OSTEX INTERNATIONAL INC /WA/
Form 10-Q
August 14, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2002

or

o Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from to

0-25250

Commission File Number

OSTEX INTERNATIONAL, INC.

Name of Registrant as Specified in Its Charter

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

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

[n/a]

Former name, address and fiscal year, if changed since last report

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

The number of shares of the Registrant s common stock outstanding as of August 12, 2002 was 12,581,216.

OSTEX INTERNATIONAL, INC.

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PART I - FINANCIAL INFORMATION

OSTEX INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

(Unaudited)

	June 30, 2002	December 31, 2001
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 476,000	$ 1,284,000
Short-term investments	933,000	2,543,000
Trade receivables, net of allowance of $66,000 in 2002 and $54,000 in 2001	1,258,000	815,000
Inventory, at cost	1,543,000	994,000
Other current assets	187,000	33,000
Total Current Assets	4,397,000	5,669,000
Property, Plant and Equipment, net	3,085,000	3,272,000
Other Assets	737,000	694,000
Total Assets	$ 8,219,000	$ 9,635,000
LIABILITIES AND SHAREHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 692,000	$ 279,000
Customer deposits	109,000	156,000
Accrued liabilities	405,000	495,000
Current portion of notes payable	684,000	635,000
Total Current Liabilities	1,890,000	1,565,000
Noncurrent Liabilities:		
Deferred revenue	431,000	
Notes payable, net of current portion	801,000	1,138,000
Commitments and Contingencies		
Shareholders Equity:		
Common stock, $.01 par value, 50,000,000 authorized; 12,581,216 and 12,558,174 issued and outstanding at June 30, 2002 and December 31, 2001 respectively	126,000	126,000
Additional paid-in capital	45,753,000	45,709,000
Accumulated other comprehensive income	2,000	6,000
Accumulated deficit	(40,784,000)	(38,909,000)

Total Shareholders Equity			5,097,000	6,932,000
Total Liabilities and Shareholders Equity		$	8,219,000	$ 9,635,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarter Ended		Year to Date	
	June 30, 2002	**June 30, 2001**	**June 30, 2002**	**June 30, 2001**
Product sales and other revenue	$ 1,572,000	$ 1,492,000	$ 2,495,000	$ 3,021,000
Cost of products sold	726,000	590,000	1,019,000	1,204,000
Gross profit	846,000	902,000	1,476,000	1,817,000
Operating Expenses:				
POC facility start-up costs	138,000	170,000	569,000	250,000
Research and development	408,000	427,000	871,000	996,000
Selling, general and administrative	839,000	858,000	1,838,000	2,040,000
Total operating expenses	1,385,000	1,455,000	3,278,000	3,286,000
Loss from operations	(539,000)	(553,000)	(1,802,000)	(1,469,000)
Interest (expense) income, net	(43,000)	52,000	(73,000)	110,000
Net loss	$ (582,000)	$ (501,000)	$ (1,875,000)	$ (1,359,000)
Basic and diluted net loss per common share	$ (0.05)	$ (0.04)	$ (0.15)	$ (0.11)
Weighted average shares used in calculation of net loss per share	12,562,000	12,484,000	12,560,000	12,484,000

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

OSTEX INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Year to Date	
	June 30, 2002	**June 30, 2001**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	$ (1,875,000)	$ (1,359,000)
Adjustments to reconcile net loss to net cash used in operating activities -		
Depreciation and amortization	349,000	248,000
Expense from issuance of warrants	27,000	7,000
Loss on disposal of property, plant, and equipment		2,000
Changes in current assets and current liabilities -		
Trade receivables	(443,000)	(42,000)
Inventory	(549,000)	(171,000)
Other assets	(197,000)	(60,000)
Accounts payable	413,000	(759,000)
Customer deposits	(47,000)	
Deferred revenue	431,000	
Accrued expenses	(90,000)	274,000
Net cash used in operating activities	(1,981,000)	(1,860,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of short-term investments		(911,000)
Proceeds from sales and maturities of short-term investments	1,606,000	1,535,000
Purchases of property, plant and equipment	(162,000)	(421,000)
Net cash provided by investing activities	1,444,000	203,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from the issuance of common stock	17,000	32,000
Repurchase of common stock		(19,000)
Proceeds from notes payable		831,000
Payments on notes payable	(288,000)	(245,000)
Net cash (used by) provided by financing activities	(271,000)	599,000
NET DECREASE IN CASH AND EQUIVALENTS	(808,000)	(1,058,000)
CASH AND CASH EQUIVALENTS, beginning of period	1,284,000	1,348,000
CASH AND CASH EQUIVALENTS, end of period	$ 476,000	$ 290,000

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 (the Company). 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 which 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 footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. For further information, refer to the financial statements and footnotes thereto included in the Company s Annual Report filed on Form 10-K for the year ended December 31, 2001.

The Company s future capital requirements depend upon many factors, including the effectiveness of its Osteomark® NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for the Company s products, continued scientific progress in research and development programs; the costs involved in filing, prosecuting, enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining regulatory approvals. Because of the Company s near-term cash requirements, it may seek to raise additional capital by sales of equity or debt securities, if conditions in the public equity markets are favorable, or through private placements. There can be no assurance that additional funds will be available on favorable terms, if at all. If additional financing is not available, the Company believes that its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales and interest income from short-term investments will be adequate to fund operations through the first quarter of 2003. If funding is insufficient at any time in the future, the Company may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to develop on its own.

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

2. Earnings Per Share

As presented, basic and diluted loss per share are equal since common equivalent shares are excluded from the calculation of diluted earnings per share because their effects are antidilutive to the Company s net losses. The calculation of dilutive shares excludes approximately 2,806,000 and 3,025,000 of stock options outstanding as of June 30, 2002 and June 30, 2001, respectively, because of their antidilutive effect.

3. Revenue Recognition

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

4. Concentration of Credit Risk

Trade receivables potentially subject the Company to credit risk. The Company extends credit to its customers based upon an evaluation of the customer s financial condition and credit history and generally does not require collateral. The Company historically has incurred minimal credit losses. For the three-month period ended June 30, 2002, domestic product sales accounted for 72% of total revenue and product sales to foreign countries accounted for 28% of total revenue. For the six-month period ended June 30, 2002, domestic product sales accounted for 66% of total revenue and product sales to foreign countries accounted for 34% of total revenue.

5. Inventory

Inventory consists principally of raw materials. 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. All of the Company s finished goods inventory has a certain shelf life and the Company may write down those items in inventory approaching expiration.

The components of inventory are:

Raw materials	$	943,000
Work in process	$	499,000
Finished goods	$	101,000
Total inventory	$	1,543,000

6. Comprehensive Income

The components of comprehensive income for the three-month and six-month periods ended June 30, 2002 and June 30, 2001, are as follows:

		QTD June 30, 2002		QTD June 30, 2001		YTD June 30, 2002		YTD June 30, 2001
Net Loss	$	(582,000)	$	(501,000)	$	(1,875,000)	$	(1,359,000)
Unrealized gain/loss on short-term investments		(4,000)		7,000		(4,000)		49,000
Total comprehensive loss	$	(586,000)	$	(494,000)	$	(1,879,000)	$	(1,310,000)

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

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

8. Other Assets

Other assets primarily represent a $599,000 investment in the preferred stock of Metrika, Inc. (Metrika). The investment is recorded in the accompanying financial statements at cost and represents an ownership interest of less than 2%. The Company periodically assesses the valuation of this asset based on historical financial data, assumed valuations of Metrika, relevant liquidation preferences made during additional investment rounds, future projections, and Metrika s performance. The value of Metrika may also fluctuate with general changes in the U.S. equity markets. Management has considered recent market volatility and continues to believe that the investment is not impaired. However, given the nature of the business, there is a risk that the investment may become impaired in the future as a result of adverse changes in any of the factors noted above.

9. Common Stock Warrants

For the six months ended June 30, 2002, the Company issued warrants to two outside consultants for the purchase of 23,000 shares of common stock, with exercise prices ranging from $1.56 - $2.53, in exchange for services to be provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. These warrants were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that the transaction did not involve a public offering. Total expense recognized in 2002 for these warrants was $27,000.

10. Mochida License Agreement

On March 5, 2002, the Company announced that it had entered into a Serum License Agreement with its Japanese partner, Mochida Pharmaceutical Co. Ltd. (Mochida), under which the Company will sell the Osteomark NTx Serum test, in the microtiter format, exclusively to Mochida for distribution in Japan. Under the terms of the agreement, Mochida will pay the Company $750,000, less a 10% withholding tax, $500,000 of which was paid upfront as a nonrefundable license fee and $250,000 of which is to be paid within thirty days of receipt of the official announcement of the Japanese reimbursement price from the Ministry of Health, Labor and Welfare. Mochida received the official announcement of the Japanese reimbursement price in July 2002 and has advised the Company that it will remit the $250,000 milestone payment in August 2002. The Company will record revenue under the Serum License Agreement as earned ratably over the nine-year license period. Deferred revenue related to this agreement was $431,000 at June 30, 2002. Mochida will be purchasing finished Osteomark NTx Serum kits manufactured by the Company at its production facility in Seattle, Washington.

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

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

Although the Company believes the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, product demand, performance or achievements. You should not place undue reliance on the Company s forward-looking statements, which apply only as of the date of this report.

Overview

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

Osteoporosis is a significant health problem. Recently, the National Osteoporosis Foundation (the NOF) issued an update to its first prevalence report published in 1997 entitled America s Bone Health: The State of Osteoporosis and Low Bone Mass in our Nation. Based on 2000 Census data, the disease statistics indicate that 44 million U.S. women and men aged 50 and older have or are at high risk for developing osteoporosis due to low bone mass. Of these 44 million, over 10 million people, approximately 80 percent of them women, already have

osteoporosis and an estimated 34 million have low bone mass density. By the year 2010, it is estimated that over 52 million American women and men in this same age category will be affected and, if current trends continue, the figure will climb to over 61 million by 2020. Additionally, millions of people are at risk of skeletal degradation associated with Paget s disease of bone, cancer that metastasizes to bone, hyperparathyroidism (overactivity of the parathyroid gland characterized by a reduction of bone mass) and renal osteodystrophy. Despite the serious human and economic consequences of these diseases (according to the NOF, the national direct expenditures for osteoporotic and associated fractures was $17 billion in 2001), medical intervention usually commences only after pain, immobility, fractures, or other symptoms have appeared. The Company expects the osteoporosis therapeutic market will continue to grow as the population ages.

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

The Osteomark test is a non-invasive test that quantitatively indicates the level of bone resorption. Individuals who are losing bone collagen at accelerated rates may progress to low bone mass, a major cause of osteoporosis. Identification of high levels of bone resorption provides the opportunity to predict skeletal response (bone mineral density) to hormonal antiresorptive therapy, such as Wyeth s Premarin®, in postmenopausal women, which is intended for the prevention and treatment of osteoporosis. In addition, the Company s Osteomark test can aid clinicians in monitoring in postmenopausal women and those diagnosed with osteoporosis the effects of antiresorptive therapies, such as Merck & Co., Inc. s Fosamax®, Eli Lilly and Company s Evista®, and Procter & Gamble Pharmaceuticals, Inc. s and Aventis Pharmaceuticals, Inc. s Actonel®, in a matter of three months versus one to two years with conventional technology.

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

The Company s first Osteomark test became commercially available in May 1995 as a urinary test that provides a quantitative measure of the excretion of cross-linked N-telopeptides of Type I collagen (NTx) as an indicator of human bone resorption. In July 1996, the Company received expanded claims for the 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 microtiter tests claims were further expanded by allowing that an Osteomark test measurement can identify the probability for a decrease in bone mineral density in postmenopausal women taking calcium supplements relative to those treated with hormonal antiresorptive therapy.

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

The Osteomark NTx Point-of-Care device (the NTx Point-of-Care) became commercially available in October 1999 for use in the physician s office. The Company and Metrika, Inc. (Metrika) developed a physician s office Point-of-Care Osteomark test device which is a fully disposable point-of-care NTx test for urine as an indicator of bone resorption that computes an NTx value and displays it digitally. In May 2000, the

Company announced it had acquired the exclusive right from Metrika to manufacture the Osteomark NTx Point-of-Care device, as well as the exclusive worldwide license to manufacture, market and sell this device for the measurement

of other connective tissue markers, including those associated with osteoarthritis. Under the agreement, Metrika receives a royalty based on the sales of the NTx Point-of-Care device. In August 2001, the Company received Rx Home-Use clearance and CLIA Waiver status for its NTx Point-of-Care device from the FDA. This allows the device to be used in essentially all physician offices, and physicians can write a prescription for the device so that patients will be able to purchase it at the pharmacy and use it in their own homes under the direction of their physicians.

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

The Company began working with Procter & Gamble in 2000 to launch a test program in Germany to use the NTx Point-of-Care device with Actonel, Procter & Gamble s osteoporosis drug for the management of osteoporosis. This program initially was expanded by Procter & Gamble and its partner, Aventis Pharmaceuticals, and tested in a number of countries. Because of delays encountered with the start-up of the Company s manufacturing facility, the Company was unable to deliver NTx Point-of-Care devices to Procter & Gamble and Aventis during most of the first half of 2002. As a result, Procter & Gamble and Aventis cancelled a portion of their NTx Point-of-Care back orders or switched to the Osteomark NTx Urine test in the microtiter plate format. The Company validated its manufacturing process late in the second quarter of 2002 and has shipped NTx Point-of-Care devices to Aventis. The Company has maintained a continuing dialogue with Procter & Gamble and Aventis and is working to rebuild their confidence in the Company s manufacturing capabilities. The Company is also working to expand sources of demand for its products.

The Company and Mochida Pharmaceutical Co., Ltd. (Mochida), a Japanese pharmaceutical company, entered into a research and development agreement and a license agreement in 1992 for the commercialization of the Osteomark NTx Urine test in Japan. Under the license agreement, the Company granted Mochida exclusive marketing and distribution rights to certain products in Japan. In January 1998, Mochida launched the Osteomark test in Japan for the management of patients with hyperparathyroidism and for patients with metastatic bone tumors. In December 1999, Mochida received an additional regulatory indication from the Japanese Ministry of Health, Labor and Welfare for the Osteomark test for selecting suitable drugs for the treatment of osteoporosis and monitoring efficacy of drug therapy for osteoporosis. In March 2002, Mochida exercised its option to license the serum test in Japan and paid the Company $500,000 for the license. There is one milestone payment of $250,000 left under the serum license agreement. That milestone was achieved in July 2002 when Mochida received the official announcement of the Japanese reimbursement price from the Ministry of Health, Labor and Welfare. Mochida has advised the Company that it will remit the $250,000 milestone payment in August 2002.

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

The Company has technology for measuring Type II and Type III collagen degradation. Type II collagen is a primary constituent of joint cartilage. Osteoarthritis, a degenerative disease of joint cartilage, affects over 20 million people in the United States alone. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. Further development of the Company s Type II collagen degradation test will be needed to allow reliable monitoring of joint cartilage changes, for validating the effectiveness of drugs under development and for identifying patients with early-stage disease. Similar to the Osteomark NTx test used in connection with osteoporosis, the Company believes

that the Type II collagen degradation test will aid in the clinical management of osteoarthritis patients. Type III collagen is a significant constituent of blood vessels such as coronary arteries. Measuring degradation of this type of collagen may be useful in identifying cardiovascular disease. The Company has no

immediate plans to commercialize tests for Type II or Type III collagen degradation, but has patents in these areas if it decides to commercialize tests for Type II and III in the future.

The Company also has technology to enhance artificial joint recovery. The Company is the exclusive licensee of U.S. Patent No. 6,190,412, directed to prosthetic devices having hydroxyapatite-coated bone attachment surfaces to which tartrate-resistant acid phosphatase (TRAP) is absorbed. Research supported by the Company established that the human TRAP enzyme has a direct role as a local factor in the recruitment of osteoclasts from hematopoietic cells. Also that recombinantly produced TRAP absorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. The Company may seek collaborations to confirm whether or not such TRAP-induced stimulation of osteoclast recruitment results in osteointegration and enhanced bonding of the graft or prosthesis to the patient s bone.

OSTEOMARK and OSTEX are registered United States trademarks of the Company. The Company has also registered its OSTEOMARK trademark in 46 other countries. The Company s collagen breakdown test technology is covered by 36 U.S. patents, 3 European patents, 6 Japanese patents, and patents in Australia, Canada, Ireland, Korea, Russia, Spain, Norway, Hong Kong, and Singapore. Two of the European patents are in opposition proceedings. Additional patent applications are pending. The Company s patents are variously directed to Type I collagen breakdown products, including NTx, CTx, and deoxypyridinoline, as well as related breakdown products of Type II and Type III collagen. The Company s Type I collagen patents will begin to expire in late 2007 for the US and in 2010 for Europe and Japan. The Company is the exclusive worldwide licensee of Metrika s patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013.

Results of Operations for the Three months Ended June 30, 2002 and June 30, 2001

Total revenues were $1,572,000 for the quarter ended June 30, 2002, compared to $1,492,000 for the quarter ended June 30, 2001. The increase in revenues was primarily due to higher sales of the Company s NTx serum kits which was, in part, due to the fulfillment of backorders from the first quarter of 2002.

The Company recorded a net loss of $582,000 ($0.05 per share) for the quarter ended June 30, 2002 compared to a net loss of $501,000 ($0.04 per share) for the quarter ended June 30, 2001. The increase in loss was due to lower margins in 2002 and lower interest income on smaller balances of cash and short-term investments. The Company completed the validation of the Point-of-Care manufacturing process late in the second quarter of 2002 and does not anticipate further significant start-up costs in connection with that manufacturing facility.

Total cost of products sold was $726,000 for the quarter ended June 30, 2002, compared to $590,000 for the quarter ended June 30, 2001. The increase in 2002 over 2001 was primarily related to manufacturing time and effort utilized to resolve the difficulties in manufacturing the serum kit product and the ensuing scrapped material cost which is expensed through cost of product sold. Cost of products sold for the NTx Point-of-Care device in 2002 include production expenses associated with the Company s Point-of-Care manufacturing facility as opposed to the price paid to Metrika for the devices in cost of products sold for 2001.

The Company s research and development expenditures totaled $408,000 for the quarter ended June 30, 2002, compared to $427,000 for the quarter ended June 30, 2001 due to slightly lower personnel-related expenditures. Selling, general and administrative expenses totaled $839,000 for the quarter ended June 30, 2002, compared to $858,000 for the quarter ended June 30, 2001.

Net interest expense totaled $43,000 for the quarter ended June 30, 2002, compared to net interest income of $52,000 for the quarter ended June 30, 2001. In 2002, the Company earned lower interest income due to lower balances of cash and short-term investments as compared with the same period in 2001.

Results of Operations for the Six months Ended June 30, 2002 and June 30, 2001

Total revenues were $2,495,000 for the six-month period ended June 30, 2002, compared to $3,021,000 for the six-month period ended June 30, 2001. The $526,000 decrease was primarily the result of manufacturing delays in the first quarter of 2002 related to the NTx Point-of-Care device and lower NTx urine kit sales in 2002 as compared to the same period for 2001.

For the six months ended June 30, 2002, the Company recorded a net loss of $1,875,000 ($0.15 per share) relative to a net loss of $1,359,000 ($0.11 per share) for the corresponding period last year. Expenses associated with the start-up of the Company s Point-of-Care manufacturing facility contributed $319,000 to the year-to-date increase in loss. The Company completed the validation of the Point-of-Care manufacturing process late in the second quarter and does not anticipate further significant start-up costs in connection with that manufacturing facility.

Total cost of products sold were $1,019,000 for the six-month period ended June 30, 2002, compared to $1,204,000 for the six-month period ended June 30, 2001. The $185,000 decrease was primarily the result of lower sales volume in the first quarter of 2002. The Company s Point-of-Care manufacturing facility was validated to produce a high volume of devices. This production capacity may exceed the production plan for devices in the near-term future. If this were to occur, the resulting excess capacity may have a negative impact to the Company s gross profit margins until demand increases.

The Company s research and development expenditures totaled $871,000 for the six-month period ended June 30, 2002, compared to $996,000 for the six-month period ended June 30, 2001. The $125,000 decrease was due to slightly lower personnel and consulting related expenses. Selling, general and administrative expenses totaled $1,838,000 for the six-month period ended June 30, 2002, compared to $2,040,000 for the six-month period ended June 30, 2001. The $202,000 decrease resulted from lower sales and marketing related expenditures.

Net interest expense totaled $73,000 for the six-month period ended June 30, 2002, compared to net interest income of $110,000 for the six-month period ended June 30, 2001. In 2002, the Company earned lower interest income due to lower balances of cash and short-term investments as compared to the same period in 2001.

Liquidity and Capital Resources

As of June 30, 2002, the Company had cash and cash equivalents and short-term investments of $1,409,000, working capital of $2,507,000 and total shareholders equity of $5,097,000. As a result of funding operating losses during the six months ended June 30, 2002, cash, cash equivalents and short-term investments decreased by $2,418,000, accounts receivable, inventory and other current assets increased by $1,146,000, working capital decreased by $1,597,000 and shareholders equity decreased by $1,835,000. During the six-month period ended June 30, 2002, the Company purchased $162,000 of manufacturing and office equipment, and reduced notes payable by $288,000.

The Company s future capital requirements depend upon many factors, including the effectiveness of its Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; market demand for the Company s products; continued scientific progress in research and development programs; the costs involved in filing, prosecuting, enforcing and defending patent claims; the manufacturing needs for new and existing products; relationships with existing and future corporate collaborators; and the time and costs involved in obtaining

regulatory approvals. Because of the Company s near-term cash requirements, it may seek to raise additional capital by sales of equity or debt securities, if conditions in the public equity markets are favorable, or through private placements. There can be no assurance that additional funds will be available on favorable terms, if at all. If additional financing is not available, the Company believes that its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales and interest income from short-term investments will be adequate to fund operations through the first quarter of 2003. If funding is insufficient at any time in the future, the Company may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to develop on its own. The Company s financial statements are

presented on a going concern basis and assume that assets will be realized in the normal course of business. See discussion under Need for Additional Capital below.

Critical Accounting Policies

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

ADDITIONAL FACTORS THAT MAY AFFECT RESULTS

History of Losses and Limited Operating History

The Company has not been profitable for any year since its formation in 1989. The Company has a limited operating history and had an accumulated deficit through June 30, 2002 of $40,784,000. The Company expects to incur additional costs as it continues with its existing operations, marketing and sales efforts for its products, and research and development activities. The Company s lead product, the Osteomark NTx test, became commercially available in May 1995 in the U.S., but sales to date have not been significant enough to generate net income. The Company s ability to achieve long-term profitability is dependent upon successfully manufacturing, marketing, and commercializing existing products. The Company expects to continue to incur additional losses in the near-term future and the Company is unable to predict when, if ever, it will achieve profitability.

Need for Additional Capital; Uncertainty of Sources of Capital

The Company may require additional funds to sustain, expand or enhance its sales and marketing activities and continue product development. The Company s future capital requirements will depend on numerous factors, including:

the continued progress and costs of its research and development programs;

the costs of developing and expanding its manufacturing operations,

the costs of developing and expanding its marketing and sales operations;

the timing and amount of milestone payments received from strategic partners;

market demand for its products;

the time and costs involved in obtaining regulatory approvals;

relationships with existing and future corporate collaborators, if any;

the emergence of competing technologies and adverse market developments; and

the costs of filing, prosecuting, defending and enforcing patent claims.

As of June 30, 2002, the Company had cash and cash equivalents of $1,409,000. The Company estimates that, at its planned rate of spending, its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales, and interest income from short-term investments will be sufficient to meet its capital requirements through the first quarter of 2003. There can be no assurance that the underlying assumed levels of revenue and expense will prove accurate. Whether or not these assumptions prove to be accurate, the Company may need to raise additional capital. The Company may be required to seek additional funding through public or private financing, including equity financing, or through collaborative arrangements.

Adequate funds for these purposes, whether obtained through financial markets or from collaborative or other arrangements with corporate partners or other sources, may not be available when needed or may not be available on terms favorable to the Company. If issuing equity securities raises additional funds, dilution to existing shareholders will result. In addition, in the event that additional funds are obtained through arrangements with collaborative partners, such arrangements may require the Company to relinquish its rights to certain technologies or products that it would otherwise seek to develop or commercialize on its own. If funding is insufficient at any time in the future, the Company may be required to: delay, scale back or eliminate some or all of its marketing and sales and research and development programs; sell assets; or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to develop on its own. Furthermore, the terms of any such license agreements or asset sales might be less favorable than if the Company were negotiating from a stronger position.

Uncertainty of Market Acceptance and Product Demand

The Company s lead product, the Osteomark NTx test, became commercially available in May 1995 in the U.S., but sales to date have not been significant enough to generate net income. There can be no assurance that the Company s 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 the Company will be able to develop significant market share for its products or maintain or increase its current market share. Because of delays encountered with the start-up of the Company s Point-of-Care manufacturing facility, the Company was unable to deliver NTx Point-of-Care devices to Procter & Gamble and Aventis during most of the first half of 2002. As a result, Procter & Gamble and Aventis cancelled a portion of their NTx Point-of-Care back orders or switched to the Company s Osteomark NTx Urine test in the microtiter plate format. The Company resolved its manufacturing problems late in the second quarter of 2002 and has shipped NTx Point-of-Care devices to Aventis. The Company has maintained a continuing dialogue with Procter & Gamble and Aventis and is working to rebuild their confidence in the Company s manufacturing capabilities. The Company is also working to expand sources of demand for its products. The Company s Point-of-Care manufacturing facility was validated to produce a high volume of devices. This production capacity may exceed the production plan for devices in the near-term future. If this were to occur, the resulting excess capacity may have a negative impact to the Company s margins in future periods. The inability of the Company to increase market acceptance and demand for its products would have a material adverse effect on the Company s business, financial condition and results of operation.

Risk of Loss of Significant Customer

The Company s current operations are dependent upon a relatively small number of customers, which change from time to time. The Company s most significant customers during the first six months of 2002 were Mochida, Quest Diagnostics Incorporated, Covance Central Lab Services, Johnson & Johnson and Fisher Scientific. The customers collectively accounted for approximately 47% of the Company s total sales during that period. The Company 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 the Company s current significant customers will continue to buy products at their current or increased levels. As discussed elsewhere in this report, the Company lost a number of orders from significant customers as a result of manufacturing delays encountered with the start-up of the Company s Point-of-Care manufacturing facility earlier this year. Loss of a significant customer or further reduction of the level of orders from a significant customer would have a material adverse effect on the Company's operating results.

Dependence on Therapeutics Developed by Others

Acceptance of and demand for the Company s products will be affected by physicians perceived needs to diagnose bone resorption for the purposes of prevention, treatment and monitoring. There are currently a limited number of therapies that are effective in preventing, treating and

monitoring osteoporosis or other bone disorders, or in treating these disorders. In the event new therapies do not receive regulatory approval or experience delayed market acceptance, the Company could be adversely affected. Unfavorable publicity concerning a product of the

Company or therapeutic products for osteoporosis could also have an adverse effect on the Company s ability to obtain regulatory approvals or to achieve market acceptance.

Limited Marketing and Distribution Experience

The Company has limited marketing and distribution experience. To market any of its products directly, the Company must develop and implement a substantial marketing and sales effort with technical expertise and supporting distribution capability. The Company intends to continue to market and sell its products in the U.S. through research and clinical laboratories, distributors, 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 the Company will be able to establish effective marketing and distribution capabilities or that its collaborators will be successful in gaining market acceptance for the Company s products or that the Company will achieve or maintain significant market share for its products.

Limited Manufacturing Experience

The Company has, through an agreement with Metrika, developed an adaptation of its core technology for use in physicians offices, called the Osteomark NTx Point-of-Care device. Until year-end 2001, the Company depended upon the efforts of Metrika for the production of the NTx Point-of-Care device. In the second quarter of 2002, the Company itself began manufacturing the NTx Point-of-Care device, but continues to rely on Metrika for supply of certain components. The Company has limited manufacturing experience with a product like the NTx Point-of-Care device. Although the Company believes that its new manufacturing facility is capable of producing commercial-scale quantities of the Osteomark product, if the Company is unable to manufacture the NTx Point-of-Care device and other products in significant quantities in a cost-effective manner, it will not become profitable. Because of delays encountered with the start-up of the Company s Point-of-Care manufacturing facility, the Company was unable to deliver NTx Point-of-Care devices to customers during most of the first half of 2002. The Company resolved its manufacturing problems late in the second quarter of 2002 and has shipped NTx Point-of-Care devices to customers. The Company has maintained a continuing dialogue with its customers and is working to rebuild customer confidence in the Company s manufacturing capabilities. Future interruptions in the manufacturing process could seriously hinder the Company s efforts in this regard and may have a material adverse effect on the Company s results of operations.

Dependence on Licensed Patents and Proprietary Rights

The Company s 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 the Company operates is still evolving and, consequently, patent positions in the Company s industry may not be as strong as in other better-established fields. Accordingly, the United States Patent and Trademark Office (USPTO) and foreign patent offices may not issue patents from the patent applications owned by or licensed to the Company. If issued, the patents may not give the Company an advantage over competitors with similar technology.

The Company is the exclusive licensee of 58 patents in North America, Europe, and Asia. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be given to the Company s 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 USPTO or foreign patent office. It is possible that a competitor may successfully challenge the Company s 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 the Company, third parties may be able to use the Company s patented invention without payment to the Company. Moreover, it is possible that competitors may infringe the Company s patents or successfully avoid them through design innovation. To stop these activities, the Company may need to file a lawsuit. These lawsuits are expensive and would consume time and other resources, even if the Company is successful in stopping the violation of its patent rights. In addition, there is a risk that a court

9. Common Stock Warrants 30

would decide that the Company s patents are not valid and that the Company 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 the Company s patents are upheld, a court would refuse to stop the other party on the ground that its activities do not infringe the Company s patents. Further, once a patent has expired, the technology is no longer protected. The Company s Type I collagen patents will begin to expire in late 2007 for the U.S. and in 2010 for Europe and Japan. The Company is the exclusive worldwide licensee of Metrika s patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and other connective tissue markers. The Metrika patents will begin to expire in 2013.

In addition to the intellectual property rights described above, the Company 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 the Company s technology. The Company may not be able to effectively protect its rights in unpatented technology, trade secrets and confidential information. The Company requires each of its employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with the Company. However, these agreements may not provide effective protection of the Company s information or, in the event of unauthorized use or disclosure, they may not provide adequate remedies.

Potential Conflict with Patent Rights of Others

The Company s competitors or others may have or acquired patent rights that they could enforce against the Company. If they do so, the Company may be required to alter its products, pay licensing fees or cease activities. If the Company s products conflict with patent rights of others, third parties could bring legal actions against the Company 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, the Company could be required to obtain a license in order to continue to manufacture or market the affected products. The Company 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 (Osteometer) and its licensee Roche Diagnostics GmbH sent the Company two notification letters concerning Osteometer s European Patent No. 0742902 which issued November 21, 2001. The patent claims synthetic NTx peptides in assays for bone resorption. The Company believes that its Osteomark products do not infringe upon the Osteometer patent and that the patent is invalid in light of prior art that was not taken into consideration by the issuing European Patent Office. In January 2002, the Company filed an action in the Court of Monza, Italy, seeking a pan-European declaration of noninfringement. Said action included a request to stay any such noninfringement determination pending the outcome of an opposition proceeding that the Company intends to initiate in the European Patent Office against this patent.

Significant Costs of Litigation Relating to Intellectual Property

The cost to the Company of any litigation or other proceedings relating to intellectual property rights, even if resolved in the Company s favor, could be substantial. Some of the Company s competitors may be better able to sustain the costs of complex patent litigation because they have substantially greater resources. If there is litigation against the Company, the Company may not be able to continue its operations. If third parties file patent applications, or are issued patents claiming technology also claimed by the Company in pending applications, the Company may be required to participate in interference proceedings in the USPTO, or opposition proceedings abroad, to determine priority of invention. The Company may be required to participate in interference proceedings involving its issued patents and pending applications. The Company 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. A prevailing party in that case may not offer the Company a license on commercially acceptable terms.

Lengthy Regulatory Processes and Uncertainty of Regulatory Approvals

The manufacture and marketing and sales of the Company s 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 the Company. Significant difficulties or costs may be encountered by the Company in its efforts to obtain approvals that could delay or preclude the Company from marketing and selling its products. The FDA may request the development of additional data following original submissions, causing the Company 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 the Company s products outside the United States can vary widely from country to country. Foreign approvals may take longer than FDA approvals and can involve additional testing. Foreign regulatory approval processes include all of the risks associated with the FDA approval processes. Also, approval of a product by the FDA does not ensure approval of the same product by health authorities of other countries.

Extensive Continuing Government Regulation

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

Intense Competitive Environment

Competition from biotechnology companies, diagnostic companies, pharmaceutical companies, and research and academic institutions is intense and is based on price as well as product performance. The Company s main competitors are Osteometer Biotech A/S (aka Nordic Bioscience A/S) (Osteometer) and Quidel Corporation (Quidel) and licensees and distributors of their technologies and products. A number of diagnostic tests and procedures, and other non-invasive tests for osteoporosis and other bone disorders currently exist and others are in development, and the manufacturers of these tests will continue to improve them. In addition, the diagnostic industry is subject to rapid technological change. The Company s competitors may succeed in developing products which are more effective or less expensive than those that have been or are being developed by the Company or which would render the Company s core technology obsolete, uneconomical or non-competitive. Many of the Company s competitors have, or have access to substantially greater financial, technical and human resources than the Company. In addition, many of these competitors have significantly greater experience and resources than the Company in undertaking clinical trials and other regulatory approval procedures, as well as in marketing and 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.

Dependence on Core Technology; Uncertainty of Adaptation to Different Formats

The Company currently relies exclusively upon its core technology for the development of products associated with osteoporosis and other collagen-related diseases. The Company s Type I collagen patents will begin to expire in late 2007 for the U.S. and in 2010 for Europe and Japan. The Company is the exclusive worldwide licensee of Metrika s patents relating to point-of-care devices and subcomponents thereof for the measurement of NTx and

other connective tissue markers. The Metrika patents will begin to expire in 2013. There can be no assurance that competitors of the Company will not be successful in developing new or more efficient or cost effective tests or diagnostics that are more readily accepted than the Company s products. The Company 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 the Company 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. The Company may not be successful in adapting and further developing its core technology to meet such needs. In addition, technological changes or medical advancements could diminish or eliminate the commercial viability of the Osteomark tests or future products based upon the Company s core technology. The failure to adapt the Company s core technology to different or more cost effective formats, instruments, and other delivery platforms, or otherwise to commercialize such core technology, would have a material adverse effect on the Company s business, financial condition, and results of operation.

Reliance on Collaborative Agreements and Certain Relationships

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

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

The testing, manufacturing, marketing and sale of the Company s products may subject the Company to product liability claims. The Company 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. The Company may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regardless of merit or eventual outcome, product liability claims may result in decreased demand for a product, injury to its reputation, withdrawal of clinical trial volunteers and loss of revenues. As a result, regardless of whether the Company is insured, a product liability claim or product recall may result in losses that could be material.

Limited Suppliers

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

with product supply. Interruptions in the availability of products could have a material adverse effect on the Company s results of operations.

Uncertainty of Healthcare Reimbursement

The Company s ability to commercialize its products will depend in part on the extent to which reimbursement for the cost of such products and related treatment will be available from third-party payors, such as government health administration authorities, private health coverage insurers and other organizations. The status of the scope of healthcare programs worldwide is uncertain and there can be no assurance that adequate third-party coverage will be available for the Company to maintain price levels sufficient for realization of an appropriate return on its investment in product development. Third-party payors are increasingly challenging the price and cost effectiveness of medical products and services. There can be no assurance that the Company s existing or any future products will provide sufficient value or be considered cost effective and that reimbursement to the consumer will be available or sufficient to allow the Company to sell its products on a competitive basis. 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. Even though Osteomark NTx Serum received FDA approval in 1999, because negotiated rulemaking decision was based on clinical studies with urine tests, it was determined to be inappropriate to include additional tests that were not subject to negotiation in this final rule. 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 therapy.

Volatility of Stock Price

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

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

Nasdaq Listing and Liquidity of Common Stock

The Company s common stock is currently listed on the Nasdaq National Market. To maintain such listing, the Company must continue to satisfy ongoing listing requirements, including maintaining certain equity standards. In June 2001, the SEC approved the change from a minimum of $4,000,000 net tangible assets requirement for continued listing on the Nasdaq National Market to a minimum $10,000,000 stockholders equity requirement. The Company currently does not qualify under the minimum $10,000,000 stockholder s equity requirement. If the Company does not satisfy the new stockholders equity requirement by November 1, 2002, or if it otherwise fails to meet Nasdaq s ongoing listing criteria at any time, Nasdaq could initiate delisting procedures. If Nasdaq moves to delist the Company s common stock securities, the Company could spend material financial and management resources in an attempt to avoid delisting, which could cause its business to suffer. If the Company s common stock is subsequently delisted, the Company would likely seek listing of its common stock on the Nasdaq SmallCap Market or AMEX or, failing that, on the over-the-counter Electronic Bulletin Board. These are less liquid marketplaces than the Nasdaq National Market. Accordingly, a delisting of the Company s common stock could adversely affect the liquidity and trading prices of its

securities. Loss of Nasdaq National Market status could also make it more difficult for the Company to raise capital or complete acquisitions and would also complicate compliance with state blue sky laws.

Change of Control Provisions in Articles of incorporation and Washington State Law

The Company s articles of incorporation authorize the board of directors to issue up to 10,000,000 shares of preferred stock and to determine the price, rights, preference, privileges and restrictions, including voting rights, of those shares without any further vote or action by its shareholders. The issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control of the Company, even if this change would benefit the Company s shareholders. In addition, the issuance of preferred stock may adversely affect the market price of the Company s common stock and the voting and other rights of the holders of the Company s common stock.

The Company has adopted a shareholders rights plan, which is intended to protect the rights of shareholders by deterring coercive or unfair takeover tactics. The board of directors declared a dividend to holders of the Company s common stock of one preferred share purchase right for each outstanding share of the common stock. The right is exercisable ten days following the offer to purchase or acquisition of beneficial ownership of 20% of the outstanding common stock by a person or group of affiliated persons. Each right entitles the registered holder, other than the acquiring person or group, to purchase from the Company one-hundredth of one share of Series A Junior Participating Preferred Stock at the price of $38, subject to adjustment. The rights expire January 27, 2007. In lieu of exercising the right by purchasing one one-hundredth of one share of Series A Preferred Stock, the holder of the right, other than the acquiring person or group, may purchase for $38 that number of shares of the Company s common stock having a market value of twice that price.

Washington law imposes restrictions on certain transactions between a corporation and significant shareholders. Chapter 23B.19 of the Washington Business Corporation Act prohibits a target corporation, with some exceptions, from engaging in particular significant business transactions with an acquiring person, which is defined as a person or group of persons that beneficially owns 10% or more of the voting securities of the target corporation, for a period of five years after the acquisition, unless the transaction or acquisition of shares is approved by a majority of the members of the target corporation s board of directors prior to the acquisition. Prohibited transactions include, among other things:

a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from the acquiring person;

termination of 5% or more of the employees of the target corporation; or

receipt by the acquiring person of any disproportionate benefit as a shareholder.

A corporation may not opt out of this statute. This provision may have the effect of delaying, deterring or preventing a change in control of the Company or limiting future investment in the Company by significant shareholders.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. The Company s exposure to market rate risk, as a result of changes in interest rates, relates primarily to the Company s investment portfolio. At June 30, 2002, the Company held $476,000 in cash and cash equivalents and $933,000 in Federal and Government agency obligations, and corporate and municipal bonds. Although the Company holds both fixed and adjustable rate investments and each carry a certain degree of interest rate risk, the Company

does not consider this risk to be material to the accompanying financial statements.

Currency risk. The Company conducts all financial transactions in U.S. currency. However, currency fluctuations may impact a foreign customer s ability to meet its payment obligations and/or future product pricing to that customer. Based upon the Company s credit authorization policy, current economic conditions in countries in which the

Company does significant business, and the level of outstanding foreign receivables, the Company does not consider this risk to be material to the accompanying financial statements.

PART II OTHER INFORMATION

Item 2. Changes in Securities

For the six month period ended June 30, 2002, the Company issued warrants to two outside consultants for the purchase of 23,000 shares of common stock, with exercise prices ranging from $1.56 - $2.53, in exchange for services provided to the Company. The warrants vest upon issuance and expire in two years from the date of grant. Total expense recognized in 2002 for these warrants was $27,000. These warrants were exempt from registration under the Securities Act pursuant to Section 4(2) of the Securities Act on the basis that the transaction did not involve a public offering.

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

On May 22, 2002 the Company held its 2001 Annual Meeting of Shareholders (the Annual Meeting), at which the following members were elected to the Board of Directors:

	Affirmative Votes	Votes Withheld
Thomas J. Cable	11,713,697	586,195
John H. Trimmer	11,714,344	585,548

The following members continued their terms on the Board of Directors:

Thomas A. Bologna

Elisabeth L. Evans, M.D.

David R. Eyre, Ph.D.

Fredric J. Feldman, Ph.D.

The following proposals were also approved at the Annual Meeting:

	Affirmative Votes	Votes Against	Votes Abstained
To approve an increase in the number of shares authorized under the Company s 1994 Stock Option to 3,750,000	5,372,113	2,211,911	117,166
Ratification of Arthur Andersen LLP as the Company s independent auditors for the fiscal year ending December 31, 2002	10,087,913	2,056,797	155,182

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits (see note 1)

EXHIBIT INDEX

Exhibit Number	Description	Notes
3.1	Articles of Incorporation, as amended, dated January 1997	(2)
3.2	Bylaws, as amended	(3)
4.1	Specimen Common Stock Certificate	(3)
10.1A	Amended and Restated Stock Option Plan*	(3)
10.1B	Amended and Restated 1994 Stock Option Plan*	(4)
10.1C	Amended and Restated Directors Nonqualified Stock Option Plan*	(5)
10.5	Form of Indemnification Agreement with officers and directors*	(3)
10.7	Agreement with Thomas A. Bologna Executive Employment Agreement dated July 16, 1997*	(6)
	Agreements with Mochida Pharmaceutical Co., Ltd.	
10.12A	Research and Development Agreement dated August 1992	(3)
10.12B	Osteomark License Agreement Dated August 1992	(3)
10.12D	Second Amendment to Osteomark License Agreement dated December 24, 1997	(7)
10.12E	Mochida 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)
	Agreements with the University of Washington	
10.15A	Research Agreement dated July 1, 1996 (Molecular Markers of Connective Tissue Degradation)	(7)(8)
10.15B	Research Agreement dated October 1, 1996 (Role of O-CSF in OsteoclastRegulation)	(7)(8)
10.16A	Know-How Transfer and Consulting Agreement dated September 18, 1989 with David R. Eyre, Ph.D.*	(3)
10.16B	Extension and Amendment dated May 1, 1992*	(3)
	Lease Agreements	

10.27A	Lease Agreement dated October 2, 1995, with David A. Sabey and Sandra L. Sabey First Amendment of Lease dated October 15, 1996, with the City of Seattle,	(9)
10.27B	successor-in-interest to David A. Sabey and Sandra L. Sabey	(2)
	Agreements with Johnson & Johnson Clinical Diagnostics, Inc.	
10.28A	Distribution Agreement dated June 7, 1995	(10)
10.28B	Research, Development, License and Supply Agreement dated June 7, 1995	(10)

10.29	Clinical Laboratory Services License and Supply Agreement dated October 25, 1995, with SmithKline Beecham Clinical Laboratories, Inc.	(9)
10.35	Shareholder Rights Agreement dated January 21, 1997	(11)
10.37	Metrika Manufacturing and License Agreement dated March 10, 2000	(12)
10.38	Transamerica Business Credit Corporation Master Loan and Security Agreement dated October 23, 2000	(13)
99.1	Certification of Periodic Report by CEO	(15)
99.2	Certification of Periodic Report by CFO	(15)

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

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

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

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

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

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

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

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

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

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

(b) Reports on Form 8-K

On May 30, 2002 the Company filed with the SEC on Form 8-K reporting the dismissal of Arthur Andersen LLP as its independent auditors on May 22, 2002. The Company also reported the engagement of KPMG LLP as it independent auditors for the fiscal year ended December 31, 2002.

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: August 14, 2002 By /S/ Thomas A. Bologna
Thomas A. Bologna
Chairman, President and Chief Executive Officer

DATED: August 14, 2002 By /s/ Hans van Houte
Hans van Houte
Vice President, Finance
(Principal financial and accounting officer)