

OSTEK INTERNATIONAL INC /WA/
Form 10-Q
May 14, 2001

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2001

-- or --

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

For the transition period from _____ to _____

0-25250

Commission File Number

OSTEK INTERNATIONAL, INC.

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

No

The number of shares of the Registrant's common stock outstanding as of May 2, 2001 was 12,473,347.

OSTEX INTERNATIONAL, INC.

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OSTEX INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

March 31, December 31,
2001 2000

(Unaudited)

ASSETS

Current Assets:

Cash and cash equivalents	\$536,000	\$1,348,000
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Short-term investments	5,130,000	5,230,000
Receivables, net of allowance	1,224,000	1,072,000
Inventory, at cost	526,000	465,000
Other current assets	209,000	122,000
	<hr/>	<hr/>
Total Current Assets	7,625,000	8,237,000
	<hr/>	<hr/>
Property, Plant and Equipment, net	3,651,000	3,413,000
Other Assets	658,000	661,000
	<hr/>	<hr/>
Total Assets	\$11,934,000	\$12,311,000
	<hr/>	<hr/>

LIABILITIES AND SHAREHOLDERS' EQUITY

Current Liabilities:

Accounts payable	\$436,000	\$988,000
Accrued liabilities	664,000	364,000
Current portion of notes payable	481,000	285,000
	<hr/>	<hr/>
Total Current Liabilities	1,581,000	1,637,000
	<hr/>	<hr/>

Noncurrent Liabilities

Notes payable, net of current portion	1,277,000	768,000
	<hr/>	<hr/>

Shareholders' Equity:

Common stock, \$.01 par value, 50,000,000 authorized; 12,473,347 and 12,487,047 issued and outstanding at March 31, 2001 and December 31, 2000 respectively	125,000	125,000
Additional paid-in capital	45,636,000	45,651,000
Accumulated items of comprehensive loss	(18,000)	(60,000)
Accumulated deficit	(36,667,000)	(35,810,000)
	<hr/>	<hr/>
Total Shareholders' Equity	9,076,000	9,906,000
	<hr/>	<hr/>

Total Liabilities and Shareholders' Equity	\$11,934,000	\$12,311,000
	<hr/>	<hr/>

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

OSTEK INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Quarter Ended	
	March 31, 2001	March 31, 2000
	<hr/>	<hr/>
Revenues	\$1,529,000	\$887,000

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Cost of products sold	614,000	78,000
Gross Profit	915,000	809,000
Operating Expenses:		
Research and development	569,000	374,000
Selling, general and administrative	1,262,000	1,137,000
Total operating expenses	1,831,000	1,511,000
Loss from operations	(916,000)	(702,000)
Other Income, net	58,000	90,000
Net loss	\$(858,000)	\$(612,000)
Basic and diluted net loss per common share	\$(0.07)	\$(0.05)
Weighted average shares used in calculation of net loss per share	12,485,000	12,472,000

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

OSTECH INTERNATIONAL, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

	Quarter Ended	
	March 31, 2001	March 31, 2000
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net Loss	\$(858,000)	\$(612,000)
Adjustments to reconcile net loss to net cash used in operating activities -		
Depreciation and amortization	123,000	126,000
Expense from issuance of warrants	4,000	22,000
Loss on disposal of property, plant & equipment	1,000	27,000
(Increase) decrease in receivables	(152,000)	445,000
Increase in inventory	(61,000)	(433,000)
Increase in other current assets	(84,000)	(96,000)
Decrease in accounts payable	(552,000)	(31,000)
Increase in accrued expenses	300,000	61,000
Net cash used in operating activities	\$(1,279,000)	\$(491,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of short-term investments	(507,000)	(2,057,000)
Proceeds from sales and maturities of short-term investments	649,000	2,666,000
Purchases of property, plant and equipment	(361,000)	(40,000)

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Net cash (used in) provided by investing activities	(219,000)	569,000
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from the exercise of stock options	-	26,000
Repurchase of common stock	(19,000)	-
Proceeds from notes payable	831,000	-
Payments on notes payable	(126,000)	(57,000)
Net cash provided by (used in) financing activities	686,000	(31,000)
NET (DECREASE) INCREASE IN CASH AND EQUIVALENTS	(812,000)	47,000
CASH AND CASH EQUIVALENTS, beginning of period	1,348,000	1,562,000
CASH AND CASH EQUIVALENTS, end of period	\$536,000	\$1,609,000
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for interest	\$32,000	\$3,000

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 generally accepted accounting principles 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 generally accepted accounting principles 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, 2000.

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 2,931,000 and 2,123,000 of options outstanding as of March 31, 2001 and March 31, 2000, respectively, because of their antidilutive effect.

3. Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income", which was effective for the Company beginning January 1, 1998, establishes standards for reporting and disclosure of comprehensive income. The components of comprehensive income for the three months ended March 31, 2001 and March 31, 2000, are as follows:

March 31,	March 31,
2001	2000

Net Loss	\$(858,000)	\$(612,000)
Unrealized gain (loss) on short-term investments	42,000	(8,000)
Total comprehensive loss	\$(816,000)	\$(620,000)

4. Property, Plant And Equipment

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

	March 31, 2001	December 31, 2000
Leasehold improvements	\$4,047,000	\$2,405,000
Laboratory and manufacturing equipment	1,431,000	1,431,000
Computers and office equipment	1,137,000	1,037,000
Construction-in-progress	501,000	1,898,000
	7,116,000	6,771,000
Accumulated depreciation and amortization	(3,465,000)	(3,358,000)
Net property, plant and equipment	\$3,651,000	\$3,413,000

5. Notes Payable

On October 2, 2000, the Company and Transamerica Business Credit Corporation ("Transamerica") signed a letter of commitment whereby Transamerica will provide up to \$2.8 million in debt financing for the Company's manufacturing expansion plan. Each draw down is on a separate note, secured by real property and equipment, payable in 36 equal monthly installments with a balloon payment at the end of the term, and must be for a minimum of \$100,000. As of March 31, 2001, the Company has received \$1,918,000 in proceeds under four separate note agreements, with a balance due of \$1,758,000. The annual interest rate under the four notes is approximately 14.5%. The interest rate on future notes may change based on changes in the rate of 3-year U.S. Treasury Securities. The Company expects to draw down the remaining funds by the end of 2001.

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 which 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, including those discussed below, 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 believes, anticipates, expects, intends, and similar expressions are intended to identify forward-looking statements but are not the exclusive means of identifying such statements. In addition, the disclosures in this Item 2 under the caption "Other Factors that May Affect Operating Results" consist principally of a brief discussion of risks which may affect future results and are thus, in their entirety, forward-looking in nature. Readers are urged to carefully review and consider the various disclosures made by the Company in this report and in the Company's other reports previously filed with the Securities and Exchange Commission (the "Commission"), including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, that attempt to advise interested parties of the risks and factors that may affect the Company's business.

Overview

Osteon was incorporated in the State of Washington in 1989. The Company is engaged in the discovery and commercialization of products associated with osteoporosis and other collagen-related diseases. The Company believes that its lead product, the OSTEOMARK® test, now available in multiple test formats, incorporates breakthrough and patented technology in the area of bone resorption measurement. As of March 31, 2001, the Company had 44 employees.

Osteoporosis is a significant health problem. According to the National Osteoporosis Foundation (the "NOF"), osteoporosis afflicts over 28 million people in the U.S. alone. Additionally millions of people are at risk of skeletal degradation associated with Paget's disease of bone, cancer that metastasizes to bone, hyperparathyroidism (overactivity of the parathyroid gland, characterized by a reduction of bone mass) and renal osteodystrophy. In spite of the serious human and economic consequences of these diseases (according to the NOF, the national direct

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expenditures for osteoporosis and associated fractures exceed \$14 billion annually in the U.S. alone), medical intervention usually commences only after pain, immobility, fractures, or other symptoms have appeared. The Company expects the osteoporosis therapeutic market will continue to increase 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 in postmenopausal women, which are intended to prevent the onset of osteoporosis. In addition, the Company's Osteomark test aids clinicians in monitoring the effects of antiresorptive therapies in postmenopausal women and those diagnosed with osteoporosis, in a matter of three months versus one to two years with conventional technology.

In May 1995, the Company's Osteomark test became commercially available in the United States 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 urine test. The 1996 claims 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 individuals diagnosed with osteoporosis and Paget's disease. In March 1998, the claims were further expanded by allowing that, in addition to the 1996 claims, an Osteomark test measurement can identify the probability for a decrease in bone mineral density in postmenopausal women taking calcium supplements relative to those treated with hormonal antiresorptive therapy.

In February 1999, Osteomark NTx Serum became the first and only commercially available 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 testing laboratories, including the elimination of the requirement to normalize NTx values to creatinine concentration. The Company is manufacturing and marketing the Osteomark test in an Enzyme-linked Immunosorbent Assay (ELISA) format for testing urine or serum samples.

The Company has, through an agreement with Metrika, Inc. (Metrika), a privately-held, medical device company, developed a physician's office point-of-care Osteomark test device. The Company and Metrika developed the fully disposable point-of-care NTx test as an indicator of bone resorption that computes a NTx value and displays it digitally. In October 1999, the Osteomark NTx Point-of-Care device became commercially available for use in the physician's office. On May 10, 2000, the Company announced it had acquired the exclusive right from Metrika to manufacture the Osteomark NTx Point-of-Care device as well as exclusive worldwide license to manufacture, market and sell this device for the measurement of other connective tissue markers, including those associated with arthritis.

In 1992, the Company entered into a research and development agreement and a license agreement with Mochida Pharmaceutical Co., Ltd. ("Mochida"), a Japanese pharmaceutical company, for the commercialization of the Osteomark test in Japan. Under the research and development agreement, Mochida has an option to license the NTx serum test and has paid the Company \$3,350,000 in development fees to date. Future payments of \$750,000 under the agreement are contingent upon Mochida's decision to exercise its option. Under the license agreement, the Company granted Mochida exclusive marketing and distribution rights to certain products in Japan. Since 1992, Mochida has paid the Company \$2,500,000 in licensing fees for the Osteomark test. In January 1998, Mochida launched the Osteomark test in Japan for the management of patients with hyperparathyroidism and for patients with metastatic bone tumors. In December 1999, Mochida received an additional regulatory indication from the Japanese Ministry of Health and Welfare for the Osteomark test for selecting suitable drugs for the treatment of osteoporosis and monitoring efficacy of drug therapy for osteoporosis. During 1999, the Company sold Mochida the critical reagents to be assembled into finished products in Japan by Mochida. In first quarter 2000, the Company moved from selling just the critical reagents to providing the finished product to Mochida.

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

The Company manufactures its Osteomark NTx Urine and Serum kits in the ELISA format at its manufacturing facility in Seattle, Washington. During 2000, the Company leased additional space in Seattle, Washington, and began improvements to the facility in preparation for the manufacturing transfer of the Osteomark NTx Point-of-Care device from Metrika. The Company anticipates manufacturing the NTx Point-of-Care device at its new facility later this year.

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The Company is investigating the use of its NTx test in patients diagnosed with metastatic cancer and those on renal dialysis. Independent researchers have shown that the level of bone resorption increases significantly when cancer metastasizes to bone and in patients with renal disease. A patient's NTx level may be useful to identify cancer patients with elevated bone turnover who might warrant a bone scan to detect metastatic bone disease and/or monitor the effect of antiresorptive therapy.

The Company is developing an assay for Type II collagen degradation. Type II collagen is a primary constituent of joint cartilage. Osteoarthritis, a degenerative disease of joint cartilage, affects over 15 million people in the United States alone. The disease first appears in a limited number of joints. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. Eventually, pain and tenderness increase and the joint motion becomes diminished. The Ostone Type II collagen degradation test under development has been designed 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 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 by monitoring the effectiveness of therapy.

The Company is also in the early stages of developing an assay for measuring Type III collagen degradation. 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 is also developing a way 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 adsorbed. 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 adsorbs readily to hydroxyapatite, a bone-like mineral used to coat medical and dental implants. The Company is seeking collaborations to confirm that such TRAP-induced stimulation of osteoclast recruitment results in osteointegration and enhanced bonding of the graft or prosthesis to the patient's bone.

OSTEOMARK and OSTONE are registered United States (U.S.) trademarks of the Company. The Company has also registered its OSTEOMARK trademark in 47 other countries. The Company's collagen breakdown test technology is covered by 35 U. S. patents, 3 European patents, 5 Japanese patents, and patents in Australia, Canada, Ireland, Korea, Russia, Spain, 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 deoxypridinoline, as well as related breakdown products of type II and type III collagen. The Company's patents will expire in 2007 or later.

Results of Operations for the Three Months Ended March 31, 2001 and March 31, 2000

Total revenues were \$1,529,000 for the quarter ended March 31, 2001, compared to \$887,000 for the quarter ended March 31, 2000. The \$642,000 increase was due primarily to shipments of the NTx Point-of-Care devices, increased NTx Serum kits, and increased shipments of NTx Urine kits to the Company's Japanese partner Mochida and to Johnson & Johnson. Total cost of products sold were \$614,000 for the quarter ended March 31, 2001, compared to \$78,000 for the quarter ended March 31, 2000. The \$536,000 increase was primarily the result of higher sales volume, product mix, and updating the Company's standard costs in first quarter 2000 to better reflect inventory valuation.

The Company's research and development expenditures totaled \$569,000 for the quarter ended March 31, 2001, compared to \$374,000 for the quarter ended March 31, 2000. The \$195,000 increase was driven by increased activities associated with the NTx Point-of-Care device including clinical trials related to seeking approval for CLIA waiver and Prescription Home Use. Selling, general and administrative expenses totaled \$1,262,000 for the quarter ended March 31, 2001, compared to \$1,137,000 for the quarter ended March 31, 2000. The \$125,000 increase resulted from higher investor relations' expenditures and startup costs related to the new NTx POC manufacturing facility.

Net other income totaled \$58,000 for the quarter ended March 31, 2001, compared to \$90,000 for the quarter ended March 31, 2000. The decrease is due to higher interest expense related to notes payable associated with the build-out of the NTx Point-of-Care manufacturing facility and lower interest income due to lower investment balance.

Liquidity and Capital Resources

As of March 31, 2001, the Company had cash and cash equivalents and short-term investments of \$5,666,000, working capital of \$6,044,000 and total shareholders' equity of \$9,076,000. As a result of funding operating losses during the three months ended March 31, 2001, cash, cash equivalents and short-term investments decreased by \$912,000, working capital decreased by \$556,000 and shareholders' equity decreased by \$830,000. During the three-month period ended March 31, 2001, the Company purchased \$361,000 of leasehold improvements, manufacturing and office equipment, received proceeds from notes under the Transamerica loan agreement totaling \$831,000 and reduced notes payable by \$126,000.

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The Company's future capital requirements depend upon many factors, including the effectiveness of the Osteomark NTx Serum, Urine, and Point-of-Care commercialization activities and arrangements; continued scientific progress in its research and development programs; the costs involved in filing, prosecuting and enforcing patent claims; the manufacturing needs for new and existing products; and the time and costs involved in obtaining regulatory approvals. Additional funds from equity or debt financing may be required. There can be no assurance that such additional funds will be available on favorable terms, if at all. Because of the Company's significant long-term cash requirements, it may seek to raise additional capital if conditions in the public equity markets are favorable or through private placements, even if the Company does not have an immediate need for additional cash at that time. If additional financing is not available, the Company believes that its existing available cash, its future license and research revenues from existing collaboration agreements, its current level of product sales and interest income from short-term investments will be adequate to fund operations for approximately the next 18 to 24 months.

Other Factors that May Affect Operating Results

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk. Our exposure to market rate risk, as a result of changes in interest rates, relates primarily to the Company's investment portfolio. At March 31, 2001, the Company held \$0.5 million in cash and cash equivalents and \$5.1 million in Federal and Government agency obligations, and Corporate and municipal bonds. Although we hold 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 1. Legal Proceedings

No material developments occurred.

Item 2. Changes in Securities and Use of Proceeds

None.

Item 3. Default Upon Senior Securities

None.

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

No matters were submitted to Security Holders this quarter.

Item 5. Other Information

None.

Item 6. Exhibits and Reports on Form 8-K

- | | |
|-----|------------------------------------|
| (a) | Exhibits
None |
| (b) | Reports on Form 8-K
None |

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, 2001

By

/S/ Thomas A. Bologna

Thomas A. Bologna
Chairman, President and Chief Executive
Officer
(Principal financial and principal
accounting officer)