003 to vote on the approval of the merger. There can be no assurance, however, that Inverness lenders will give their consent to the proposed merger. Likewise, there can be no assurance that Ostex shareholders will approve the merger. Failure to complete the merger could have a material adverse effect on Ostex financial condition and results of operations. Ostex has provided additional information about some of these potential adverse effects under the captions Liquidity and Capital Resources and Additional Factors That May Affect Results below.

Inverness and Ostex have filed relevant documents concerning the merger with the Securities and Exchange (SEC), including a registration statement on Form S-4, as amended (File No. 333-101178), and the definitive prospectus/proxy statement dated April 28, 2003, filed with the SEC under Rule 424(b) under the Securities Act of 1933. You should refer to these documents, including most particularly the definitive prospectus/proxy statement, for further information about the proposed merger.

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 Ostex 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 Ostex actual results to differ materially from any forward-looking statement.

Although Ostex believes the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, product demand, performance or achievements. Readers are cautioned not to place undue reliance on such forward-looking statements, which apply only as of the date of this Report. Ostex undertakes 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

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

Osteoporosis is a significant health problem. 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. Ostex expects the osteoporosis therapeutic market will continue to grow as the population ages.

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

The Osteomark NTx test is a non-invasive test that quantitatively indicates the level of bone resorption. Individuals who are losing bone collagen at accelerated rates may progress to low bone mass, a major cause of osteoporosis. Identification of high levels of bone resorption

provides the opportunity to predict skeletal response (bone mineral density) to hormonal antiresorptive therapy, such as Wyeth s Premarin®, in postmenopausal women, which is intended for the prevention and treatment of osteoporosis. In addition, Ostex 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.

Ostex has the worldwide exclusive right to commercialize technology developed from certain research conducted by the University of Washington under license agreements with the Washington Research Foundation. As consideration for the licenses acquired and for the attainment of certain milestones, Ostex paid the Washington Research Foundation certain nonrefundable fees and issued common stock to the Washington Research Foundation and the University of Washington. All legal costs incurred by the Washington Research Foundation, in connection with the filing, prosecution, and maintenance of certain defined patent rights, are paid by Ostex. Ostex is obligated to pay the Washington Research Foundation royalties on net sales of any licensed products and also pays royalties to the Washington Research Foundation on milestones received from licensees of the products.

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

Ostex second Osteomark test is a serum microtiter plate test that became commercially available in February 1999. This was the first commercially available serum test in the United States that measures specific bone breakdown by osteoclasts using a blood sample. Ostex believes that the use of a serum NTx test provides a number of advantages to centralized testing laboratories, including the elimination of the requirement to normalize NTx values to creatinine concentration.

The Osteomark NTx Point-of-Care device became commercially available in October 1999 for use in the physician s office..

Ostex and Metrika, Inc. developed a physician s office Point-of-Care Osteomark test device which is a fully disposable point-of-care NTx test for urine as an indicator of bone resorption that computes an NTx value and displays it digitally. In May 2000, Ostex announced it had acquired the exclusive right from Metrika to manufacture the Osteomark NTx Point-of-Care device, as well as the exclusive worldwide license to manufacture, market and sell this device for the measurement of NTx and other connective tissue markers, including those associated with osteoarthritis. Under the agreement, Metrika receives a royalty based on the sales of the NTx Point-of-Care device. In August 2001, Ostex received Rx Home-Use clearance and CLIA Waiver status for its NTx Point-of-Care device from the FDA. This allows the device to be used in essentially all physician offices, and physicians can write a prescription for the device so that patients can purchase it at the pharmacy and use it in their own homes under the direction of their physicians.

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

Ostex began working with Procter & Gamble in 2000 to launch a test program in Germany to use the NTx Point-of-Care device with Actonel, Procter & Gamble s osteoporosis drug for the management of osteoporosis. This program initially was expanded by Procter & Gamble and its partner, Aventis Pharmaceuticals, and tested in a number of countries. Ostex 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 Ostex manufacturing facility, Ostex was unable to deliver NTx Point-of-Care devices to Procter & Gamble and Aventis during most of the first half of 2002. As a result, Procter & Gamble and Aventis cancelled a portion of their NTx Point-of-Care back orders or switched to the Osteomark NTx Urine test in the microtiter plate format. Ostex validated its manufacturing process late in the second quarter of 2002 and has shipped NTx Point-of-

Care devices to Procter & Gamble and Aventis. Ostex has maintained a continuing dialogue with Procter & Gamble and Aventis and is working to rebuild their confidence in Ostex manufacturing capabilities. Ostex is also working to expand sources of demand for its products and has shipped NTx Point-of-Care devices to other large pharmaceutical companies.

Ostex and Mochida Pharmaceutical Co., Ltd., a Japanese pharmaceutical company, entered into a research and development agreement and a license agreement in 1992 for the commercialization of the Osteomark NTx Urine test in Japan. Under the license agreement, Ostex granted Mochida exclusive marketing and distribution rights to certain products in Japan. In January 1998, Mochida launched the Osteomark 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 Ostex in March 2002, 30 days after the time it exercised the option to license, and $250,000 of which Mochida paid to Ostex in August 2002, after Mochida received the official announcement of the Japanese reimbursement price from the Ministry of Health. Mochida obtained the Import Approval for Osteomark NTx Serum from the Japanese Ministry of Health, Labor and Welfare in July 2002 and launched the product for sale in November 2002.

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

Ostex has technology for measuring Type II and Type III collagen degradation. Type II collagen is a primary constituent of joint cartilage. Osteoarthritis, a degenerative disease of joint cartilage, affects over 20 million people in the United States alone. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. Further development of Ostex Type II collagen degradation test will be needed to allow reliable monitoring of joint cartilage changes, for validating the effectiveness of drugs under development and for identifying patients with early-stage disease. Similar to the Osteomark NTx test used in connection with osteoporosis, Ostex believes that the Type II collagen degradation test will aid in the clinical management of osteoarthritis patients. Type III collagen is a significant constituent of blood vessels such as coronary arteries. Measuring degradation of this type of collagen may be useful in identifying cardiovascular disease. Ostex has no immediate plans to commercialize tests for Type II or Type III collagen degradation, but has patents in these areas if it decides to commercialize these tests in the future.

Ostex also has technology to enhance artificial joint recovery. Ostex is the exclusive licensee of U.S. Patents No. 6,190,412 and No. 6,508,838, directed to prosthetic devices having hydroxyapatite-coated bone attachment surfaces to which tartrate-resistant acid phosphatase (TRAP) is absorbed. Research supported by Ostex established that the human TRAP enzyme has a direct role as a local factor in the recruitment of osteoclasts from hematopoietic cells. Such research also established that recombinantly produced

TRAP absorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. Ostex may seek collaborations to confirm whether or not such TRAP-induced stimulation of osteoclast recruitment results in osteointegration and enhanced bonding of the graft or prosthesis to the patient s bone.

OSTEOMARK and OSTEX are registered United States trademarks of Ostex. Ostex has also registered its OSTEOMARK trademark in 47 other countries. The collagen breakdown test technology is covered by 37 U.S. patents, 3 European patents, 6 Japanese patents, and patents in Australia, Canada, Ireland, Korea, Russia, Spain, Norway, Hong Kong, and Singapore. Two of the European patents are in opposition

proceedings. Additional patent applications are pending. These patents are variously directed to Type I collagen breakdown products, including

NTx, CTx, and deoxypyridinoline, as well as related breakdown products of Type II and Type III collagen. The Type I collagen patents will begin to expire in late 2007 for the U.S. and in 2010 for Europe and Japan. Ostex is also the exclusive worldwide licensee of Metrika s patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013.

Pending Merger with Inverness

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

issued in exchange for all outstanding Ostex common stock; and

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

The merger cannot be completed unless certain conditions are satisfied, including Inverness obtaining the final consent of certain of its lenders and the approval by the affirmative vote of two-thirds of the outstanding shares of Ostex common stock. Ostex directors and their affiliates, who collectively own an aggregate of approximately 19.6% of the total outstanding common stock of Ostex, have entered into a voting agreement with Inverness, which provides that they will vote their shares in favor of the acquisition. Additionally, in connection with the acquisition, Inverness received an option to purchase up to 19.9% of Ostex common stock that will be exercisable under certain circumstances.

On January 2, 2003, Ostex and Inverness announced that Inverness had been unable to obtain the required consent of certain of its lenders to the merger. The amendment to the merger agreement, which, among other things, reduced the aggregate number of shares of Inverness common stock to be issued in the merger from 2.3 million shares to 1.9 million shares, is intended to increase the likelihood of Inverness receiving the consent of certain of its lenders. On April 17, 2003, Inverness obtained the written consent of its lenders to the proposed transaction, subject to the condition that the merger be completed by June 30, 2003 and other conditions relating to the addition of Ostex as a party to the credit facility, the lenders obtaining a security interest in Ostex assets, the delivery of various certificates and updating schedules, the amount of Inverness fees and expenses in connection with the proposed transaction and the repayment of Ostex indebtedness with the completion of the merger. A special meeting of shareholders of Ostex will be held on June 20, 2003 to vote on the approval of the merger. There can be no assurance, however, that Inverness lenders will give their consent to the proposed merger. Likewise, there can be no assurance that Ostex shareholders will approve the merger. Failure to complete the merger could have a material adverse effect on Ostex financial condition and results of operations. Ostex has provided additional information about some of these potential adverse effects under the captions Liquidity and Capital Resources and Additional Factors That May Affect Results below.

Inverness and Ostex have filed relevant documents concerning the merger with the Securities and Exchange (SEC), including a registration statement on Form S-4, as amended (File No. 333-101178), and the definitive prospectus/proxy statement dated April 28, 2003, filed with the

SEC under Rule 424(b) under the Securities Act of 1933. You should refer to these documents, including most particularly the definitive prospectus/proxy statement, for further information about the proposed merger.

Results of Operations for the Three Months Ended March 31, 2003 and March 31, 2002

Total revenues were $1,651,000 for the quarter ended March 31, 2003, compared to $923,000 for the quarter ended March 31, 2002. The increase in revenues for the quarter was primarily due to higher sales of the Osteomark NTx Urine and Serum kits and the Point-of-Care device, as compared to the same period in 2002. Sales of serum kits were particularly strong and sales of urine kits increased over last year to Ostex Japanese partner, Mochida.

Ostex recorded a net loss of $638,000 ($0.05 per share) for the quarter ended March 31, 2003 compared to a net loss of $1,292,000 ($0.10 per share) for the quarter ended March 31, 2002. The decrease in loss was primarily due to higher sales in the quarter ended March 31, 2003.

Total cost of products sold was $772,000 for the quarter ended March 31, 2003, compared to $293,000 for the quarter ended March 31, 2002. The increase in 2003 over 2002 was primarily due to higher product sales of the NTx Urine and Serum kits and the excess capacity of Ostex point-of-care manufacturing facility, which is being expensed through cost of goods sold. Ostex production capacity exceeded the actual production of point-of-care devices in the first quarter and the resulting excess capacity had a negative impact to Ostex 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.

Point-of-care facility start-up costs are related to the operation and validation of the facility, associated tooling, and production prior to the production of sellable devices. These costs were expensed as incurred. Ostex did not incur any point-of-care facility start-up costs for the three-month period ended March 31, 2003 as compared to the same period in 2002 which totaled $431,000.

Ostex research and development expenditures totaled $367,000 for the quarter ended March 31, 2003, compared to $463,000 for the quarter ended March 31, 2002. The decrease in 2003 as compared to 2002 is related to slightly lower personnel related expenditures. Selling, general and administrative expenses totaled $1,078,000 for the quarter ended March 31, 2003, compared to $999,000 for the quarter ended March 31, 2002. The increase in 2003 is due to higher legal, investment banking, and accounting fees of approximately $268,000 incurred in connection with the proposed merger with Inverness offset by a decrease in other selling, general and administrative expenses.

Net interest expense totaled $72,000 for the quarter ended March 31, 2003, compared to net interest expense of $29,000 for the quarter ended March 31, 2002. In 2003, Ostex incurred higher interest expense due to higher borrowing activities.

Liquidity and Capital Resources

As of March 31, 2003 Ostex had cash and cash equivalents and short-term investments of $1,256,000, working capital of negative $82,000 and total shareholders equity of $1,943,000. As a result of funding operating losses during the three months ended March 31, 2003, cash and cash equivalents decreased by $74,000, accounts receivable, inventory and other current assets decreased by $9,000, working capital decreased by $679,000 and shareholders equity decreased by $638,000. During the three-month period ended March 31, 2003, Ostex purchased $1,000 of manufacturing and office equipment, and increased notes payable by $449,000.

These financial statements have been prepared assuming that Ostex will continue as a going concern. In their report dated January 24, 2003 on the financial statements as of December 31, 2002 and for the year then ended, Ostex independent auditors expressed substantial doubt about Ostex ability to continue as a going concern.

Ostex future capital requirements depend upon many factors, including Ostex proposed merger with Inverness and the realization of the benefits expected from the proposed merger; effectiveness of its Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for Ostex products; continued scientific progress in research and development programs; the costs involved in filing, prosecuting,

enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining regulatory approvals.

The following table summarizes Ostex contractual obligations and other commercial commitments as of March 31, 2003, and the effect such obligations and commitments are expected to have on liquidity for future periods. Long-term debt payments are principal portions only.

Contractual obligations	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long-term debt	$ 2,642,000	$ 2,467,000	$ 175,000	$	$
Operating leases	2,245,000	662,000	1,203,000	217,000	163,000
Total cash obligations	$ 4,887,000	$ 3,129,000	$ 1,378,000	$ 217,000	$ 163,000

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

Ostex has incurred substantial expenses in connection with the proposed merger with Inverness. If the merger does not occur, Ostex currently expects to incur approximately $1.2 million to $1.6 million in merger related expenses, excluding any termination fees, if applicable. These expenses will have a material adverse effect on the results of operations and financial condition of Ostex because Ostex will have not realized the expected benefits of the merger. As a result of the delays and the renegotiation of the merger agreement, Ostex will incur more expenses than originally anticipated due to additional legal, accounting and investment banking costs and fees and the cost of extending the term of Ostex current directors and officers insurance coverage.

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 borrowed an additional $233,000 on December 9, 2002, at an interest rate of 6.16%. Ostex borrowed an additional $379,000 on January 14, 2003, at an interest rate of 6.02%. Ostex borrowed an additional $246,000 on February 25, 2003 at an interest rate of 5.90%. Ostex borrowed the remaining $375,000 on May 12, 2003, at an interest rate of 5.79%. As of March 31, 2003, Ostex had borrowed $1,625,000 under the loan agreement.

The loans must be repaid at the earliest of:

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

acceleration upon an event of default;

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

December 31, 2003.

If the merger is not consummated, Ostex believes that it will be able to fund its operations through August 2003, based on current projections. Ostex $2,000,000 loan liability to Inverness, however, would have a material impact on the results of operations and financial condition of Ostex because Ostex will not have realized the expected benefits of the merger.

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

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

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

Critical Accounting Policies

Ostex critical accounting policies used in the preparation of the financial statements relate to revenue recognition. The reader is advised to refer to Ostex Form 10-K for the period ending December 31, 2002 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 December 31, 2003 at the latest;

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

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

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

The obligations of the parties to effect the merger are subject to a number of conditions, including obtaining final 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.

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Risks Related to Ostex Business

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

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

Ostex has not been profitable for any year since its formation in 1989. Ostex had an accumulated deficit through March 31, 2003 of $43,947,000. Ostex expects to incur additional costs as it continues with its existing operations, marketing and sales efforts for its products, and research and development activities. Ostex lead product, the Osteomark NTx Urine test, became commercially available in May 1995 in the United States, but sales to date have not been significant enough to generate net income. Ostex ability to achieve long-term profitability is dependent upon successfully manufacturing, marketing, and commercializing existing products. Ostex expects to continue to incur additional losses in the near-term future and Ostex is unable to predict when, if ever, it will achieve profitability. Ostex ability to continue as a going concern is dependant upon numerous factors, including its ability to obtain additional financing, its ability to increase its level of future revenues and its ability to reduce operating expenses.

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

On March 18, 2003, Ostex received formal written notice of the Nasdaq Staff s determination that Ostex securities should be delisted from The Nasdaq National Market in light of Ostex on-going failure to satisfy the $10,000,000 minimum shareholders equity requirement set forth in Marketplace Rule 4450(a)(3). On March 21, 2003, Ostex requested a hearing before a Nasdaq Listing Qualifications Panel to review the Staff delisting determination. At the hearing, Ostex requested continued listing on The Nasdaq National Market pending completion of the merger with Inverness. On May 6, 2003, the Panel granted Ostex request and determined to continue the listing of Ostex Common Stock on The Nasdaq National Market, subject to certain conditions, including that the merger is consummated no later than June 30, 2003. Ostex Common Stock would not meet the minimum stockholders equity requirement for transfer to The Nasdaq SmallCap Market and therefore would be listed on the over-the-counter bulletin board. If the merger is not consummated and Ostex Common Stock is delisted from the Nasdaq system, the delisting could have a material adverse effect on the trading price and liquidity of the stock, and shareholders ability to sell shares of Ostex stock would be severely limited. Among other things, if not listed on The Nasdaq National Market or The Nasdaq SmallCap Market, Ostex Common Stock may then constitute penny stock which would place increased regulatory burdens on brokers, making them less likely to make a market in Ostex stock. Loss of Ostex Nasdaq listing could also make it more difficult for Ostex to raise capital and would also complicate compliance with state blue sky laws.

The market acceptance and demand for Ostex products is uncertain.

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 three months of 2003 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 60 patents in North America, Europe, and Asia. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to Ostex patents if it attempts to enforce them and they are challenged in court or in other proceedings, such as oppositions, which may be brought in foreign jurisdictions to challenge the validity of a patent. A third party may challenge the validity or enforceability of a patent after its issuance by the PTO or a foreign patent office. It is possible that a competitor may successfully challenge Ostex patents or that a challenge will result in limiting their coverage. Moreover, the cost of litigation to uphold the validity of patents and to prevent infringement can be substantial. If the outcome of litigation is adverse to Ostex, third parties may be able to use Ostex patented invention without payment to Ostex. Moreover, it is possible that competitors may infringe Ostex patents or successfully avoid them through design innovation. To stop these activities, Ostex may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if Ostex is successful in stopping the violation of its patent rights. In addition, there is a risk that a court would decide that Ostex patents are not valid and that Ostex does not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of Ostex patents are upheld, a court would refuse to stop the other party on the ground that its activities do not infringe Ostex patents.

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

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

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

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

In December 2001, Osteometer Biotech A/S, also known as Nordic Bioscience A/S, and its licensee Roche Diagnostics GmbH sent Ostex two notification letters concerning Osteometer s European Patent No. 0742902 which issued November 21, 2001. The patent claims synthetic NTx peptides in assays for bone resorption. Ostex believes that its Osteomark products do not infringe upon the Osteometer patent and that the patent is invalid in light of prior art that was not taken into consideration by the issuing European Patent Office. In January 2002, Ostex filed an action in the Court of Monza, Italy, seeking a pan-European declaration of noninfringement. This action included a request to stay any such noninfringement determination pending the outcome of an opposition proceeding that Ostex initiated on August 20, 2002, in the European Patent Office against this patent. By letter dated October 24, 2002,

Nordic Bioscience A/S informed Ostex that it had filed infringement proceedings in July 2002 against Ostex before the District Court of Düsseldorf, Germany. Ostex was served notification on December 12, 2002 of the German proceeding. On January 9, 2003, Ostex filed a notification of appearance in Germany and indicated that it will contest the matter.

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

The cost to Ostex of any litigation or other proceedings relating to intellectual property rights, even if resolved in Ostex favor, could be substantial. Some of Ostex competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If third parties file patent applications, or are issued patents claiming technology also claimed by Ostex in pending applications, Ostex may be required to participate in interference proceedings in the 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. Additionally, technological changes or medical advancements could diminish or eliminate the commercial viability of the Osteomark tests or future products based upon Ostex core technology. The failure to adapt Ostex core technology to different or more cost effective formats, instruments, and other delivery platforms, or otherwise to commercialize such core technology, could have a material adverse effect on Ostex results of operations.

Ostex is reliant on collaborative agreements and other relationships.

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

fails to conduct its collaborative activities in a timely manner, the commercialization of existing and future products could be slowed down or blocked completely. Disputes may arise between Ostex and its collaborators on a variety of matters, including financial or other obligations under the business relationships and arrangements between the companies. These disputes may be both expensive and time consuming and may result in delays in the development and commercialization of Ostex products.

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

The testing, manufacturing, marketing and sale of Ostex products may subject Ostex to product liability claims. Ostex maintains coverage against product liability risks up to a $2,000,000 aggregate limit. However, continuing insurance coverage may not be available at an acceptable cost, if at all. Ostex may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to its reputation, withdrawal of clinical trial volunteers and loss of revenues. As a result, regardless of whether Ostex is insured, a product liability claim or product recall may result in losses that could be material to Ostex.

Ostex has limited suppliers.

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

The healthcare reimbursement for Ostex products is uncertain.

Ostex ability to commercialize its products will depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from third-party payors, such as government health administration authorities, private health coverage insurers and other organizations, and the amount of such reimbursement. The status of the scope of healthcare programs worldwide is uncertain and there can be no assurance that adequate third-party coverage will be available for Ostex to maintain price levels sufficient for realization of an appropriate return on its investment in product development. Third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. There can be no assurance that Ostex existing or any future products will provide sufficient value or be considered cost effective and that reimbursement to the consumer will be available or sufficient to allow Ostex to sell its products on a competitive basis. The U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services issued its Final Rule for National Medicare Coverage in November 2001. The Rule established mandatory national Medicare coverage for the use of the Osteomark NTx Urine test. The implementation date for this coverage was January 1, 2003. However, because the Rule was negotiated based on earlier clinical studies with urine tests, the rulemaking did not extend to the Osteomark NTx Serum test. In the absence of a national coverage decision, Medicare contractors will have local discretion in deciding whether the Osteomark NTx Serum test is reimbursable as a medically necessary procedure for assessing and monitoring bone loss resorption.

Ostex has experienced volatility of stock price

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. Ostex exposure to market rate risk, as a result of changes in interest rates, relates primarily to its investment portfolio. At March 31, 2003, Ostex held $1,256,000 in cash and cash equivalents and no fixed or adjustable rate investments that would carry any significant degree of interest rate risk. Additionally, at March 31, 2003 Ostex had $2,642,000 of notes payable. While fluctuations in interest rates may affect the fair value of this debt, Ostex debt payments will not be affected due to fixed interest rates on this debt.

Currency risk. Ostex conducts all financial transactions in U.S. currency. However, currency fluctuations may impact a foreign customer s ability to meet its payment obligations and/or future product pricing to that customer. Based upon Ostex credit authorization policy, current economic conditions in countries in which Ostex does significant business, and the level of outstanding foreign receivables, Ostex does not consider this risk to be material 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 its Chief Executive Officer who is also acting as Ostex chief financial officer and its Controller, 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 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 was served notification on December 12, 2002 of the German proceeding. On January 9, 2003, Ostex filed a notification of appearance in Germany and indicated that it will contest the matter.

Item 5. Other Events

On May 6, 2003, the Nasdaq Listing Qualifications Panel, after an oral hearing, granted Ostex request to continue the listing of Ostex Common Stock on The Nasdaq National Market, subject to certain conditions, including that the merger with Inverness Medical Innovations, Inc. is consummated no later than June 30, 2003. If the merger is not consummated, Ostex Common Stock would not meet the minimum stockholders equity requirement for transfer to The Nasdaq SmallCap Market and therefore would be listed on the over-the-counter bulletin board.

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)
2.1A	Amendment to Agreement and Plan of Merger dated as fo February 18, 2003	(17)
2.2	Voting Agreement dated as of September 6, 2002	(15)
2.2A	Letter Agreement dated as of February 18, 2003, amending the Voting Agreement	(17)
2.3	Stock Option Agreement dated as of September 6, 2002	(15)
2.3A	Second Amended and Restated Loan Agreement dated as of February 18, 2003	(17)
3.1	Articles of Incorporation, as amended, dated January 1997	(2)
3.2	Bylaws, as restated	(16)
4.1	Specimen Common Stock Certificate	(3)
10.1A	Amended and Restated Stock Option Plan*	(3)
10.1B	Amended and Restated 1994 Stock Option Plan*	(4)
10.1C	Amended and Restated Directors Nonqualified Stock Option Plan*	(5)
10.5	Form of Indemnification Agreement with officers and directors*	(3)
	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	(6), (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	(3)
10.13C	Second Amendment effective June 2, 1994	(3)
10.14	Exclusive License Agreement dated February 10, 1994 (O-CSF)	(3)
10.14A	Amendment to Exclusive License Agreement effective September 5, 2002	(16)
	Agreements with the University of Washington	
10.15A	Research Agreement dated July 1, 1996 (Molecular Markers of Connective Tissue Degradation)	(7)(8)
10.15B	Research Agreement dated October 1, 1996 (Role of O-CSF in Osteoclast Regulation)	(7)(8)
	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 February 18, 2003	(11)
10.37	Metrika Manufacturing and License Agreement dated March 10, 2000	(12)
10.38	Transamerica Business Credit Corporation Master Loan and Security Agreement dated October 23, 2000	(13)
99.1	Certification of Periodic Report by CEO and Principal Financial and Accounting Officer	(18)

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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) Incorporated herein by reference to exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended September 30, 2002.

(17) Incorporated herein by reference to exhibit of the same number filed with Form 8-K dated February 20, 2003 with the Commission.

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

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

Form 8-K dated January 2, 2003, updating status of Ostex pending merger with Inverness Medical Innovations, Inc.

Form 8-K dated February 19, 2003, announcing amendment of agreement and plan of merger between Ostex and Inverness Medical Innovations, Inc.

Form 8-K dated February 28, 2003, announcing resignation of Ostex principal accounting and financial officer

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: May 14, 2003

By: /s/ Thomas A. Bologna
Thomas A. Bologna
Chairman, President and Chief Executive 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and I have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to 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. I have disclosed, based on my most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

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

6. I have indicated in this 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 my most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

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