FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2001-08-03** | Period of Report: **2001-06-30**
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SIC: **3841** Surgical & medical instruments & apparatus

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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

[X] Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the Quarterly Period Ended June 30, 2001.

[_] Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the Transition Period from _____ to _____.

Commission File Number 0-24517.

ORTHOVITA, INC.

(Exact Name of Registrant as Specified in its Charter)

Pennsylvania	23-2694857
(State Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
45 Great Valley Parkway, Malvern, PA	19355
(Address of Principal Executive Offices)	(Zip Code)
Registrant's Telephone Number, Including Area Code	(610) 640-1775

Not Applicable

Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report

Indicate by check mark 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 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 __X___ No ____

Applicable only to corporate issuers:

Indicate the number of shares outstanding of each of the issuer's classes of Common Stock, as of the latest practicable date.

Class	Outstanding as of June 30, 2001
Common Stock, par value $.01	17,130,762 Shares

This Report Includes a Total of 21 Pages

ORTHOVITA, INC. AND SUBSIDIARIES

INDEX

PART I. FINANCIAL INFORMATION
ITEM I. FINANCIAL STATEMENTS

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2001	December 31, 2000
ASSETS	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents (Notes 2 and 4)	$ 8,946,838	$ 3,614,626
Short-term investments (Notes 2 and 4)	---	200,366
Restricted cash (Note 7)	---	400,000
Accounts receivable, net	677,608	80,050
Inventories (Note 3)	911,750	182,399
Other current assets	46,944	21,721
Total current assets	10,583,140	4,499,162
PROPERTY AND EQUIPMENT, net	5,693,724	5,321,228
OTHER ASSETS (Note 4)	418,002	367,977
	$ 16,694,866	$ 10,188,367
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Short-term bank borrowings (Note 4)	$ 750,000	$ ---
Current portion of bank term loan (Note 4)	173,912	---
Current portion of long-term capital lease obligations	543,785	654,063
Accounts payable	1,186,459	1,156,533
Deferred gain (Note 7)	---	400,000
Accrued compensation and related expenses	354,832	734,820
Other accrued expenses	902,506	805,911
Total current liabilities	3,911,494	3,751,327
LONG-TERM LIABILITIES:		
Capital lease obligations	556,446	807,425
Bank term loan (Note 4)	326,088	500,000
Total long-term liabilities	882,534	1,307,425
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY (Note 5):		
Preferred Stock, $.01 par value, 20,000,000 shares authorized, no shares issued and outstanding	---	---
Common Stock, $.01 par value, 50,000,000 shares authorized, 17,130,762 and 13,426,988 shares issued and outstanding	171,308	134,270

Additional paid-in capital	66,412,233	52,929,538
Deferred compensation	(48,750)	(97,500)
Accumulated deficit	(54,698,386)	(47,809,103)
Accumulated other comprehensive income (loss)	64,433	(27,590)
Total shareholders' equity	11,900,838	5,129,615
	$ 16,694,866	$ 10,188,367

</TABLE>

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>
<CAPTION>

	Three Months Ended June 30		Six Months Ended June 30	
	2001	2000	2001	2000
	(Unaudited)			
<S>	<C>	<C>	<C>	<C>
REVENUES :				
VITOSS/TM/ (Note 6)	$ 953,603	$ --	$ 1,180,009	$ --
BIOGRAN/(R)/ (Note 7)	--	--	--	532,967
Total revenues	953,603	--	1,180,009	532,967
COST OF SALES (Note 3)	253,638	--	273,038	164,041
Gross profit	699,965	--	906,971	368,926
OPERATING EXPENSES:				
General and administrative	1,136,616	1,077,867	2,045,649	2,044,455
Selling and marketing	1,350,302	679,419	2,521,610	1,508,170
Research and development	1,881,165	1,925,100	3,702,559	3,310,634
Total operating expenses	4,368,083	3,682,386	8,269,818	6,863,259
Operating loss	(3,668,118)	(3,682,386)	(7,362,847)	(6,494,333)
INTEREST EXPENSE	(34,221)	(32,488)	(70,782)	(71,197)
INTEREST INCOME	103,853	79,750	169,346	164,648
Loss before extraordinary item	(3,598,486)	(3,635,124)	(7,264,283)	(6,400,882)
NET GAIN ON SALE OF PRODUCT LINE (Note 7)	--	--	375,000	3,070,921
NET (LOSS)	$(3,598,486)	$(3,635,124)	$(6,889,283)	$ (3,329,961)
NET INCOME (LOSS) PER COMMON SHARE, BASIC AND DILUTED:				
Before extraordinary Item	$ (.22)	$ (.31)	$ (.47)	$ (.56)
Extraordinary item	$ --	$ --	$ .02	$ .27
	$ (.22)	$ (.31)	$ (.45)	$ (.29)
WEIGHTED AVERAGE NUMBER OF OF COMMON SHARES OUTSTANDING (Note 1):				
BASIC and DILUTED	16,633,954	11,584,563	15,404,842	11,486,953

</TABLE>

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>
<CAPTION>

	Six Months Ended June 30	
	2001	2000
	(Unaudited)	
<S>	<C>	<C>
OPERATING ACTIVITIES:		
Net (loss)	$(6,889,283)	$(3,329,961)
Adjustments to reconcile net (loss) to net cash used in operating activities -		
Depreciation and amortization	667,778	384,818
Amortization of deferred compensation	48,750	---
Services provided for Common Stock options and warrants	64,792	287,381
Loss on disposal of property and equipment	12,692	---
Net gain on sale of product line	(375,000)	(3,070,921)
(Increase) decrease in -		
Accounts receivable	(597,558)	---
Inventories	(729,351)	---
Other current assets	(25,223)	236,402
Other assets	(50,026)	(10,062)
Increase (decrease) in -		
Accounts payable	29,926	(315,644)
Accrued compensation and related expenses	(379,988)	(290,474)
Other accrued expenses	96,595	(226,716)
Net cash used in operating activities	(8,125,896)	(6,335,177)
INVESTING ACTIVITIES:		
Purchases of investments	---	(199,887)
Proceeds from sale of investments	199,866	3,933,127
Proceeds from sale of product line	---	3,900,000
Decrease (increase) in restricted cash	375,000	(400,000)
Purchase of property and equipment	(1,052,965)	(822,772)
Net cash (used in) provided by investing activities	(478,099)	6,410,468
FINANCING ACTIVITIES:		
Proceeds from short term bank borrowings	750,000	2,000,000
Repayments of short term bank borrowings	---	(2,000,000)
Repayments of capital lease obligations	(361,257)	(297,792)
Net proceeds from sale of Common Stock and warrants	13,396,868	---
Proceeds from exercise of Common Stock options and warrants and Common Stock purchased under the Employee Stock Purchase Plan	58,073	860,483
Net cash provided by financing activities	13,843,684	562,691
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	92,523	(1,650)
NET INCREASE IN CASH AND CASH EQUIVALENTS	5,332,212	636,332
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,614,626	2,487,343
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 8,946,838	$ 3,123,675

</TABLE>

The accompanying notes are an integral part of these statements.

ORTHOVITA, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

The Company:

Orthovita, Inc. ("Orthovita" or the "Company"), a Pennsylvania corporation, began operations in November 1993. Orthovita is a biomaterials company with

proprietary technologies applied to the development of novel products for use by orthopaedics surgeons. Our focus is on developing products for use in spine surgery and in the repair of osteoporotic fractures. We are also addressing a broad range of clinical needs in the trauma market. Our efforts to-date have resulted in the development of three products, VITOSS(TM) Synthetic Cancellous Bone Void Filler, CORTOSS(TM) Synthetic Cortical Bone Void Filler and RHAKOSS(TM) Synthetic Bone Implants.

We initiated European sales of VITOSS in October 2000 following receipt of its CE Certification allowing its sale in all of the countries of the European Union. In December 2000, the U.S. Food and Drug Administration (the "FDA") granted 510(k) marketing clearance for VITOSS, and we began selling VITOSS in the U.S. during March 2001. In addition, during the first quarter of 2001, we received regulatory clearance to sell VITOSS and CORTOSS in Australia.

Our operations are subject to certain risks including but not limited to the need to successfully market and sell VITOSS and to develop, obtain regulatory approval for, and commercialize CORTOSS and RHAKOSS, and our need for additional capital. We have incurred losses each year since our inception in 1993 and we expect to continue to incur losses for at least the next several years. As of June 30, 2001, we had an accumulated deficit of approximately $54,698,000. Our products under development may never be commercialized or if commercialized, may never generate substantial revenue and therefore we may never become profitable.

We believe our existing cash as of June 30, 2001 of approximately $8,947,000 will be sufficient to meet our currently estimated operating and investing requirements into 2002. We intend to seek additional funds in 2001. We may seek equity financing which, if satisfactorily completed, would result in dilution to our existing shareholders of Common Stock. Additionally, we may seek funding through debt, strategic alliances with third parties, off-balance sheet or other structured financing arrangements either alone or in combination with equity. These financings could require debt service and/or royalty payment arrangements, which could represent significant expenses and use of cash in future periods and could increase our cash used in operating activities. Additionally, the terms of any such financings may affect our rights to our products. In addition, while terms of such financings are begin negotiated, restrictions may be imposed that affect our ability to concurrently pursue alternative financing arrangements. The terms of these financings could place restrictions on how we may operate our business, sell or license our products, or our ability to enter into business combinations with, or sell a product line to, other corporate entities. Although we have no present commitments or understandings, we may seek to expand our operations and product line via acquisitions or joint ventures and any such acquisitions or joint ventures may increase our capital requirements.

Basis of Presentation

Our consolidated interim financial statements are unaudited and, in our opinion, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of results for these interim periods. The preparation of financial statements requires that we make assumptions and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the interim financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. The consolidated interim financial statements do not include all of the information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States and should be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2000 filed with the Securities and Exchange Commission, which includes financial statements as of December 31, 2000 and 1999 and for the years ended December 31, 2000, 1999 and 1998. The results of our operations for any interim period are not necessarily indicative of the results of our operations for any other interim period or for a full year.

Reclassifications

We have reclassified certain amounts in prior period's financial statements to conform to the presentation for the current period.

Basis of Consolidation

The consolidated financial statements include the accounts of Orthovita, Inc., our European branch operations, and our wholly owned subsidiaries. We have eliminated all intercompany balances in consolidation.

Net Income (Loss) Per Common Share

We have presented per share data pursuant to Statement of Financial Accounting Standards ("SFAS") No. 128, "Earnings per Share." Basic per share data excludes potentially dilutive securities and is computed by dividing net income or loss applicable to common shareholders by the weighted average number of shares of

Common Stock outstanding for the period. Diluted per share data is computed assuming the conversion or exercise of all dilutive securities such as Common Stock options and warrants; however, Common Stock options and warrants were excluded from our computation of diluted net income (loss) per common share for the three and six months ended June 30, 2001 and 2000 because they were anti-dilutive, due to our losses.

Revenue Recognition

We sell VITOSS to stocking distributors in Europe and Australia and directly to hospitals through commissioned sales agents in the U.S. In Europe and Australia, revenue is recognized upon the shipment of the product to the distributor, net of applicable provisions for discounts and allowances. We do not allow product to be returned from our distributors. In the U.S., revenue is recognized when the product is shipped to the end user hospital.

2. CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS:

We invest excess cash in highly liquid investment-grade marketable securities including corporate commercial paper and U.S. government agency bonds. For financial reporting purposes, we consider all highly liquid investment instruments purchased with an original maturity of three months or less to be cash equivalents. All investments are considered available-for-sale and, accordingly, unrealized gains and losses are included in a separate component of shareholders' equity. As further discussed in Note 4, our debt covenants require us to maintain a minimum level of aggregate cash, cash equivalents and investments.

As of June 30, 2001, cash, cash equivalents and short-term investments consisted of the following:

<TABLE>
<CAPTION>

	Original Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
<S>	<C>	<C>	<C>	<C>
Cash and cash equivalents	$ 8,946,838	$ ---	$ ---	$ 8,946,838
Short-term investments	---	---	---	---
	$ 8,946,838	$ ---	$ ---	$ 8,946,838

</TABLE>

3. INVENTORIES:

Inventories are stated at the lower of cost or market on a first-in, first-out basis. As of June 30, 2001 and December 31, 2000, inventories consisted of the following:

<TABLE>
<CAPTION>

	June 30, 2001	December 31, 2000
<S>	<C>	<C>
Raw materials	$ 43,573	$ 2,042
Work-in-process	300,982	180,357
Finished goods	567,195	--
	$ 911,750	$ 182,399

</TABLE>

All of the VITOSS product sold during 2000 and during the first three months of 2001 was produced prior to the receipt of VITOSS's regulatory approval. In accordance with SFAS No. 2 "Accounting for Research and Development Costs," the costs of that material were recorded in research and development expense when produced and, accordingly, were not reflected in cost of sales when later sold. All VITOSS product sold during the three months ended June 30, 2001 was produced subsequent to receipt of regulatory approval, with related production costs reflected in cost of sales for the second quarter of 2001.

4. BORROWINGS:

We have a bank credit arrangement for a $1,500,000 line of credit and a $500,000 capital expenditure term note ("Term Note"). The line of credit expires on June 30, 2002. As of June 30, 2001, $750,000 was outstanding under the line of credit, which was repaid during July 2001. As of December 31, 2000, no amounts were outstanding under the line of credit. The Term Note and line of credit bear interest at an annual rate of the prime rate plus 1.0%. Principal on the Term Note is due in 23 equal installments beginning November 1, 2001. Both the line

of credit and Term Note are secured by our general assets and a $250,000 bank certificate of deposit which is included in Other Assets as of June 30, 2001 and December 31, 2000. The line of credit and Term Note require us to maintain a minimum aggregate level of cash and investments of $3,000,000 and minimum working capital of $3,000,000.

5. SHAREHOLDERS' EQUITY:

Common Stock

During June 2001, the investor in the August 2000 private placement acquired 206,830 shares of our Common Stock for $.01 per share in accordance with the anti-dilution provisions contained in a subscription agreement dated August 22, 2000 due to the equity transactions in January, March and April 2001.

During April 2001, we entered into a Development and Distribution Agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), a Japanese orthopaedic company, under which MDM will be responsible for conducting any development efforts required to apply for the regulatory clearance to market VITOSS in Japan. If clearance is obtained, MDM will distribute, sell and market VITOSS in Japan. In connection with this arrangement, we sold 189,394 shares of Common Stock at $5.28 per share to MDM raising net proceeds of $1,000,000.

Additionally, during April 2001, we sold 740,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $2,692,000.

During March 2001, we sold 1,975,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $7,290,000.

In addition, during January 2001, we sold 566,894 shares of our Common Stock and warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share, raising net proceeds of approximately $2,413,000.

Stock Options

During the six months ended June 30, 2001, stock options to purchase 13,350 shares of Common Stock were exercised for proceeds of $18,175. There were no stock option exercises during the second quarter of 2001. Additionally, during the three and six months ended June 30, 2001, we issued stock options for the purchase of 30,000 shares and 33,000 shares of Common Stock with various fair market value exercise prices to certain vendors in consideration for services valued at $57,470 and $64,792, respectively.

Employee Stock Purchase Plan

During the three and six months ended June 30, 2001, 5,553 shares and 12,306 shares of Common Stock were purchased by the Employee Stock Purchase Plan for proceeds of $18,314 and $39,898, respectively.

Common Stock Purchase Warrants

In connection with the March 2001 and April 2001 equity financings described above, we issued warrants to our placement agents to purchase an aggregate of 81,450 shares of our Common Stock at $4.00 per share as a placement agent fee. These warrants were exercisable when issued and expire in March 2003 and April 2003.

During January 2001, in connection with the private equity offering described above, we issued warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share. These warrants were exercisable when issued and expire in January 2003.

Pursuant to the anti-dilution terms of warrants sold in a private equity financing transaction in August 2000, and as a result of the January, March and April 2001 financing transactions described above, the number of shares of Common Stock issuable upon the exercise of the warrants increased from 762,712 to 1,125,000 shares, and the exercise price was adjusted from $5.90 per share to $4.00 per share.

6. REVENUE:

We initiated sales of VITOSS in Europe and the United States in October 2000 and March 2001, respectively. For the three and six months ended June 30, 2001, VITOSS revenues by geographic market consisted of the following:

<TABLE>
<CAPTION>

	Three Months Ended June 30, 2001	Six Months Ended June 30, 2001
<S>	<C>	<C>
VITOSS Revenues:		
United States	$ 715,777	$ 820,587
Outside the United States	237,826	359,422
Total revenues	$ 953,603	$ 1,180,009

</TABLE>

7. SALE OF PRODUCT LINE:

On March 22, 2000, we sold all rights to our BIOGRAN dental grafting product line to Implant Innovations, Inc. ("3i") for $3,900,000 and recorded a net gain on the sale of the product line of $3,500,000. An additional $400,000 was held in an escrow account until March 2001 and was reflected as a deferred gain and restricted cash as of December 31, 2000. A gain of $375,000 was recorded in March 2001 when that portion of the escrow account was released. The remaining $25,000 is to be applied to certain patent related costs that we expect to incur in the future. BIOGRAN product sales of $532,967 were realized during the first three months of 2000 prior to the sale of the product line.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

Various statements made in this report on Form 10-Q and in our other reports and public filings are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, information about the following:

- costs relating to the development of our products;
- the potential timing of obtaining regulatory approval for our products;
- market size estimates;
- healthcare reimbursement for procedures using our products;
- potential sales and expense levels;
- sufficiency of available resources to fund operations; and
- anticipated losses.

When used in this report on Form 10-Q, the words "may," "will," "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are generally intended to identify forward-looking statements, but are not the exclusive expressions of forward-looking statements. Readers are cautioned that such forward-looking statements are only predictions and, because forward-looking statements involve risks and uncertainties, there are important factors that could cause our actual results and financial position to differ materially from those expressed or implied by these forward-looking statements, including, but not limited to:

- difficulties in obtaining or maintaining regulatory approval for our products;
- lack of market acceptance by surgeons for our products;
- limited clinical data to support product effectiveness;
- difficulties in obtaining adequate third party reimbursement;
- difficulties in maintaining an effective sales and distribution network;
- difficulties in maintaining commercial scale manufacturing capacity and capability;
- lack of financial resources to adequately support operations;
- unanticipated cash requirements to support operations;
- inability to attract qualified personnel to market and train surgeons on the use of our products;
- increased competition;
- technological changes;

- enactment of new legislation or administrative regulation;

- application to our business of court decisions and regulatory interpretations;

- intellectual property infringement claims by others;

- loss of key personnel;

- claims that exceed our insurance coverage; and

- imposition of penalties for failure to comply with regulatory guidelines.

Factors that could cause actual events or results to differ materially from those expressed or implied by forward-looking statements are addressed in the Certain Risks Related to Our Business section of this report on Form 10-Q. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made. Furthermore, we undertake no obligation to publicly update any forward-looking statements.

Overview

Orthovita is a biomaterials company with proprietary technologies applied to the development of novel products for use in orthopaedics. Our focus is on developing products for use in spine surgery and in the repair of osteoporotic fractures. We are also addressing a broad range of clinical needs in the trauma market. Our efforts to-date have resulted in the development of three products, VITOSS(TM) Synthetic Cancellous Bone Void Filler, CORTOSS(TM) Synthetic Cortical Bone Void Filler and RHAKOSS(TM) Synthetic Bone Implants. VITOSS is a resorbable calcium phosphate scaffold used as a bone graft in trauma and spinal fusion procedures. CORTOSS is under development as a high-strength, bone-bonding, self-setting composite engineered specifically to mimic the strength characteristics of human cortical bone. We are pursuing clinical studies for multiple indications of CORTOSS, including the augmentation of screws used in a variety of orthopaedic procedures and vertebral fractures. RHAKOSS is under development as a high-strength, bone-bone bonding preformed composite interbody fusion implant. RHAKOSS is designed to mimic the strength and flexibility characteristics of bone and is being designed to address the needs of the vertebral interbody fusion and spinal reconstruction markets.

We initiated European sales of VITOSS in October 2000 following receipt of its CE Certification allowing its sale in all of the countries of the European Union. In December 2000, the U.S. Food and Drug Administration granted 510(k) marketing clearance for VITOSS and we began selling the product in the U.S. in March 2001. In March 2001, we received regulatory clearance to sell VITOSS and CORTOSS in Australia. We have built a network of independent stocking distributors in Europe and Australia and commissioned sales agencies in the U.S. in order to market VITOSS and may utilize this network for CORTOSS, if CORTOSS receives regulatory approval in countries in addition to Australia. In April 2001, we entered into a development and distribution agreement with a Japanese orthopaedic company to apply for regulatory clearance to market VITOSS in Japan and, if the clearance is obtained, the Japanese entity will distribute, sell and market VITOSS in Japan.

Certain Risks Related to Our Business

As further described above, our performance and financial results are subject to risks and uncertainties including the following specific risks.

We have a history of operating losses and we will need additional funds that may not be available in the future.

We have experienced negative operating cash flows since our inception, and we have funded our operations primarily from the proceeds received from sales of our Common Stock. We expect to continue to use cash and investments to fund operating and investing activities. We plan to continue to spend substantial funds for preclinical studies and clinical trials in support of regulatory approvals, research and development, and the further development of marketing product literature and sales activities. We believe our existing cash as of June 30, 2001 of approximately $8,947,000 will be sufficient to meet our currently estimated operating and investing requirements into 2002. However, we do not expect sales to generate cash flow in excess of operating expenses for at least the next year or two, if at all. We believe our existing cash as of June 30, 2001 of approximately $8,947,000 will be sufficient to meet our currently

estimated operating and investing requirements into 2002. We intend to seek additional funds in 2001. We may seek equity financing which, if satisfactorily

completed, would result in dilution to our existing shareholders of Common Stock. Additionally, we may seek funding through debt, strategic alliances with third parties, off-balance sheet or other structured financing arrangements either alone or in combination with equity. These financings could require debt service and/or royalty payment arrangements, which could represent significant expenses and use of cash in future periods and could increase our cash used in operating activities. Additionally, the terms of any such financings may affect our rights to our products. In addition, while terms of such financings are begin negotiated, restrictions may be imposed that affect our ability to concurrently pursue alternative financing arrangements. The terms of these financings could place restrictions on how we may operate our business, sell or license our products, or our ability to enter into business combinations with, or sell a product line to, other corporate entities. Although we have no present commitments or understandings to do so, we may seek to expand our operations and product line via acquisitions or joint ventures and any such acquisitions or joint ventures may increase our capital requirements.

Our future capital requirements will depend upon numerous factors, including the extent to which unforeseen clinical, regulatory, manufacturing or sales and marketing difficulties arise, the rate at which our products gain market acceptance, the acquisition and defense of intellectual property rights, the development of strategic alliances for the marketing of certain of our products, and other competitive developments. In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line via acquisitions or joint ventures. Any such acquisitions or joint ventures may increase our capital requirements.

We have incurred substantial operating losses since our inception and, as of June 30, 2001, had an accumulated deficit of approximately $54,698,000. These losses have resulted principally from expenses incurred in the development of our products and in seeking their regulatory approval, including the development and patenting of our technologies, preclinical and clinical studies, and preparation of submissions to the FDA and foreign regulatory bodies, as well as in the development of sales, marketing and manufacturing capabilities. We expect to continue to incur significant operating losses for at least the next year or two and there is no assurance that we will ever achieve profitable operations.

Our product sales and results of operations may fluctuate due to a number of factors.

VITOSS is currently our only product that has received regulatory clearance for sale in the U.S. or Europe. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the U.S. late in the first quarter of 2001. Future levels of VITOSS product sales are difficult to predict at this early stage of the product launch process and VITOSS sales to-date may not be indicative of future sales levels. VITOSS sales levels in Europe may fluctuate due to the timing of any distributor stocking orders. Sales of VITOSS in the U.S. may fluctuate due to the timing of orders from hospitals.

Our results of operations may vary significantly in the future as a result of fluctuations in sales levels and a number of other factors, many of which are outside of our control. These other factors include, but are not limited to, the timing of governmental approvals, unanticipated events associated with clinical and preclinical trials, the medical community's acceptance of our products, the success of competitive products, expenses associated with development and protection of intellectual property matters, and the timing of expenses related to further development of new products. The results of our operations may fluctuate significantly from quarter to quarter and may not meet expectations of securities analysts and investors.

Amendments to the Nasdaq marketplace rules which became effective on June 29, 2001 may affect our ability to maintain our listing on the National Market.

Amendments to the Nasdaq marketplace rules, which became effective on June 29, 2001, may require us to raise more capital than what is required to fund our operations in order to satisfy the Nasdaq equity listing standard. Beginning November 1, 2002, we will be required to maintain a minimum net equity in excess of $10,000,000. The additional capital may not be available on satisfactory terms, if at all. Any additional equity capital raised could result in substantial dilution to the holders of our Common Stock.

Additional specific risks, to which our performance and financial results are subject, are detailed in our Annual Report on Form 10-K for the year ended December 31, 2000 and include the following:

We are dependent on the commercial success of CORTOSS and VITOSS, and our ability to achieve this is subject to certain risks, including:

- the need to operate an effective sales and distribution network,
- the need for the market place to commercially accept VITOSS and CORTOSS,
- the need to obtain and maintain their regulatory approval,
- the need to implement and manage commercial scale manufacturing

capability and capacity,
- the uncertainty of operating in international markets, and
- the need to obtain adequate third-party reimbursement for the use of our products.

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products.

The orthopaedic market is highly competitive.

We may be sued in a product liability action.

Our business could suffer if we cannot attract and retain the services of key employees.

In addition, there are other risks, which are also detailed in our Form 10-K for the year ended December 31, 2000, which you should read in its entirety, that relate principally to the securities market and ownership of our securities, including:

We may issue preferred stock as an anti-takeover provision.

Our executive officers and directors own a large percentage of our voting stock and could exert significant influence over matters requiring shareholder approval.

We have not and do not intend to pay any dividends on our Common Stock.

Our stock price is highly volatile.

Liquidity and Capital Resources

We have experienced negative operating cash flows since our inception, and we have funded our operations primarily from the proceeds received from the sale of our Common Stock. Cash, cash equivalents and short-term investments were approximately $8,947,000 at June 30, 2001 and $3,815,000 at December 31, 2000, representing 54% and 37% of our total assets, respectively. We invest excess cash in highly liquid investment-grade marketable securities including corporate commercial paper and U.S. government agency bonds.

The following is a summary of selected cash flow information for the six months ended June 30:

<TABLE>
<CAPTION>

	Six Months Ended June 30,	
	2001	2000
<S>	<C>	<C>
Net cash used in operating activities	$ (8,125,896)	$ (6,335,177)
Net cash (used in) provided by investing activities	(478,099)	6,410,468
Net cash provided by financing activities	13,843,684	562,691

</TABLE>

Net cash used in operating activities

Operating Cash Inflows -

Operating cash inflows for the first six months of 2001 have been derived from VITOSS product sales. We have also received cash inflows from interest income on cash equivalents and short-term investments. Operating cash inflows for the same period during 2000 were derived from BIOGRAN product sales realized prior to the close of the sale of all rights to our BIOGRAN dental grafting product line to 3i, and cash inflows were also received from interest income on cash equivalents and short-term investments.

Operating Cash Outflows -

Our operating cash outflows have continued to be primarily used for development, manufacturing scale-up qualification, pre-clinical and clinical activities in preparation for regulatory filings of our products in development. In addition, funds have been used for the production of inventory, development of marketing materials and sales activities related to the commercialization of VITOSS product.

Operating Cash Flow Requirements Outlook -

We expect our cash flow from operating activities to continue to be negative until such time, if ever, as cash generated from product sales exceeds funding of operating costs.

There may be future quarterly fluctuations in spending. We expect sales

commission expense to increase in proportion to any increase in U.S. VITOSS product sales. In addition, we expect increases in the use of cash to build inventory and fund receivables. We also expect to continue to use cash in operating activities associated with the development, manufacturing scale-up qualification, pre-clinical activities, clinical trials and further research and development activities in support of our other products under development as well as to the expanded efforts associated with VITOSS marketing and sales activities in the U.S., Europe and Australia.

VITOSS is currently our only product that has received regulatory clearance for sale in the U.S. or Europe. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the U.S. late in the first quarter of 2001. Future levels of cash flows from VITOSS product sales are difficult to predict at this early stage of the product launch process and

VITOSS sales to-date may not be indicative of future sales levels. VITOSS sales levels in Europe may fluctuate due to the timing of any distributor stocking orders. Sales of VITOSS in the U.S. may fluctuate due to the timing of orders from hospitals. In addition, any future cash flows from product sales, if any, to be realized from CORTOSS are dependent upon the receipt of the CE Mark from our notified body in Europe, which is outside of our control.

Finally, we may enter into financing arrangements where we would pay royalty amounts on the sales of certain product lines. Any such arrangements could decrease the net revenues received by us from the sale of our products, and could materially increase cash used by operations and net losses. We do not expect sales to generate cash flow in excess of operating expenses for at least the next year or two, if at all.

Net cash (used in) provided by investing activities

We have invested $1,052,965 and $822,772 for the six months ended June 30, 2001 and 2000, respectively, primarily for the purchase of leasehold improvements, manufacturing equipment and research and development equipment in order to further expand of our product development and manufacturing capabilities.

During the six months ended June 30, 2001 and 2000, $199,866 and $3,733,240, respectively, were provided by the net sale of investment grade marketable securities. Additionally, during the first six months of 2000, we received $3,900,000, of which $400,000 was being held in escrow until March 23, 2001, in connection with the sale of the BIOGRAN dental grafting product line to Implant Innovations, Inc. During March 2001, $375,000 of the escrow account was released with the remaining $25,000 held for costs related to certain patent litigation.

Investing Cash Outlook -

Of the approximately $1,053,000 invested in 2001, approximately $529,000 was invested in leasehold improvements associated with the scale-up to the manufacturing facility for VITOSS and CORTOSS which is substantially completed. Accordingly, we expect to decrease the rate at which we invest funds related to improvements to our leased office and manufacturing facility. We anticipate new capital spending will be required in support of the RHAKOSS Synthetic Bone Implant program.

Net cash provided by financing activities

During June 2001, the investor in the August 2000 private placement acquired 206,830 shares of our Common Stock for $.01 per share in accordance with the anti-dilution provisions contained in a subscription agreement dated August 22, 2000 due to the equity transactions in January, March and April 2001.

During April 2001, we entered into a Development and Distribution Agreement with Japan Medical Dynamic Marketing, Inc. ("MDM"), a Japanese orthopaedic company, under which MDM will be responsible for conducting any development efforts required to apply for the regulatory clearance to market VITOSS in Japan. If clearance is obtained, MDM will distribute, sell and market VITOSS in Japan. In connection with this arrangement, we sold 189,394 shares of Common Stock at $5.28 per share to MDM, raising net proceeds of $1,000,000. Additionally, during April 2001, we sold 740,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $2,692,000.

During March 2001, we sold 1,975,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $7,290,000. In addition, during January 2001, we sold 566,894 shares of our Common Stock and warrants to purchase 566,894 shares of Common Stock at an exercise price of $4.41 per share raising net proceeds of approximately $2,413,000.

During the first six months of 2001 and 2000, we received $58,073 and $860,483,

respectively, from stock option and warrant exercises and purchases of Common Stock under our Employee Stock Purchase Plan. In addition, $361,257 and $297,792 were used to repay capital lease obligations during the first six months of 2001 and 2000, respectively. In June 2001, we borrowed $750,000 on a line of credit with our bank, and we repaid the line in full during July 2001.

Financing Requirements Outlook

The extent and timing of proceeds from future stock option and warrant exercises, if any, are primarily dependent upon our Common Stock's market price, as well as the exercise prices and expiration dates of the stock options and warrants.

We expect to continue to use cash and investments to fund operating and investing activities. We believe our existing cash as of June 30, 2001 of $8,946,838 will be sufficient to meet our currently estimated operating and investing requirements into 2002. However, we do not expect sales to generate cash flow in excess of operating expenses for at least the next year or two, if at all. Prior to exhausting our current cash, we will need to raise additional funds to finance our operating activities. We believe our existing cash as of June 30, 2001 of approximately $8,947,000 will be sufficient to meet our currently estimated operating and investing requirements into 2002. We intend to seek additional funds in 2001. We may seek equity financing which, if satisfactorily completed, would result in dilution to our existing shareholders of Common Stock. Additionally, we may seek funding through debt, strategic alliances with third parties, off-balance sheet or other structured financing arrangements either alone or in combination with equity. These financings could require debt service and/or royalty payment arrangements, which could represent significant expenses and use of cash in future periods and could increase our cash used in operating activities. Additionally, the terms of any such financings may affect our rights to our products. In addition, while terms of such financings are begin negotiated, restrictions may be imposed that affect our ability to concurrently pursue alternative financing arrangements. The terms of these financings could place restrictions on how we may operate our business, sell or license our products, or our ability to enter into business combinations with, or sell a product line to, other corporate entities. Our future capital requirements will depend upon numerous factors, including the extent to which unforeseen clinical, regulatory, manufacturing or sales and marketing difficulties arise or to which our products gain market acceptance, the acquisition and defense of intellectual property rights, the development of strategic alliances for the marketing of certain of our products, and other competitive developments. In addition, although we have no present commitments or understandings to do so, we may seek to expand our operations and product line via acquisitions or joint ventures and any such acquisitions or joint ventures may increase our capital requirements.

Results of Operations

This section should be read in conjunction with the more detailed discussion under "Liquidity and Capital Resources." A summary of net revenues and expenses for the three and six months ended June 30, 2001 and 2000 are as follows:

<TABLE>
<CAPTION>

	Three Months Ended June 30,		% Increase (Decrease)	Six Months Ended June 30,		% Increase (Decrease)
	2001	2000	2001 versus 2000	2001	2000	2001 versus 2000
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Revenues:						
VITOSS	$ 953,603	$ --	100 %	$ 1,180,009	$ ---	100 %
BIOGRAN	---	--	--	---	532,967	(100)
	953,603	--		1,180,009	532,967	
Gross Profit	699,965	--	100	906,971	368,926	146
General and Administrative Expenses	1,136,616	1,077,867	5	2,045,649	2,044,455	--
Selling and Marketing Expenses	1,350,302	679,419	99	2,521,610	1,508,170	67
Research and Development Expenses	1,881,165	1,925,100	(2)	3,702,559	3,310,634	12

Total Operating Expenses	4,368,083	3,682,386	19	8,269,818	6,863,259	20
Other Income, net	69,632	47,262	47	98,564	93,451	5
Net gain on sale of product line	---	---	---	375,000	3,070,921	---
Net (Loss)	(3,598,486)	(3,635,124)	(1)	(6,889,283)	(3,329,961)	107

</TABLE>

Revenues Revenue for the three and six months ended June 30, 2001 were $953,603 and $1,180,009, respectively, which reflect VITOSS product sales to stocking distributors in Europe and Australia, and to hospitals in the U.S. VITOSS is currently our only product, which has received regulatory clearance for sale in the U.S. or Europe. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the U.S. late in the first quarter of 2001. Future levels of VITOSS product sales are difficult to predict at this early stage of the product launch process and VITOSS sales to-date may not be indicative of future sales levels. Revenues during the first three months of 2000 reflect sales of BIOGRAN product to 3i under a global distribution agreement prior to the closing of the sale of all rights to our BIOGRAN dental grafting product line to 3i in March 2000. There were no revenues from product sales during the second quarter of 2000.

Gross Profit Our VITOSS gross profit for the three and six months ended June 30, 2001 was $699,965, or 73% of revenues and $906,971, or 77% of revenues, respectively. Since all VITOSS product sold during the first three months of 2001 was produced prior its regulatory approval, the costs of producing that product was recorded as research and development expense in prior periods and in accordance with SFAS No. 2 "Accounting for Research and Development Costs," which stipulates that the costs of producing inventory prior to the receipt of

regulatory approval be recorded as research and development expense. Accordingly, a substantial portion of the costs of producing the VITOSS product sold during the first quarter of 2001 was not reflected in cost of sales; however, VITOSS gross profit for the three months ended June 30, 2001 reflects product produced subsequent to regulatory approval (see Operating Expenses, below).

The gross profit as a percentage of revenues is expected to vary depending upon the proportion of sales derived from stocking distributors outside of the U.S., where margins are lower, in comparison to sales derived from commissioned sales agents in the U.S., where margins are higher.

Gross profit for the six months ended June 30, 2000 was $328,926 or 69% of revenues and related to sales of BIOGRAN(R).

Operating Expenses Operating expenses for the three and six months ended June 30, 2001 and 2000 were $4,368,083 and $8,269,818 compared to $3,682,386 and $6,863,259, respectively. Selling and marketing expenses increased for both the three and six month periods ended June 30, 2001 as a result of the development and printing of marketing and sales literature and the hiring of employees in support of the VITOSS product launch in the U.S. late in the first quarter of 2001. The 2001 increase is also attributable to the commission expense incurred on U.S. VITOSS product sales to the independent commissioned sales agencies in the U.S.

The increase from year-to-date 2000 to the same period in 2001 in research and development expenses is attributable to the further development of our product pipeline, including pre-clinical and clinical activities associated with CORTOSS and RHAKOSS. As discussed in Gross Profit above research and development expenses decreased during the second quarter of 2001 in comparison to the same quarter last year as a result of certain costs being capitalized in inventory that are associated with the manufacturing of VITOSS. In addition, research and development expenses during the second quarter of 2001 include significant pre-production and validation costs associated with CORTOSS.

Other income During the three and six months ended June 30, 2001, net interest income increased as a result of higher average cash balances during 2001 in comparison to 2000.

Net gain on sale of product line In March 2000, we sold our BIOGRAN dental grafting product line to 3i for $3,900,000. We received proceeds of $3,500,000, with an additional $400,000 that was held in an escrow account until March 2001. In March 2000, we realized a net gain on the transaction of $3,070,921. During March 2001, an additional gain of $375,000 was realized when these proceeds from the escrow account were released.

Net Loss As a result of the above noted items, we had a net loss for the three and six months ended June 30, 2001 of $3,598,486 and $6,889,283 as compared to net losses for the same periods in 2000 of $3,635,124 and $3,329,961, respectively. VITOSS is currently our only product, which has received regulatory clearance for sale in the U.S. or Europe. We began selling VITOSS in Europe in the fourth quarter of 2000 and began selling VITOSS in the U.S. late in the first quarter of 2001. While our goal is to reduce our net losses in future periods, we expect to continue to incur operating expenses related to regulatory approval for CORTOSS, product development efforts for RHAKOSS as well as for expanding the clinical applications for CORTOSS and VITOSS, expanding our marketing and sales activities and further development of our manufacturing capabilities. Future levels of VITOSS product sales are difficult to predict at this early stage of the product launch process and VITOSS sales to-date may not be indicative of future sales levels. We expect to continue to incur significant operating losses for at least the next year or two.

Net Loss Per Common Share As a result of the above noted items, for the three months ended June 30, 2001, we have a net loss per common share of $(.22) on 16,633,954 weighted average common shares outstanding compared to a net loss per common share of $(.31) on 11,584,563 weighted average common shares outstanding for the same period during 2000.

For the six months ended June 30, 2001, we have a net loss per common share of $(.45) on 15,404,842 weighted average common shares outstanding compared to a net loss per common share of $(.29) on 11,486,953 weighted average common shares outstanding for the same period during 2000.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Currency Risk

The functional currency for our European branch operation is the Euro. Accordingly, all assets and liabilities related to this operation are translated at the current exchange rates at the end of each period. The resulting translation adjustments are accumulated in a separate component of Shareholders' Equity.

Market Risk

We are exposed to market risk through changes in market interest rates that could affect the value of our short-term investments. Interest rate changes would result in unrealized gains or losses in the market value of the short-term investments due to differences between the market interest rates and rates at the inception of the short-term investment.

PART II. OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

During June 2001, Brown Simpson Partners I, Ltd. acquired 206,830 shares of our Common Stock for $.01 per share in accordance with the anti-dilution provisions contained in a subscription agreement dated August 22, 2000, due to the equity transactions in January, March and April 2001.

During April 2001, we entered into a Development and Distribution Agreement with an orthopaedic company in Japan under which the orthopaedic company will be responsible for conducting any development efforts required to apply for the regulatory clearance to market VITOSS in Japan. If clearance is obtained, the orthopaedic company will distribute, sell and market VITOSS in Japan. In connection with this arrangement, we sold 189,394 shares of Common Stock at $5.28 per share to the Japanese company raising net proceeds of $1,000,000. The issuance of these securities was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D as an issuer transaction not involving a public offering.

In addition, during April 2001, we sold 740,000 shares of our Common Stock at $4.00 per share in a private equity financing raising net proceeds of approximately $2,692,000. In connection with this financing, we paid placement agent fees consisting of two-year warrants to purchase a total of 22,200 shares of our Common Stock at an exercise price of $4.00 per share valued at $27,500 and cash commissions of $207,200. The issuance of these securities was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D as an issuer transaction not involving a public offering.

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.

ORTHOVITA, INC.
(Registrant)

August 3, 2001

By: /s/ Bruce A. Peacock

Bruce A. Peacock
Chief Executive Officer and President
(Principal executive officer)

August 3, 2001

By: /s/ Joseph M. Paiva

Joseph M. Paiva
Vice President and Chief Financial Officer
(Principal financial and accounting officer)