

OSTEK INTERNATIONAL INC /WA/
Form 10-Q
May 01, 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 March 31, 2002

or

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

For the transition period from to

0-25250

Commission File Number

OSTEK INTERNATIONAL, INC.

Name of Registrant as Specified in Its Charter

State of Washington

State or Other Jurisdiction of Incorporation or Organization

91-1450247

I.R.S. Employer Identification Number

2203 Airport Way South, Suite 400, Seattle, Washington 98134

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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 April 30, 2001 was 12,558,174.

OSTECH INTERNATIONAL, INC.

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OSTECH INTERNATIONAL, INC.

CONDENSED BALANCE SHEETS

| | March 31, 2002 (Unaudited) | December 31, 2001 |
|--|----------------------------------|----------------------|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 1,214,000 | \$ 1,284,000 |
| Short-term investments | 1,921,000 | 2,543,000 |
| Trade receivables, net of allowance | 452,000 | 815,000 |
| Inventory | 1,324,000 | 994,000 |
| Other current assets | 178,000 | 33,000 |
| Total current assets | 5,089,000 | 5,669,000 |
| Property, plant and equipment, net | 3,203,000 | 3,272,000 |
| Other assets | 733,000 | 694,000 |
| Total Assets | \$ 9,025,000 | \$ 9,635,000 |
| LIABILITIES AND SHAREHOLDERS EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 614,000 | \$ 279,000 |
| Customer deposits | 255,000 | 156,000 |
| Accrued expenses | 454,000 | 495,000 |
| Current portion of notes payable | 651,000 | 635,000 |
| Total current liabilities | 1,974,000 | 1,565,000 |
| Noncurrent Liabilities: | | |
| Deferred revenue | 445,000 | |
| Notes payable, net of current portion | 966,000 | 1,138,000 |
| Shareholders Equity: | | |
| Common stock, \$.01 par value, 50,000,000 authorized; 12,558,174 and 12,558,174 issued and outstanding at March 31, 2002 and December 31, 2001, respectively | 126,000 | 126,000 |
| Additional paid-in capital | 45,709,000 | 45,709,000 |
| Accumulated items of comprehensive loss | 6,000 | 6,000 |
| Accumulated deficit | (40,201,000) | (38,909,000) |
| Total shareholders equity | 5,640,000 | 6,932,000 |
| Total Liabilities and Shareholders Equity | \$ 9,025,000 | \$ 9,635,000 |

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

OSTECH INTERNATIONAL, INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

| | Quarter Ended | |
|---|-------------------|-------------------|
| | March 31, 2002 | March 31, 2001 |
| Revenues | \$ 923,000 | \$ 1,529,000 |
| Cost of products sold | 293,000 | 614,000 |
| Gross Profit | 630,000 | 915,000 |
| Operating Expenses: | | |
| POC facility start-up costs | 431,000 | 80,000 |
| Research and development | 463,000 | 569,000 |
| Selling, general and administrative | 999,000 | 1,182,000 |
| Total operating expenses | 1,893,000 | 1,831,000 |
| Loss from operations | (1,263,000) | (916,000) |
| Other (Expense) Income, net | (29,000) | 58,000 |
| Net loss | \$ (1,292,000) | \$ (858,000) |
| Basic and diluted net loss per common share | \$ (0.10) | \$ (0.07) |
| Weighted average shares used in calculation of net loss per share | 12,558,000 | 12,485,000 |

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, 2002 | March 31, 2001 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net Loss | \$ (1,292,000) | \$ (858,000) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 173,000 | 123,000 |
| Expense from issuance of warrants | | 4,000 |
| Loss on disposal of property, plant & equipment | | 1,000 |
| Changes in current assets and current liabilities | | |
| Trade receivables | 363,000 | (152,000) |
| Inventory | (330,000) | (61,000) |
| Other assets | (184,000) | (84,000) |
| Accounts payable | 335,000 | (552,000) |
| Customer deposits | 99,000 | |
| Deferred revenue | 445,000 | |
| Accrued liabilities | (41,000) | 300,000 |
| Net cash used in operating activities | \$ (432,000) | \$ (1,279,000) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Purchases of short-term investments | | (507,000) |
| Proceeds from sales and maturities of short-term investments | 622,000 | 649,000 |
| Purchases of property, plant and equipment | (104,000) | (361,000) |
| Net cash provided by (used in) investing activities | 518,000 | (219,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Repurchase of common stock | | (19,000) |
| Proceeds from notes payable | | 831,000 |
| Payments on notes payable | (156,000) | (126,000) |
| Net cash (used in) provided by financing activities | (156,000) | 686,000 |
| NET DECREASE IN CASH AND EQUIVALENTS | (70,000) | (812,000) |
| CASH AND CASH EQUIVALENTS, beginning of period | 1,284,000 | 1,348,000 |
| CASH AND CASH EQUIVALENTS, end of period | \$ 1,214,000 | \$ 536,000 |

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, 2001.

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 2,878,000 and 2,931,000 of stock options and warrants outstanding as of March 31, 2002 and March 31, 2001, respectively, because of their antidilutive effect.

3. Comprehensive Income

The components of comprehensive income for the three months ended March 31, 2002 and March 31, 2001, are as follows:

| | March 31, | March 31, |
|---|------------------|------------------|
| | 2002 | 2001 |
| Net Loss | \$ (1,292,000) | \$ (858,000) |
| Unrealized gain on short-term investments | | 42,000 |

| | | | | |
|--------------------------|----|-------------|----|-----------|
| Total comprehensive loss | \$ | (1,292,000) | \$ | (816,000) |
|--------------------------|----|-------------|----|-----------|

4. Property, Plant And Equipment

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

| | | March 31, 2002 | | December 31, 2001 |
|---|----|-------------------|----|----------------------|
| Leasehold improvements | \$ | 4,059,000 | \$ | 4,058,000 |
| Laboratory and manufacturing equipment | | 1,947,000 | | 1,909,000 |
| Computers and office equipment | | 1,427,000 | | 1,370,000 |
| Construction-in-progress | | 8,000 | | |
| | | 7,441,000 | | 7,337,000 |
| Accumulated depreciation and amortization | | (4,238,000) | | (4,065,000) |
| Net property, plant and equipment | \$ | 3,203,000 | \$ | 3,272,000 |

5. Notes Payable

The Company and Transamerica Business Credit Corporation (Transamerica) entered into a debt financing arrangement for the Company's manufacturing expansion plan. As of December 31, 2001, the Company had drawn down \$2,316,000 under six, separate notes, secured by real property and equipment, payable in 36 equal monthly installments with a balloon payment at the end of the term. The annual interest rate under the six notes is approximately 14.5%. The Company has no further availability of funds under this lease line.

6. Mochida License Agreement

On March 5, 2002, the Company announced that it had entered into a License Agreement with its Japanese partner, Mochida Pharmaceutical Co. Ltd. (Mochida), under which the Company will manufacture and 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 of which \$500,000 was paid upfront as a nonrefundable license fee and an additional \$250,000 milestone is payable upon receipt of the official announcement of the Japanese reimbursement price from the Ministry of Health, Labor and Welfare. Mochida will be purchasing finished Osteomark Serum NTx kits manufactured by Ostex at its production facility in Seattle, Washington. The Company will record revenue as earned over the nine-year license period.

PART I FINANCIAL INFORMATION (Continued)

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 the exclusive means of identifying such statements. 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 U.S. Securities and Exchange Commission (the Commission), including the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, which describe some of the risk factors that may affect the Company's business. You should not place undue reliance on our 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 are women, already have osteoporosis and an estimated 34 million more 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. In spite of 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 to prevent the onset of osteoporosis. In addition, the Company's Osteomark test aids clinicians in monitoring the effects of antiresorptive therapies, such as Merck & Co., Inc.'s Fosamax®, Eli Lilly and Company's Evista®, and Proctor & Gamble Pharmaceuticals, Inc.'s and Aventis Pharmaceuticals, Inc.'s

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Actonel®, in postmenopausal women and those diagnosed with osteoporosis, in a matter of three months versus one to two years with conventional technology.

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 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 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.

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 Company is manufacturing and marketing the Osteomark test in an Enzyme-linked Immunosorbent Assay (ELISA) format for testing urine or serum samples.

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 that 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. The Company started to work with Procter & Gamble in 2000 to launch a test program in Germany to use with the NTx Point-of-Care device with its osteoporosis drug, Actonel, for the management of osteoporosis. This program has since been expanded by Procter & Gamble and Aventis Pharmaceuticals and is being tested in a number of countries. In August 2001, the Company announced that it received Rx Home-Use clearance and CLIA Waiver status for its NTx Point-of-Care device from the Food and Drug Administration. This allows the device to be used in essentially all physician offices, and physicians can write a prescription for the device so that patients may purchase it at the pharmacy and use it in their own homes under the direction of their physician.

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 started shipping NTx Point-of-Care devices that were assembled at its new facility in the fourth quarter of 2001. The Company currently is producing certain critical components for the NTx Point-of-Care device. The NTx Point-of-Care device will not be available for sale from the Company's new facility until it has completed its validation process.

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. To date, Mochida has paid the Company \$3,000,000 in licensing fees for the Osteomark test under the license agreement and \$3,350,000 in development fees under the research and development agreement. 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. 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 license agreement payable upon receipt of the official announcement of the Japanese reimbursement price from the Ministry of Health, Labor and Welfare.

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 urine test on its Vitros® automated analyzer. The Company receives payments for materials supplied by the Company 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 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 15 million people in the United States alone. The first symptom, joint pain, occurs after substantial cartilage damage has taken place. The Company's Type II collagen degradation test will be further developed 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 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 OSTEON are registered United States trademarks of the Company. The Company has also registered its OSTEOMARK trademark in 45 other countries. The Company's collagen breakdown test technology is covered by 37 U.S. patents, 3 European patents, 5 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 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, 2002 and March 31, 2001

Total revenues were \$923,000 for the quarter ended March 31, 2002, compared to \$1,529,000 for the quarter ended March 31, 2001. The decrease in revenues was largely the result of minimal shipments of the Osteomark NTx Point-of-Care device while the Company completes the validation of its Point-of-Care manufacturing facility and lower sales of the Company's NTx Serum and Urine kits relative to the first quarter in 2001. In the first quarter of 2001, the Company sold Point-of-Care devices manufactured by Metrika, Inc. which no longer manufactures the device for the Company. The Company is currently on back order for the NTx Point-of-Care device and the NTx Serum kits and anticipates that shipments of both products will resume by the end of the second quarter.

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The Company will not ship the NTx Point-of Care device from its new facility until it completes the validation process. The Company currently has purchase orders for NTx Point-of Care devices from customers and customer deposits for this product.

The total cost of products sold was \$293,000 for the quarter ended March 31, 2002, compared to \$614,000 for the quarter ended March 31, 2001. The decrease in 2002 from 2001 was primarily due to the lower amount of product sold.

The Company's research and development expenditures totaled \$463,000 for the quarter ended March 31, 2002, compared to \$569,000 for the quarter ended March 31, 2001. In 2001, the Company had higher expenses resulting from increased activities associated with the NTx Point-of-Care device, including clinical trials related to obtaining, during the second half of 2001, approval for CLIA Waiver and Rx Home-Use for the device. Selling, general and administrative expenses totaled \$999,000 for the quarter ended March 31, 2002, compared to \$1,182,000 for the quarter ended March 31, 2001. The decrease resulted from slightly lower sales and marketing related expenditures. Start-up costs for the Company's Point-of-Care facility increased to \$431,000 for the three-month period as compared to \$80,000 for the same period in 2001 due to the scale-up of operations to validate the facility and scale-up of capacity to meet the expected initial market demand for the product.

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Net other expense totaled \$29,000 for the quarter ended March 31, 2002, compared to net other income of \$58,000 for the quarter ended March 31, 2001. 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 balances and lower interest rates.

Liquidity and Capital Resources

As of March 31, 2002, the Company had cash, cash equivalents and short-term investments of \$3,135,000, working capital of \$3,115,000 and total shareholders' equity of \$5,640,000. As a result of funding operating losses during the three months ended March 31, 2002, cash, cash equivalents and short-term investments decreased by \$692,000, working capital decreased by \$989,000 and shareholders' equity decreased by \$1,292,000. During the three-month period ended March 31, 2002, the Company purchased \$104,000 of manufacturing and office equipment, and reduced notes payable by \$156,000.

The Company's future capital requirements depend upon many factors, including the timeliness and cost-effectiveness of Osteomark NTx Urine, Serum, and Point-of-Care commercialization, production and delivery 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; the time and costs involved in obtaining regulatory approvals, as well as other factors discussed in the section entitled "Other Factors that May Affect Operating Results" below and in the Form 10-K for the year ended December 31, 2001. Additional funds from equity or debt financing may be required, especially in light of the increasing costs associated with the manufacturing scale up of the NTx Point-of-Care device and uncertainties related to the timing of final production validation, market acceptance and demand for products. There can be no assurance that such additional funds will be available on favorable terms, if at all. The Company 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 through at least the first quarter of 2003.

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, cost, 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, 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2001 filed with the Commission. These factors are

difficult for the Company to predict and could materially and 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, 2002, the Company held \$1.2 million in cash and cash equivalents and \$1.9 million in federal and other government agency obligations. Although we hold both fixed and adjustable rate investments and each carries 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.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

Item 2. Changes in Securities and Use of Proceeds

Not applicable.

Item 3. Default Upon Senior Securities

Not applicable.

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

No matters were submitted to Security Holders this quarter.

Item 5. Other Information

Not applicable.

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 | (15) |
| | 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 Osteoclast Regulation) | (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) |

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| | | |
|--------|--|------|
| | Lease Agreements | |
| 10.27A | Lease Agreement dated October 2, 1995, with David A. Sabey and Sandra L. Sabey | (9) |
| 10.27B | First Amendment of Lease dated October 15, 1996, with the City of Seattle, successor-in-interest to David A. Sabey and Sandra L. Sabey | (2) |
| | Agreements with Johnson & Johnson Clinical Diagnostics, Inc. | |
| 10.28A | Distribution Agreement dated June 7, 1995 | (10) |
| 10.28B | Research, Development, License and Supply Agreement dated June 7, 1995 | (10) |
| 10.29 | Clinical Laboratory Services License and Supply Agreement dated October 25, 1995, with SmithKline Beecham Clinical Laboratories, Inc. | (9) |
| 10.35 | Shareholder Rights Agreement dated January 21, 1997 | (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) |
| 23.1 | Consent of Arthur Andersen LLP | (14) |
| 99.1 | Letter from Arthur Andersen | (14) |

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* Management contract or compensatory plan or agreement.

- (1) Copies of exhibits may be obtained at prescribed rates from the Public Reference Section of the Commission at 450 5th Street NW, Room 1024, Washington, D.C. 20549, or through the Commission's Edgar system located on the internet at www.sec.gov.
- (2) Incorporated herein by reference to exhibit of the same number filed with Form 10-K with the Commission for the year ended December 31, 1996.
- (3) Incorporated herein by reference from Item 16(a) of Registrant's Form S-1 Registration Statement as declared effective January 24, 1995 (No. 33-86118).
- (4) Incorporated herein by reference to Appendix B of the Registrant's Proxy Statement on schedule 14A filed on March 22, 2001.
- (5) Incorporated herein by reference to Appendix B of the Registrant's Proxy Statement on schedule 14A filed on March 30, 2000.
- (6) Incorporated herein by reference to exhibits of the same number filed with Form 10-K with the Commission for the year ended December 31, 1997.
- (7) Confidential treatment requested. Exhibit omits information that has been filed separately with the Commission.
- (8) Incorporated herein by reference to exhibits of the same number filed with Form 10-K with the Commission for the year ended December 31, 1996, and as amended with Form 10-K/A on October 17, 1997.
- (9) Incorporated herein by reference to exhibit of the same number filed with Form 10-K with the Commission for the year ended December 31, 1995.
- (10) Incorporated herein by reference to exhibit of the same number filed with Form 10-Q with the Commission for the quarter ended June 30, 1995.
- (11) Incorporated herein by reference to exhibit number 4.5 filed with Form 8-A with the Commission in January 1997.
- (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-K with the Commission for the year ended December 31, 2001.
- (15) Included with this Form 10-Q as exhibit of the same number.

(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.

OSTEK INTERNATIONAL, INC.

DATED: April 30, 2002

By

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