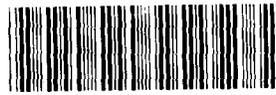
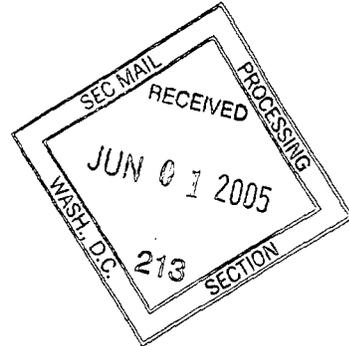


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# ORTEC INTERNATIONAL, INC.

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THOMSON *E*  
FINANCIAL

## ANNUAL REPORT

The performance of OrCel<sup>®</sup> in treating venous ulcers in our pilot trial and the recently completed pivotal clinical trial have been strong. In comparison to our 12-week data, OrCel<sup>®</sup>'s leading competition, did not achieve similar efficacy results in their clinical trial until six months. In addition, our manufacturing process controls and quality systems and safety have been reviewed by the FDA. The remaining requirement for approval of OrCel<sup>®</sup> for venous ulcers is submitting an amendment to the clinical section of our PMA which meets FDA's expectations for safety and efficacy and includes the data of this confirmatory trial.

While it was our expectation to have an FDA approval for use of OrCel<sup>®</sup> in venous ulcer patients at this time given OrCel<sup>®</sup>'s continued demonstration of efficacy in both our pilot clinical trial and our most recent pivotal trial, we believe and expect that OrCel<sup>®</sup> will perform as well in the confirmatory trial requested by the FDA and pave the way for the approvability of OrCel<sup>®</sup> for treating venous ulcer patients.

**Entered into Agreements to Leverage our Core Technologies for Potential Application to other Therapeutic Areas**

We entered into an agreement with ES Cell International, Pte Ltd (ESI) to collaborate in the development of ESI's human Embryonic Stem Cell (hES) derived cell therapy products. Under the terms of the agreement, we receive milestone payments and royalties for giving ESI the right to use human skin cells generated from a Food and Drug Administration (FDA) approved cell line developed and manufactured by Ortec for use in our OrCel<sup>®</sup> product. Cells produced from our cell line are expected to be used by ESI in research and development and in commercialization of their stem cell products.

In October, 2004 Ortec formed a joint venture partnership with Hapto Biotech Inc. (HAPTO) for the purpose of developing promising product leads identified through a research collaboration initiated in September 2002. The partnership seeks to optimize the combination of peptides (active molecules) found in Hapto's Haptide<sup>™</sup> technology with the properties of Ortec's proprietary collagen biomaterial. The joint venture will evaluate the safety and efficacy of a non cellular peptide based collagen biomaterial in promoting the attraction and attachment of healthy cells within the patient's body in regenerating new tissue or repairing wounds. It is believed that this advanced biomaterial may have application to the cosmetic, reconstructive orthopedic and dental markets, as well.

The Center for Tissue Engineering at University of California at Berkeley agreed to evaluate the potential of Ortec's proprietary collagen scaffold for application to cardiovascular tissue regeneration. The initial research will focus on the in vitro growth and differentiation of blood vessel cells, heart precursor cells and adult stem cells in Ortec's collagen scaffold. If these results prove promising, Ortec's collagen scaffold will be tested for cardiovascular therapeutic potential in animal models. Ortec will have the commercial rights to any cardiovascular therapeutic applications that emerge from these studies.

**Obtained FDA Permission to Initiate Pivotal Clinical Trial in Diabetic Foot Ulcer Patients**

The Food and Drug Administration (FDA) has given Ortec permission to initiate a pivotal trial evaluating OrCel<sup>®</sup> in the treatment of diabetic foot ulcers. The DFU trial is expected to be conducted at up to 25 clinical centers and involve up to approximately 200 patients.

The results of Ortec's multicentered controlled pilot study assessing the effectiveness of its product, OrCel<sup>®</sup> in treating diabetic foot ulcers, was featured in the July 2003 issue of the peer reviewed publication "Wounds". The article was entitled "*Effectiveness of OrCel<sup>®</sup> (Bilayered Cellular Matrix) in Health of Neuropathic Diabetic Foot Ulcers: Results of a Multicenter Pilot Trial*".

The results of the trial, as described in the article, demonstrated that in hard to heal diabetic foot ulcers that were less than or equal to 6cm<sup>2</sup> (approximately 70% of the ulcers in the trial were in that category), 47% of the patients treated with OrCel<sup>®</sup> were completely healed compared with 23% of the control group. In addition to OrCel<sup>®</sup> producing a greater percentage of patients with complete healing, the study also showed that the mean rate of reepithelization (wound closure) was significantly higher in the OrCel<sup>®</sup> treated groups.

**Raised \$16 Million of Equity Capital and Simplified our Capital Structure**

We completed a series of equity transactions resulting in gross proceeds of \$6.4 million dollars and converted \$9.6 million of promissory notes issued during the past year into common equity. As planned, we expect to raise additional equity capital during 2005 to fund our operations.

While 2004 was a year in which much was accomplished, it presented its array of challenges. While we overcame many, some remain. Looking ahead, 2005 presents an opportunity for considerable value enhancing activity and opportunity and we look forward to achieving those prospects mindful of the challenges that lay ahead, but confident we have the resolve and demonstrated ability to meet those challenges. We sincerely thank you, our shareholders, for your ongoing support and our valuable employees for their dedication. With your continued support we will continue to persevere and prevail.



Ron Lipstein  
Chief Executive Officer

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**THE COMPANY WILL PROVIDE, WITHOUT CHARGE, TO EACH PERSON SOLICITED UPON SUCH PERSON'S WRITTEN REQUEST, A COPY OF THE COMPANY'S ANNUAL REPORT ON FORM 10-KSB FOR THE FISCAL YEAR ENDED DECEMBER 31, 2004, INCLUDING THE FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES REQUIRED TO BE FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 13a-1 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. SUCH WRITTEN REQUESTS MUST BE SENT TO THE COMPANY, 3960 BROADWAY, NEW YORK 10032, ATTENTION: ALAN SCHOENBART, CHIEF FINANCIAL OFFICER.**

## **OVERVIEW OF BUSINESS**

We are a development stage tissue engineering company that has developed a proprietary and patented technology that we call OrCel® (ORCEL), which is used to stimulate the repair and regeneration of human skin. ORCEL is a two-layered tissue engineered dressing that consists of human derived skin cells, both dermal and epidermal, supported within a porous collagen matrix. The composite matrix is seeded with keratinocytes (epidermal cells) and fibroblasts (dermal cells). When ORCEL is applied to the wound site, it produces a mix of growth factors that stimulates wound closure.

## **MANAGEMENT'S PLAN OF OPERATION**

*The following discussion should be read in conjunction with our financial statements and notes thereto. This discussion may be deemed to include forward-looking statements*

### **Plan of Operation**

On January 5, 2005 we entered into a number of agreements with institutional and accredited investors that provided us with gross aggregate proceeds of \$5,403,302 from the sale of our common stock. All of our outstanding promissory notes to investors at December 31, 2004 totaling \$9,626,626 including accrued interest of approximately \$675,000 (\$658,776 at December 31, 2004) were exchanged for common stock and warrants valued at approximately \$20,600,000 resulting in an approximate loss on extinguishment of \$10,300,000. Additionally the 913 outstanding shares at December 31, 2004 of Series C preferred stock were exchanged for common stock. We also converted the 50 shares of Series B preferred stock outstanding at December 31, 2004 into common stock. Certain purchasers, Series C Holders and holders of the Notes whose participation in these transactions would result in ownership of common stock in excess of 9.99% of our issued and outstanding shares of common stock could, and did elect, to receive instead of our common stock, shares of our Series D convertible preferred stock convertible into the same number of shares of our common stock. Investors in this placement were given the right to purchase on the same terms additional common stock within 45 days of the original placement. We raised an additional \$127,719 as a result of the exercise by certain investors of this right.

In February 2005 we completed a single private placement which raised an additional \$100,000. Also in February 2005 we obtained \$220,000 of short-term financing to fund our directors and officers insurance policy.

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern. As discussed in Note 1 to the accompanying consolidated financial statements included in Item 7, we incurred a net loss applicable to common shareholders of \$17.1 million during the year ended December 31, 2004, and, as of that date, our current liabilities exceeded our current assets by \$14.6 million, our total liabilities exceeded our total assets by \$36.4 million and we have a deficit accumulated in the development stage of \$120.5 million. These factors, among others, raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. The report of our independent registered public accounting firm contains an explanatory paragraph regarding our ability to continue as a going concern.

We incur slightly in excess of \$800,000 monthly primarily on personnel and occupancy costs, insurance, fees to Cambrex for a production suite and technology transfer activities, various research and development activities, and payment of past due obligations. We anticipate that we will have to raise additional funds in the next twelve months. Our funds on hand, together with funds raised by us through February 2005, at our current utilization rate should carry us through April 2005. We require substantial funding to continue our research and development activities, clinical trials, manufacturing, sales, distribution and administrative activities, and commercialization processes. The funding we require will enable us to execute our production and distribution plans with Cambrex and prepare for sales in 2005, pay a portion of our past due obligations, initiate the pivotal clinical trial for the use of ORCEL in its cryopreserved form for the treatment of diabetic foot ulcers, and provide for our general and corporate working capital requirements for 2005. We believe that our cash and cash equivalents on hand at December 31, 2004, (approximately \$.2 million) and proceeds from the \$5.6 million financing

we completed in the first quarter of 2005, as well as an additional \$10 million we hope to raise in 2005, may enable us to continue our operations for the next twelve months. There can be no assurances that we can raise additional funds.

Our plan of operation for the next twelve months is to work towards obtaining regulatory clearance for commercial sales of cryopreserved ORCEL to heal venous stasis ulcers. In anticipation of regulatory clearance, we are working with Cambrex, our manufacturer and distribution agent, to be in a position to launch commercial sales of ORCEL. We expect to continue our preparatory commercialization activities throughout 2005. These preparatory commercialization activities include defining our market and advertising strategy, branding, market research, interviews with physicians, publishing articles, attending trade shows, reimbursement strategy and sales force training. Our research and development activities are focused on increasing production capacity without requiring Cambrex to construct a larger production facility for ORCEL and on lowering the cost of producing ORCEL. In addition to our continuing expenditures for personnel we have budgeted approximately \$325,000 for capital equipment related to these process development efforts. We hope to complete the transfer of our technology to produce ORCEL to Cambrex. This includes transferring our current ORCEL production process, and developing processes to increase manufacturing capacity and reduce manufacturing costs. We also intend to transfer to Cambrex our cell growth and expansion processes and new processes designed to increase capacity and reduce costs of the cell expansion process. Additionally we plan to:

- invest approximately \$175,000 for equipment which will allow us to expand our collagen sponge manufacturing capacity;
- invest approximately \$300,000 in developing more advanced thaw-rinse equipment which can be used by medical practitioners to prepare our cryopreserved product for patient application;
- begin clinical trials to evaluate the use of ORCEL for the treatment of diabetic foot ulcers;
- continue our collaboration with Hapto Biotech Inc. in developing an advanced biomaterial that may be used for wound healing as well as for cosmetic, reconstructive orthopedic and dental purposes; and
- explore opportunities where we can leverage our cell culturing biomaterials and regulatory knowledge base and expertise, especially with respect to application to embryonic stem cell research.

We do not presently expect any significant changes in personnel in 2005.

#### **Other Liquidity Matters**

Our agreement with Paul Royalty Fund (PRF) provides that in certain events PRF may, at its option, compel us to repurchase the interest in our revenues that we sold to PRF for a price equal to the \$10,000,000 PRF paid us plus an amount that would yield PRF a 30% per annum internal rate of return on its \$10,000,000 investment. Among the events that would entitle PRF to compel us to repurchase its interest in our revenues at that price is if we are insolvent or if we are unable to pay our debts as they become due. Our agreement with PRF provides that in determining such insolvency any amount we owe to PRF is excluded in calculating our net worth (or negative net worth). In addition, although we are currently trying to manage our debt we are not paying our debts as they become due. As defined in our agreement with PRF we are currently insolvent. As a result of this insolvency our obligation under the revenue interest assignment is stated at \$22,738,110, the amount PRF could compel us to repurchase their revenue interest at December 31, 2004. Although in December 2004 we entered into an eighteen-month forbearance agreement providing that PRF would not prior to July 1, 2006 compel us to repurchase its interest in our revenues because of our insolvency, as of December 31, 2004 we were still considered insolvent and therefore were required to record as an obligation we owe PRF the amount to provide PRF with a 30% internal rate of return on its \$10,000,000 investment. If in the future PRF exercised its right to compel us to repurchase its interest in our revenues and we did not have the funds to do so, PRF could foreclose its security interest in our U.S. patents, patent applications and trademarks and in such event we will have to discontinue our business operations. Outside of a repurchase event, more fully explained in Note 11 of the consolidated financial statements included in Item 7, PRF would be entitled to the applicable royalty percentages of our future revenues in North America. We estimate that PRF will need us to sell, over the remaining approximate six years under our agreement, at least \$300,000,000 of ORCEL to recoup an amount approximately equivalent to their initial \$10,000,000 investment.

#### **Off-Balance Sheet Arrangements**

We had no off-balance sheet arrangements as of December 31, 2004.

## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

### Market Information

Our common stock commenced trading on January 19, 1996, under the symbol "ORTC." The common stock traded on the NASDAQ Small Cap market until August 2002, when it was delisted from the Small Cap market and commenced trading on the National Association of Securities Dealers' Bulletin Board, where it presently trades under the symbol "ORTN.OB." The following table sets forth the high and low sales prices of our common stock as reported by the Bulletin Board for each full quarterly period within the two most recent fiscal years.

	<u>HIGH</u>	<u>LOW</u>
<i>2004 Quarter</i>		
First	\$3.55	\$1.95
Second	2.95	2.05
Third	2.40	1.35
Fourth	2.30	0.89
<i>2003 Quarter</i>		
First	5.00	1.50
Second	2.70	1.70
Third	2.25	1.25
Fourth	2.55	1.45

### Security Holders

To the best of our knowledge, at February 28, 2005, there were 279 record holders of our common stock. We believe there are more than 1,500 beneficial owners of our common stock whose shares are held in "street name."

### Dividends

We have not paid and have no current plans to pay dividends on our common stock. Under of our Agreement with Paul Royalty Fund we agreed not to issue any new debt or equity securities that contain cash dividend, or mandatory redemption provisions.

*You may get updated information about Ortec either through the internet at the SEC's website at <http://www.sec.gov>, or from us by calling (212) 740-6999, extension 261. Our Form 10-QSB for the quarter ended March 31, 2005 will provide you with our unaudited financial statements for the three months ended March 31, 2005.*

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ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)  
INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm - BDO Seidman, LLP	F-2
Report of Registered Independent Public Accounting Firm - Grant Thornton LLP	F-3
Consolidated Balance Sheet as of December 31, 2004	F-4
Consolidated Statements of Operations for the years ended December 31, 2004 and 2003, and for the cumulative period from March 12, 1991 (inception) to December 31, 2004	F-5
Consolidated Statements of Shareholders' Equity (Deficit) for the cumulative period from March 12, 1991 (inception) to December 31, 2004	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2004 and 2003, and for the cumulative period from March 12, 1991 (inception) to December 31, 2004	F-8
Notes to Consolidated Financial Statements	F-10

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders  
Ortec International, Inc.  
New York, New York

We have audited the accompanying consolidated balance sheet of Ortec International, Inc. (a development stage enterprise) as of December 31, 2004 and the related consolidated statements of operations, shareholders' deficit, and cash flows for the year then ended and for the period from March 12, 1991 (inception) to December 31, 2004. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We did not audit the consolidated statements of operations, shareholders' deficit and cash flows for the period from March 12, 1991 (inception) to December 31, 2003, which reflect product revenue of approximately \$.3 million, expenses of approximately \$96.9 million, preferred stock dividends and discounts of approximately \$6.7 million, cash used in operating activities of \$69.9 million, cash used in investing activities of approximately \$6.2 million and cash provided by financing activities of \$77.4 million. Those financial statements were audited by another auditor whose report has been furnished to us, and our opinion, insofar as it relates to the amounts included for such period, is based solely on the report of the other auditor.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit and the report of the other auditor provide a reasonable basis for our opinion.

In our opinion, based on our audit and the report of the other auditor, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Ortec International, Inc. at December 31, 2004, and the results of the Company's operations and cash flows for the year then ended and for the period from March 12, 1991 (inception) to December 31, 2004, in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1, the Company incurred a net loss applicable to common shareholders of \$17.1 million during the year ended December 31, 2004, and, as of that date, the Company's current liabilities exceeded its current assets by \$14.6 million, its total liabilities exceeded its total assets by \$36.4 million and the Company has a deficit accumulated in the development stage of \$120.5 million. These factors, among others, as discussed in Note 1 to the consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO Seidman, LLP

New York, New York  
March 23, 2005

## REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

Directors and Stockholders  
Ortec International, Inc.

We have audited the accompanying consolidated statements of operations, cash flows and shareholders' equity (deficit) for the year ended December 31, 2003, of Ortec International, Inc. and Subsidiary (a development stage enterprise) (the "Company") and the related consolidated statements of operations, cash flows and shareholders' equity (deficit) for the period from March 12, 1991 (inception) through December 31, 2003. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of Ortec International, Inc. and Subsidiary's operations, cash flows and changes in shareholders' equity (deficit) for the year ended December 31, 2003 and the period from March 12, 1991 (inception) through December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the 2003 financial statements, the Company incurred a net loss applicable to common shareholders of \$21,449,131 during the year ended December 31, 2003, and, as of that date, the Company's current liabilities exceeded its current assets by \$25,360,740, its total liabilities exceeded its total assets by \$24,476,407, and the Company has a deficit accumulated in its development stage of \$103,307,740. These factors, among others, as discussed in Note 1 to the 2003 financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the 2003 financial statements. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

GRANT THORNTON LLP  
New York, New York

March 12, 2004, except for Note 14 to the 2003 financial statements as to which date is March 23, 2004

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**CONSOLIDATED BALANCE SHEET**

	December 31, 2004
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	\$ 227,370
Prepaid and other current assets	128,938
Total current assets	356,308
Property and equipment, net	326,946
Patent application costs, net	587,276
Deposits	139,159
Other assets	39,667
Total assets	\$ 1,449,356
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>	
Current liabilities:	
Accounts payable and accrued expenses	\$ 4,912,195
Current maturities of loan payable	203,462
Capital lease obligation - current	51,584
Current maturities of promissory notes	9,784,691
Total current liabilities	14,951,932
Obligation under revenue interest assignment	22,738,110
Promissory notes, less current portion	91,717
Capital lease obligation, less current portion	23,951
Total liabilities	37,805,710
<b>COMMITMENTS AND CONTINGENCIES</b>	
Shareholders' deficit:	
Preferred stock, \$.001 par value; authorized, 1,000,000 shares:	
Redeemable convertible	
Series B, stated value \$10,000 per share; authorized 1,200 shares; 50 shares issued and outstanding; liquidation preference of \$500,000	270,859
Series C, stated value \$6,000 per share; authorized 2,000 shares; 913 shares issued and outstanding; liquidation preference of \$5,476,254	3,529,289
Convertible	
Series D, stated value \$10,000 per share; authorized 2,000 shares; 717 shares issued and outstanding; liquidation preference of \$7,167,124	3,567,652
Common stock, \$.001 par value; authorized, 200,000,000 shares; 6,372,052 shares issued and 6,370,052 outstanding	6,372
Additional paid-in capital	76,899,663
Deficit accumulated during the development stage	(120,452,544)
Treasury stock, 2,000 shares at cost	(177,645)
Total shareholders' deficit	(36,356,354)
Total liabilities and shareholders' deficit	\$ 1,449,356

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC  
(A DEVELOPMENT STAGE ENTERPRISE)

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year ended December 31,		Cumulative From March 12, 1991 (inception) to December 31,
	2004	2003	2004
Product Revenue	\$ -	\$ -	\$ 265,665
Expenses			
Product and laboratory costs	3,014,461	2,956,217	27,166,585
Personnel	3,857,052	3,938,116	37,185,487
General and administrative	1,664,294	2,586,476	19,035,351
Rent	481,782	627,861	3,972,294
Consulting	13,045	(27,735)	5,702,651
Interest and other expense	6,745,928	4,735,292	19,781,830
Interest and other income	(398,662)	(14,889)	(2,670,647)
Lease termination costs	-	1,119,166	1,119,166
Loss on extinguishments of debt and series A preferred shares	-	-	1,004,027
	15,377,900	15,920,504	112,296,744
Net loss	(15,377,900)	(15,920,504)	(112,031,079)
Preferred stock dividend	643,904	1,259,627	3,029,465
Preferred stock and warrants deemed dividends and discounts	1,123,000	4,269,000	5,392,000
Net loss applicable to common shareholders	\$ (17,144,804)	\$ (21,449,131)	\$ (120,452,544)
Net loss per share			
Basic and diluted	\$ (3.03)	\$ (5.11)	
Weighted average shares outstanding			
Basic and diluted	5,655,406	4,198,107	

The accompanying notes are an integral part of these statements.

**ORTEC INTERNATIONAL INC.**  
**(A DEVELOPMENT STAGE ENTERPRISE)**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**

	Common Stock		Preferred Stock			Additional paid-in capital	Deficit accumulated during the development stage	Treasury stock	Total shareholders' equity (deficit)
	Shares	Amount	Series B	Series C	Series D				
March 12, 1991 (inception) to December 31, 1991									
Founders	155,382	\$ 155	-	-	-	\$ 715	-	-	\$ 870
First private placement (\$3.00 per share)	21,744	22	-	-	-	64,978	-	-	65,000
The Director (\$11.50 and \$53.00 per share)	14,902	15	-	-	-	249,985	-	-	250,000
Second private placement (\$94.25 per share)	5,302	5	-	-	-	499,995	-	-	500,000
Share issuance expense	-	-	-	-	-	(21,118)	-	-	(21,118)
Net loss	-	-	-	-	-	-	(281,644)	-	(281,644)
Balance at December 31, 1991	197,330	197	-	-	-	794,555	(281,644)	-	513,108
Second private placement (\$94.25 per share)	2,646	3	-	-	-	250,003	-	-	250,006
Second private placement (\$94.25 per share)	2,286	2	-	-	-	215,465	-	-	215,467
Stock purchase agreement with the Director (\$94.25 per share)	3,182	3	-	-	-	299,995	-	-	299,998
Share issuance expense	-	-	-	-	-	(35,477)	-	-	(35,477)
Net loss	-	-	-	-	-	-	(785,941)	-	(785,941)
Balance at December 31, 1992	205,444	205	-	-	-	1,524,541	(1,067,585)	-	457,161
Third private placement (\$100.00 per share)	10,965	11	-	-	-	1,096,489	-	-	1,096,500
Third private placement (\$100.00 per share)	2,250	2	-	-	-	224,998	-	-	225,000
Stock purchase agreement with Home Insurance Company (\$90.00 per share)	11,112	11	-	-	-	999,988	-	-	999,999
Stock purchase agreement with the Director (\$94.25 per share)	2,122	2	-	-	-	199,998	-	-	200,000
Shares issued in exchange for commission	60	1	-	-	-	5,999	-	-	6,000
Share issuance expenses	-	-	-	-	-	(230,207)	-	-	(230,207)
Net loss	-	-	-	-	-	-	(1,445,624)	-	(1,445,624)
Balance at December 31, 1993	231,953	232	-	-	-	3,821,806	(2,513,209)	-	1,308,829
Fourth private placement (\$100.00 per share)	3,946	4	-	-	-	397,708	-	-	397,712
Stock purchase agreement with Home Insurance Company (\$100.00 per share)	5,000	5	-	-	-	499,995	-	-	500,000
Share issuance expense	-	-	-	-	-	(8,697)	-	-	(8,697)
Net loss	-	-	-	-	-	-	(1,675,087)	-	(1,675,087)
Balance at December 31, 1994	240,899	241	-	-	-	4,710,812	(4,188,296)	-	522,757
Rent forgiveness	-	-	-	-	-	40,740	-	-	40,740
Net loss	-	-	-	-	-	-	(1,022,723)	-	(1,022,723)
Balance at December 31, 1995	240,899	241	-	-	-	4,751,552	(5,211,019)	-	(459,226)
Initial public offering	120,000	120	-	-	-	5,999,880	-	-	6,000,000
Exercise of warrants	3,389	3	-	-	-	33,882	-	-	33,885
Fifth private placement (\$64.90 per share)	95,911	96	-	-	-	6,220,701	-	-	6,220,797
Share issuance expenses	-	-	-	-	-	(1,580,690)	-	-	(1,580,690)
Stock options issued for services	-	-	-	-	-	152,000	-	-	152,000
Net loss	-	-	-	-	-	-	(2,649,768)	-	(2,649,768)
Balance at December 31, 1996	460,199	460	-	-	-	15,577,325	(7,860,787)	-	7,716,998
Exercise of warrants	115,878	116	-	-	-	10,822,675	-	-	10,822,791
Share issuance expenses	-	-	-	-	-	(657,508)	-	-	(657,508)
Stock options and warrants issued for services	-	-	-	-	-	660,000	-	-	660,000
Net loss	-	-	-	-	-	-	(4,825,663)	-	(4,825,663)
Balance at December 31, 1997	576,077	576	-	-	-	26,402,492	(12,686,450)	-	13,716,618
Exercise of warrants	22,149	22	-	-	-	1,281,935	-	-	1,281,957
Stock options and warrants issued for services	-	-	-	-	-	1,920,111	-	-	1,920,111
Sixth private placement	20,000	20	-	-	-	1,788,678	-	-	1,788,698
Sixth private placement - warrants issued	-	-	-	-	-	211,302	-	-	211,302
Share issuance expenses	-	-	-	-	-	(48,000)	-	-	(48,000)
Purchase of 660 shares of treasury stock (at cost)	-	-	-	-	-	-	-	(67,272)	(67,272)
Net loss	-	-	-	-	-	-	(8,412,655)	-	(8,412,655)
Balance at December 31, 1998	618,226	618	-	-	-	31,556,518	(21,099,105)	(67,272)	10,390,759
Exercise of warrants	1,410	1	-	-	-	14,102	-	-	14,103
Stock options and warrants issued for services	-	-	-	-	-	64,715	-	-	64,715
Seventh private placement (\$87.50 per share)	38,916	39	-	-	-	3,168,746	-	-	3,168,785
Seventh private placement - investor warrants	-	-	-	-	-	236,291	-	-	236,291
Seventh private placement - placement agent warrants	-	-	-	-	-	232,000	-	-	232,000
Eighth private placement (\$55.00 per share)	163,637	164	-	-	-	8,999,838	-	-	9,000,002
Share issuance expenses	-	-	-	-	-	(619,908)	-	-	(619,908)
Purchase of 910 shares of treasury stock (at cost)	-	-	-	-	-	-	-	(75,518)	(75,518)
Net loss	-	-	-	-	-	-	(10,040,509)	-	(10,040,509)
Balance at December 31, 1999	822,189	822	-	-	-	43,652,302	(31,139,614)	(142,790)	12,370,720
Exercise of options and warrants	17,554	17	-	-	-	327,265	-	-	327,282
Stock options and warrants issued for services	-	-	-	-	-	56,265	-	-	56,265
Ninth private placement (\$150.00 per share)	6,667	7	-	-	-	999,998	-	-	1,000,005
Ninth private placement - placement agent warrants	-	-	-	-	-	23,000	-	-	23,000
Tenth private placement (\$67.50 per share)	124,757	125	-	-	-	8,420,946	-	-	8,421,071
Share issuance expenses	-	-	-	-	-	(641,500)	-	-	(641,500)
Purchase of 430 shares of treasury stock (at cost)	-	-	-	-	-	-	-	(34,855)	(34,855)
Net loss	-	-	-	-	-	-	(12,129,663)	-	(12,129,663)
Balance at December 31, 2000	971,167	971	-	-	-	52,838,276	(43,269,277)	(177,645)	9,392,325
Stock options issued for services	-	-	-	-	-	188,080	-	-	188,080
Net loss	-	-	-	-	-	-	(15,885,377)	-	(15,885,377)
Balance at December 31, 2001 (carried forward)	971,167	971	-	-	-	53,026,356	(59,154,654)	(177,645)	(6,304,972)

**ORTEC INTERNATIONAL INC.**  
**(A DEVELOPMENT STAGE ENTERPRISE)**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**

	Common Stock		Preferred Stock			Additional paid-in capital	Deficit accumulated during the development stage	Treasury stock	Total shareholders' equity (deficit)
	Shares	Amount	Series B	Series C	Series D				
Balance at December 31, 2001 (brought forward)	971,167	971	-	-	-	53,026,356	(59,154,654)	(177,645)	(6,304,972)
Exercise of options and warrants	35,720	36	-	-	-	321	-	-	357
Stock options and warrants issued for services	-	-	-	-	-	113,060	-	-	113,060
Warrants issued with convertible debentures	-	-	-	-	-	440,523	-	-	440,523
Warrants issued with convertible redeemable preferred stock	-	-	-	-	-	559,289	-	-	559,289
Convertible debenture conversion benefit	-	-	-	-	-	1,042,663	-	-	1,042,663
Redeemable convertible preferred stock conversion benefit	-	-	-	-	-	1,097,886	-	-	1,097,886
Issuance of series B preferred stock (938 shares) (\$10,000 per share)	-	-	9,382,742	-	-	-	-	-	9,382,742
Warrants issued and exercised with preferred stock	938,275	938	(3,479,043)	-	-	3,485,443	-	-	7,338
Shares issuance costs - preferred stock	-	-	(866,612)	-	-	304,615	-	-	(561,997)
Preferred stock dividends	375,315	375	-	-	-	1,125,559	(1,125,934)	-	-
Net loss	-	-	-	-	-	-	(21,578,021)	-	(21,578,021)
Balance at December 31, 2002	2,320,477	2,320	5,037,087	-	-	61,195,715	(81,858,609)	(177,645)	(15,801,132)
Exercise of options and warrants	398,750	399	-	-	-	12,567	-	-	12,966
Issuance of preferred stock: series B (200 shares), series C (948 shares)	-	-	2,000,000	5,690,000	-	-	-	-	7,690,000
Warrants issued with preferred stock	-	-	(490,567)	(1,225,632)	-	1,716,199	-	-	-
Warrants issued for services	-	-	-	-	-	87,000	-	-	87,000
Share issuance costs - preferred stock	-	-	(393,488)	(797,327)	-	359,078	-	-	(831,737)
Conversion of series B preferred stock (605 shares) into common stock	2,421,556	2,422	(3,253,571)	-	-	3,251,149	-	-	-
Conversion of series B preferred stock into series D preferred stock (483 shares)	-	-	(2,628,602)	-	2,628,602	-	-	-	-
Preferred stock deemed dividends and discounts	-	-	-	-	-	4,269,000	(4,269,000)	-	-
Preferred stock dividends	92,308	92	-	-	-	922,985	(923,077)	-	-
Common stock dividend to be distributed on series C preferred stock	-	-	-	-	-	336,550	(336,550)	-	-
Common stock to be issued in connection with promissory notes	-	-	-	-	-	287,000	-	-	287,000
Adjustment for one for ten reverse stock split	74	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(15,920,504)	-	(15,920,504)
Balance at December 31, 2003	5,233,165	5,233	270,859	3,667,041	2,628,602	72,437,243	(103,307,740)	(177,645)	(24,476,407)
Common stock issued in connection with previously issued notes	157,000	157	-	-	-	(157)	-	-	-
Common stock issued in connection with promissory notes	331,831	332	-	-	-	745,870	-	-	746,202
Common stock (277,020) and 34.31 shares of series D preferred to be issued in connection with agreements which extended due date of promissory notes	-	-	-	-	-	828,540	-	-	828,540
Common stock issued in connection with exercise of warrants	32,460	32	-	-	-	293	-	-	325
Conversion of 35.62 shares of series C preferred stock into common stock	106,872	107	-	(137,752)	-	137,645	-	-	-
Payment of dividends on 35.62 shares of series C preferred stock in common stock	13,743	14	-	-	-	30,085	(30,099)	-	-
Common stock and series D preferred (233.83 shares) issued in connection with special warrant offer	496,981	497	-	-	939,050	498,472	-	-	1,438,019
Common stock dividend to be distributed on series B and series C preferred stock	-	-	-	-	-	613,805	(613,805)	-	-
Option issued to director for services	-	-	-	-	-	398,574	-	-	398,574
Warrant issued for services	-	-	-	-	-	94,393	-	-	94,393
Warrant issued in connection with lease	-	-	-	-	-	18,500	-	-	18,500
Share issuance expenses	-	-	-	-	-	(26,600)	-	-	(26,600)
Special warrant offer deemed dividends	-	-	-	-	-	1,123,000	(1,123,000)	-	-
Net loss	-	-	-	-	-	-	(15,377,900)	-	(15,377,900)
Balance at December 31, 2004	6,372,052	\$6,372	\$270,859	\$3,529,289	\$3,567,652	\$76,899,663	\$(120,452,544)	\$(177,645)	\$(36,356,354)

The accompanying notes are an integral part of these statements.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year ended December 31,		Cumulative From March 12, 1991 (inception) to December 31, 2004
	2004	2003	2004
<b>Cash flows from operating activities</b>			
Net loss	\$ (15,377,900)	\$ (15,920,504)	\$ (112,031,079)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	466,966	651,661	5,274,872
Allowance for doubtful accounts	-	5,374	5,374
Unrealized loss on marketable securities	-	-	11,404
Realized loss on marketable securities	-	-	5,250
(Gain) / loss on sale of property and equipment	(26,802)	(40,204)	(58,642)
Cost to terminate lease on New Jersey facility	-	836,032	836,032
Non-cash stock compensation	94,000	87,000	3,335,231
Non-cash interest	1,856,832	-	1,856,832
Non-cash imputed interest	4,184,254	4,594,580	16,091,260
Gain on loan adjustment	(236,000)	-	(236,000)
Loss on extinguishments of debt & series A preferred stock	-	-	1,004,027
Purchase of marketable securities	-	-	(19,075,122)
Sales of marketable securities	-	-	19,130,920
Change in operating assets and liabilities			
Other current assets and other assets	(96,665)	54,804	(38,054)
Accounts payable and accrued liabilities	1,298,208	437,161	6,176,957
Net cash used in operating activities	<u>(7,837,107)</u>	<u>(9,294,096)</u>	<u>(77,710,738)</u>
<b>Cash flow from investing activities</b>			
Purchases of property and equipment	(81,622)	(11,823)	(4,547,342)
Proceeds from sale of property and equipment	14,025	75,000	145,926
Payments for patent applications	(48,975)	(11,589)	(1,020,706)
Organization costs	-	-	(10,238)
Deposits	-	(75,000)	(806,273)
Purchases of marketable securities	-	-	(594,986)
Sale of marketable securities	-	-	522,532
Net cash used in investing activities	<u>(116,572)</u>	<u>(23,412)</u>	<u>(6,311,087)</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of notes payable	6,506,626	3,140,000	10,162,126
Proceeds from issuance of common stock	-	-	53,550,522
Proceeds from exercise of warrants	1,338,344	12,966	1,359,004
Share issuance expenses and other financing costs	(26,600)	(831,737)	(5,370,013)
Purchase of treasury stock	-	-	(177,645)
Proceeds from issuance of loan payable	-	-	1,446,229
Proceeds from obligation under revenue interest assignment	-	-	10,000,000
Proceeds from issuance of convertible debentures	-	-	5,908,000
Proceeds from issuance of preferred stock -			
Series A	-	-	1,200,000
Series B	-	2,000,000	3,070,000
Series C	-	5,690,000	5,690,000
Advances received	-	130,000	130,000
Repayment of capital lease obligations	(154,079)	(165,718)	(518,729)
Repayment of loan payable	(173,943)	(155,578)	(1,035,699)
Repayment of obligation under revenue interest assignment	-	(265)	(11,414)
Repayment of notes payable	-	-	(515,500)
Repayment of promissory notes	(637,686)	-	(637,686)
Net cash provided by financing activities	<u>6,852,662</u>	<u>9,819,668</u>	<u>84,249,195</u>
<b>Net Increase/(Decrease) in Cash And Cash Equivalents</b>	<b>(1,101,017)</b>	<b>502,160</b>	<b>227,370</b>
<b>CASH AND CASH EQUIVALENTS:</b>			
Beginning of period	1,328,387	826,227	-
End of period	<u>\$ 227,370</u>	<u>\$ 1,328,387</u>	<u>\$ 227,370</u>

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)**

	Year ended December 31,		Cumulative From March 12, 1991 (inception) to December 31,
	2004	2003	2004
<b>Supplemental disclosures of cash flow information:</b>			
<b>Non-cash financing and investing activities</b>			
Capital lease obligations	\$ 52,462	\$ -	\$ 620,806
Deferred offering costs included in accrued professional fees	-	-	314,697
Financings costs - other long-term obligations	-	-	59,500
Forgiveness of rent payable	-	-	40,740
Share issuance expenses - warrants	-	-	255,000
Dividends on preferred stock paid in common shares -			
Series B	50,000	923,077	2,099,011
Series C	593,904	-	593,904
Accretion of discount on preferred stock and warrants	1,123,000	4,269,000	5,392,000
Share issuance expenses for preferred stock			
incurred through issuance of warrants -			
Series B	-	86,692	391,307
Series C	-	272,386	272,386
Share issuance of series D preferred stock in			
exchange from series B preferred stock	-	2,628,602	2,628,602
Promissory notes forgiven for warrant participation	100,000	-	100,000
Warrant issued in connection with lease	18,500	-	18,500
Conversion of series C preferred stock into common stock	137,645	-	137,645
Contribution of capital of amount due to founder	398,967	-	398,967
Equipment transferred in satisfaction of deposit	25,000	75,000	100,000
Discount on promissory notes	746,202	287,000	1,033,202
Accounts payable converted to promissory notes	837,468	-	837,468
Advances converted to promissory notes	130,000	-	130,000
Cash paid for interest	\$ 68,975	\$ 104,023	\$ 717,856
Cash paid for income taxes	\$ 2,835	\$ 1,000	\$ 203,411

The accompanying notes are an integral part of these statements.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1 - FORMATION OF THE COMPANY AND BASIS OF PRESENTATION**

*Formation of the Company*

Ortec International, Inc. ("Ortec" or the "Company") was incorporated in March 1991 as a Delaware corporation to secure and provide funds for the further development of the technology developed by Dr. Mark Eisenberg of Sydney, Australia, to replicate in the laboratory, a tissue engineered skin substitute for use in skin regeneration procedures (the "Technology"). Pursuant to a license agreement dated September 7, 1991, Dr. Eisenberg had granted us a license for a term of ten years, with automatic renewals by us for two additional ten-year periods, to commercially use and exploit the Technology for the development of products. In April 1998, Dr. Eisenberg assigned his patent for the Technology to us.

The Skin Group, Ltd. (the "Skin Group") also was formed as a Delaware corporation in March 1991, to raise funds for the development of the Technology. On July 27, 1992, the Skin Group was merged with and into Ortec. Owners of Skin Group shares were given .83672 of an Ortec share for each Skin Group share. The merger was accounted for as if it were a pooling of interests and, accordingly, the accompanying financial statements include the accounts of the Skin Group for all periods presented.

*Basis of Presentation*

We are a development stage enterprise which had no operating revenue prior to December 2001. During 2001, we received Food and Drug Administration (FDA) approval for the use of the fresh form of OrCel<sup>®</sup> (ORCEL) for the treatment of patients with recessive dystrophic epidermolysis bullosa and for donor sites in burn patients. We then began marketing and selling our product for use on patients with these indications. Revenues were not significant. We terminated our selling efforts and elected to focus our efforts on developing a cryopreserved form of our product and on medical indications that had broader marketability. After identifying an indication that had broad market appeal, venous stasis ulcers, we completed a clinical trial during 2003 for the use of cryopreserved form of ORCEL to treat venous stasis ulcers and filed an application for pre-market approval (PMA) with the FDA in February 2004. We are currently awaiting a determination from the FDA.

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We incurred a net loss applicable to common shareholders of \$17.1 million during the year ended December 31, 2004, and, as of that date, our current liabilities exceeded our current assets by \$14.6 million, our total liabilities exceeded our total assets by \$36.4 million and we have a deficit accumulated in the development stage of \$120.5 million. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

During 2004 we financed our operations with \$6.5 million of promissory notes payable and a special warrant offer which provided \$1.3 million in gross proceeds. In the first quarter of 2005, we raised an additional \$5.6 million through private placements of our common stock. Additionally we converted \$9.6 million of promissory notes and exchanged all of the outstanding shares of our Series B and C preferred stock into common stock. (see Note 21).

We continue to explore and, as appropriate, enter into discussions with other companies regarding the potential for equity investment, collaborative arrangements, license agreements or other funding programs with us, in exchange for marketing, distribution or other rights to our products. However, we can give no assurances that discussions with other companies will result in any additional investments, collaborative arrangements, agreements or other funding, or that the necessary additional financing through debt or equity will be available to us on acceptable terms, if at all.

We require substantial funding to continue our research and development activities, clinical trials, manufacturing, sales, distribution and administrative activities, and commercialization processes. Such funding will enable us to execute our production plan with our third party manufacturer and prepare for sales in 2005, pay a portion of our past due obligations, initiate the pivotal clinical trial for the use of ORCEL in its cryopreserved form for the treatment of diabetic foot ulcers, and provide for our general and corporate working capital requirements for 2005. We believe that our cash and cash equivalents on hand at December 31, 2004, (approximately \$.2 million) and the \$5.6 million financing we received in the first quarter of 2005, respectively, as well as the additional funds we hope to raise in 2005, may enable us

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

to continue our operations for the next twelve months. Additionally, we are continuing our equity financing efforts with an investment banking firm. There can be no assurances that we can raise additional funds.

These financial statements have been prepared assuming that we will continue as a going concern. Successful future operations depend upon the successful development and marketing of our ORCEL product. Historically we have funded our operating losses by periodically raising additional sources of capital. If additional funding is not available to us when needed, we may not be able to continue operations. No adjustments have been made to the accompanying financials as a result of this uncertainty.

***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated.

***Common Stock Reserve Split***

On June 24, 2003, we effected a reverse stock split of our common shares outstanding, whereby every stockholder, warrant and option holder, was granted one new common share or warrant or option to purchase common shares, for every ten outstanding common shares (or its equivalent). The par value of the common shares remained unchanged at \$.001 per share. The exercise prices of all warrants and options outstanding were adjusted as a result of this reverse split. The conversion rates of the preferred stock outstanding were also adjusted.

**2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Revenue Recognition***

Product revenue is recognized upon shipment of ORCEL when title and risk of loss pass to the customer, which occurs when the end user customer receives the product. Royalties from licensees will be based on third-party sales of licensed products and will be recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. Fees paid to us upon entering a license agreement are recognized when earned as defined by the terms of the agreement.

In accordance with EITF Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, we review each contract to determine if there are multiple revenue-generating activities that constitute more than one unit of accounting. Revenue is recognized for each unit of accounting based on revenue recognition criteria relevant to that unit. Up-front payments are deferred, if appropriate, and recognized into revenues over the obligation period.

***Research and Development Costs***

We are in the business of research and development and therefore, all research and development costs, including payments relating to products under development, research, consulting agreements and personnel costs, are expensed when incurred. Research and Development costs aggregated \$7,139,733 and \$7,474,067, for the years ending 2004 and 2003, respectively. Research and Development costs are comprised of production and laboratory costs, rent, consulting, personnel, and depreciation and amortization expenses.

***Depreciation and Amortization***

Property and equipment are carried at cost, less any grants received for construction. In 1996, we received a \$400,000 grant toward the construction of our new laboratory and office facilities and we received an additional grant of \$130,000 in 1998.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Office furniture and equipment and laboratory equipment are depreciated on the straight-line basis over the estimated lives of the assets (5 years). Leasehold improvements are amortized over the shorter of the term of the related lease or the life of the asset.

***Intangible Assets***

Our intangible assets consist of patent application costs. We amortize these separately identifiable assets over their estimated useful lives. Patent application costs relate to our U.S. patent application and application fees in foreign jurisdictions and consist of legal and other direct fees. The recoverability of the patent application costs is dependent upon, among other matters, obtaining further FDA approvals for the use of the underlying technology.

***Impairment of Long-Lived Assets***

We review long-lived assets, which consist of fixed assets and patent application costs, for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. We have determined, based on estimated future cash flows, that no provision is necessary for the impairment of long-lived assets at December 31, 2004.

***Foreign Currency Translation***

We conducted some of our research and development at our laboratory in Sidney, Australia. However, because all Australian expenditures were funded from the United States, we determined that the functional currency of our Australian office was the U.S. dollar. Accordingly, current assets and current liabilities are remeasured into the functional currency using current exchange rates and non-current assets and liabilities are remeasured using historical exchange rates. Expense accounts are measured using the average rate in effect for the year. Gains and losses arising from the remeasurement of foreign currency are included in the results of operations for all periods presented. As of December 31, 2002, we terminated all of our research and development activities at our laboratory in Sidney.

***Use of Estimates***

In preparing financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

***Income Taxes***

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for as it is more likely than not that the deferred tax assets will not be realized.

***Cash and Cash Equivalents***

For purposes of the statement of cash flows, we consider all highly liquid debt instruments purchased with original maturities of three months or less to be cash equivalents. Cash equivalents consist principally of money market funds. The fair value of cash and cash equivalents approximates the recorded amount because of the short-term maturity of such instruments.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Net Loss Per Share**

Net loss per common share is based on the weighted-average number of common shares outstanding during the periods.

Basic net loss per share is computed by dividing the net loss by the weighted-average common shares outstanding for the period. Diluted net loss per share reflects the weighted-average common shares outstanding plus the potential dilutive effect of securities or contracts which are convertible to common shares, such as options, warrants and convertible preferred stock.

Options and warrants to purchase shares of common stock were not included in the computation of diluted net loss per share in each of the years presented because to do so would have been antidilutive for the periods presented.

The amount of options and warrants excluded are as follows:

	Year ended December 31,	
	2004	2003
Warrants	988,603	3,085,173
Stock Options - in plan	428,324	348,199
Stock Options - outside of plan	1,374,400	1,274,400

Additionally, the effects of conversion of the preferred stock were excluded from the weighted average share calculation, as the effect would be antidilutive. An aggregate of 5,804,977 shares of common stock would be issuable upon conversion of the preferred stock outstanding at December 31, 2004.

**Employee Stock Option Plan**

We account for our employee stock options under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. No stock-based employee compensation cost is reflected in net income, as all options granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of FASB Statement No. 123, "Accounting for Stock-Based Compensation".

	Year ended December 31,	
	2004	2003
Net loss applicable to common shareholders, as reported	\$ (17,144,804)	\$ (21,449,131)
Deduct: Total stock-based employee compensation income (expense) determined under fair value based method	425,801	(1,723,343)
Pro forma net loss	\$ (16,719,003)	\$ (23,172,474)
Net loss applicable to common shareholders per share:		
Basic and Diluted - as reported	\$ (3.03)	\$ (5.11)
Basic and Diluted - pro forma	\$ (2.96)	\$ (5.52)

We utilized the Black-Scholes option-pricing model to quantify the expense of options and warrants granted to non-employees and the pro forma effects on net loss and net loss per share of the fair value of the options and warrants

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

granted to employees during the years ended December 31, 2004 and 2003. The following weighted average assumptions were made in estimating fair value.

	Year ended December 31,	
	2004	2003
Risk-free interest rate	3.1 %	3.3 %
Expected option life	5 years	5 years
Expected volatility	80.9 %	84.9 %

The weighted average fair value at the date of grant for options granted during the year ended December 31, 2004 and 2003 was \$1.92 and \$1.64, respectively.

*Effect of New Accounting Standards*

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment" which establishes accounting standards for all transactions in which an entity exchanges its equity instruments for goods and services. This statement is a revision to SFAS 123, "Accounting for Stock-Based Compensation", supersedes APB 25, "Accounting for Stock Issued to Employees," and amends FASB Statement No. 95, "Statement of Cash Flows." SFAS 123(R) eliminates the ability to account for share-based compensation using the intrinsic value method allowed under APB 25 and will require us to recognize share-based compensation as compensation expense in the statement of operations based on the fair values of such equity on the date of the grant, with the compensation expense recognized over the period in which the recipient is required to provide service in exchange for the equity award. This statement will also require us to adopt a fair value-based method for measuring the compensation expense related to share-based compensation. SFAS 123(R) must be adopted no later than periods beginning after December 15, 2005 and we expect to adopt SFAS 123(R) on the effective date. We believe the adoption of SFAS 123(R) will have a material impact on our results of operations and earnings per share.

**3 - CONCENTRATION OF CREDIT RISK**

We maintain cash and money market accounts at four financial institutions located in New York City. The FDIC insures cash accounts for amounts up to \$100,000. At times, our balances exceed such FDIC limits.

We have not experienced any losses in such accounts.

**4 - PROPERTY AND EQUIPMENT**

Property and equipment consist of the following at December 31, 2004:

Laboratory equipment	\$ 1,717,637
Office furniture and equipment	1,118,481
Leasehold improvements	1,350,176
	<u>4,186,294</u>
Accumulated depreciation	3,859,348
	<u>\$ 326,946</u>

Depreciation and amortization expense for the years ended December 31, 2004 and 2003, was approximately \$385,000 and \$556,000, respectively.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

5 - PATENTS

Patent application costs are stated at cost less amortization computed by the straight-line method over the useful life of the patent. As of December 31, 2004, patents, net of accumulated amortization, were as follows:

<u>Patents subject to Amortization</u>	<u>Expiration Date</u>	
Composite Culture Skin (CCS)	2/1/2011	\$ 910,690
Manufacturing of Bi-layered Collagen Sponge	12/28/2020	33,037
Cryopreservation Process	12/26/2021	78,759
		<u>1,022,486</u>
Accumulated amortization		435,210
		<u>\$ 587,276</u>

Amortization expense for the years ended December 31, 2004 and 2003, was approximately \$82,212 and \$129,825, respectively. The estimated annual amortization expense expected, based on current intangible balances, for the years 2005 through 2009 is \$84,645 per year.

Our U.S. patent for CCS was issued in 1994. During 2002 and 2003 we were issued two patents by the United States Patent Office. The first patent covers unique manufacturing processes for our tissue-engineered product, ORCEL. These processes specifically relate to the manufacturing of our bi-layered collagen sponge structure and when implemented, can reduce the current manufacturing costs of ORCEL. This patent was issued on December 31, 2002. The second patent covers the freezing process for ORCEL. This process, referred to as cryopreservation, gives our product a minimum shelf life of seven months, as opposed to only a few days when our product is not cryopreserved. This second patent was issued on October 28, 2003.

There can be no assurance that any patent will provide commercial benefits to us. We have determined that no provision for impairment is necessary at December 31, 2004.

We have granted a security interest in our United States and Canadian patents and trademarks relating to ORCEL to collateralize payments we will be required to make to satisfy our obligation under a Revenue Interest Assignment Agreement (see Note 11).

6 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following at December 31, 2004:

Accounts payable	\$ 3,202,905
Accrued interest	660,918
Accrued compensation	579,975
Accrued expenses	266,003
Accrued professional fees	82,500
Bank overdraft	69,894
Deferred income	50,000
	<u>\$ 4,912,195</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**7 - LEASES**

In March 1996, we entered into a five-year lease with Columbia University for our laboratory and offices in Columbia's new Audubon Biomedical Science and Technology Park in New York City. Construction of the laboratory and office facility was completed in July 1996 and became fully operational in November 1996. We utilize our laboratory facilities to produce ORCEL for research and development activities including cell expansion and biomaterial research. On December 18, 2003, we amended the lease agreement with Columbia University, extending the lease term to December 2005. With this amendment, we agreed to pay Columbia \$25,588 a month for past due rent commencing on February 1, 2004 and ending on December 31, 2005.

Total rent expense for the years ended December 31, 2004 and 2003 was approximately \$461,000 and \$432,000, respectively.

On August 5, 2002, we reached an agreement with the New Jersey Economic Development Authority (NJEDA) to terminate a 2001 lease and to enter into a new lease covering production and office space. Monthly payments under such lease began on January 1, 2003. On June 9, 2003 NJEDA and we executed an agreement to terminate this lease. Based on the terms of this settlement, a termination cost of \$978,000 was agreed upon. This termination costs was settled by applying the \$623,000 security deposit, plus accrued interest thereon, with the balance of \$340,000 paid on June 11, 2003. In 2003, we recorded a lease termination cost of \$1,119,166 consisting of the aforementioned \$978,000 together with \$141,166 of other costs that we incurred in connection with the build-out of the leasehold. We continued to rent space in North Brunswick, New Jersey pursuant to a lease until its expiration on July 31, 2004, at a rent of \$2,300 per month.

As of December 31, 2004 and 2003, we recorded \$535,000 and \$503,000 in equipment purchased under capital leases and \$460,000 and \$335,000 in accumulated amortization, respectively.

Future minimum lease payments under noncancellable operating leases primarily for office and laboratory space and the present value of future minimum lease payments under capital leases as of December 31, 2004 are as follows:

Year ending December 31,	Leases	
	Operating	Capital
2005	\$ 377,000	\$ 84,918
2006	-	20,505
2007	-	5,673
2008	-	678
Total	\$ 377,000	111,774
Less amounts representing interest		36,239
Present value of net minimum capital lease payments		75,535
Less: current portion		51,584
Long-term portion		\$ 23,951

In connection with a lease agreement dated February 27, 2004, we were obligated to issue a two-year warrant to purchase 14,052 shares of our common stock at \$3.25 per share. We have valued the warrant utilizing a Black-Scholes valuation model at \$18,500. On November 2, 2004 the Board of Directors approved the issuance of the aforementioned warrant.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**8 - LOAN PAYABLE**

We have two loans outstanding with our landlord totaling \$203,462. These loans are due in monthly installments including interest through December 2005 of \$10,103 and \$7,605, respectively, at effective rates of 7.98% and 8.6%, respectively.

Minimum payments to be made under the terms of these loans are as follows:

Year ending December 31, 2005	\$ 212,518
Less amount representing interest	9,056
Net present value of future loan payments - current portion	<u>\$ 203,462</u>

**9 - LICENSE AND OTHER ARRANGEMENTS**

In October 2003, we entered into an exclusive License Agreement with Teva Medical Limited, a subsidiary of Teva Pharmaceutical Industries Ltd. (Teva) for the sales and marketing of our ORCEL product in Israel. This ten-year agreement, beginning on the date the product is launched for marketing in Israel, requires Teva to seek regulatory and reimbursement approval for ORCEL in Israel. We received an upfront payment of \$50,000 in 2003 which we recorded as deferred income, see Note 6. We will receive an additional \$50,000 within thirty days of grant of reimbursement approval in Israel, and another \$100,000 within 30 days of attainment of aggregate net sales of \$3,000,000 in Israel within any period of twelve consecutive calendar months. The agreement also provides for ORCEL pricing and terms of payment. Additionally Teva will pay us royalties of 10% of net sales in Israel up to \$5,000,000 per annum. If sales are in excess of \$5,000,000 annually Teva will pay us 10% on the first \$5,000,000 of sales in Israel and a 20% royalty on sales above \$5,000,000 in Israel.

In April 2004, we entered into a Material Supply Agreement with ES Cell International Pte Ltd.(ESI). Under the terms of the agreement, we provided ESI with human skin cells generated from cell lines developed and manufactured by us for use in our ORCEL product. We received a \$50,000 up-front fee upon the signing of the agreement and we received an additional \$150,000 upon first delivery of certain specified cell lines. We have recorded these amounts in interest and other income. We will receive milestone payments of \$150,000 with 30 days of an investigational new drug filing for the ESI Focus Cell Therapy line and an additional \$150,000 upon ESI's receiving regulatory approval for marketing of the ESI Focus Cell Therapy product. We will additionally receive royalties equivalent to .5% of product sales revenue or license or distribution fees or other payments. The payment of these additional amounts are wholly dependent on ESI achieving their milestones.

**10 - PROMISSORY NOTES PAYABLE**

Promissory notes at December 31, 2004 consists of:

Promissory notes - investors, 8% and 12%, due December 31, 2004	\$ 9,626,626
Promissory notes - Amarex, due through February 2005	118,060
Promissory notes - CUH2A, 4%, due through February 2008	131,722
	<u>9,876,408</u>
Current portion	<u>9,784,691</u>
Noncurrent portion	<u>\$ 91,717</u>

During 2003, we received non-interest bearing advances of \$130,000 from certain investors. In 2004, this amount was converted to an 8% investor promissory note due December 31, 2004.

In connection with the promissory notes to investors we paid our placement agent a fee equivalent to 50 shares for every \$1,000 of the promissory notes and recorded this as deferred debt issuance cost which was then amortized over the life

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

of the note to interest expense. 488,831 shares were issued in 2004 consisting of 157,000 shares valued at \$287,000 (in 2003) relating to notes placed in 2003 and 331,831 shares valued at \$746,202 relating to notes placed in 2004.

On October 27, 2004 holders of \$9,206,000 of investor promissory notes agreed to extend the maturity date of their notes from November 5, 2004 to December 31, 2004. In consideration of this extension we increased the interest rate for the fourth quarter of the calendar year to 12% and issued 45,000 common shares for each \$1,000,000 of principal amount held, or 414,270 common shares. The modification was not considered significant and thus these shares were valued at \$2.00 per share, or \$828,540 in the aggregate, and was charged to interest expense in the fourth quarter. These shares were issued in 2005 upon our confirmation of each noteholders' accredited investor status. In connection therewith, we issued 277,020 shares of common shares and 34.31 shares of our Series D preferred stock (equivalent to 137,250 common shares).

As defined in the promissory notes, if we received \$5,000,000 of gross proceeds from a qualified financing, we may elect to prepay the notes and any accrued and unpaid interest in cash or in our stock. On January 5, 2005, concurrent with the closing of our private placement in excess of \$5,000,000 of gross proceeds (see Note 21), all the promissory notes and accrued interest held by investors, or an aggregate of \$10,301,213 was surrendered in exchange for our common stock and warrants. The fair value of the common stock and warrants was approximately \$20,600,000 and thus we will record a loss on extinguishment of approximately \$10,300,000 in 2005.

In December 2002, Amarex LLC commenced an action against us in the Circuit Court for Montgomery County, Maryland. Amarex provided statistical programming and data management services for us for the data generated in our clinical trials. In March 2004 we settled the litigation by agreeing to pay Amarex \$673,060. We are required to pay \$60,000 each month thereafter until the obligation is paid in full. The settlement also provides that Amarex will release to us the work they previously performed for us in connection with our diabetic foot ulcer clinical trial. This note was paid in full in February 2005.

The CUH2A promissory note was a structured payout of a previous vendor obligation. We pay them \$3,712 monthly.

Minimum payments to be made under the terms of the promissory notes are as follows:

Year ending December 31,	
2005	\$10,448,008
2006	44,546
2007	44,546
2008	6,783
	<u>10,543,883</u>
Less amount representing interest	667,475
Net present value of future loan payments	<u>\$ 9,876,408</u>

**11 - OBLIGATION UNDER REVENUE INTEREST ASSIGNMENTS**

On August 29, 2001, as amended February 2003, we entered into a Revenue Interest Assignment Agreement with Paul Royalty Fund L.P. (PRF), which terminates on December 31, 2011. Under such agreement we were eligible to receive \$10,000,000 during 2001. We received \$6,000,000 during 2001 and the remaining \$4,000,000 in January 2002.

In February 2003, PRF and the Company signed an amendment to the agreement, restating and updating certain provisions of the original agreement, including removing additional funding requirements by PRF. In connection therewith, PRF purchased 50 shares of our Series B convertible preferred stock investing \$500,000, and for which we issued to PRF 73,077 shares of our common stock and granted PRF warrants to purchase an aggregate of 50,000 shares of our common stock, at exercise prices of \$15.00 per share for 25,000 shares and at \$20.00 per share for the other 25,000 shares. The February 2003 amendments to our agreements with PRF provided, among other things, for (a) the election of one director designated by PRF, (b) the right of one observer (other than such director) selected by PRF to attend and

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

observe all meetings of our Board of Directors and (c) for us to use our best efforts to have independent directors who are acceptable to both us and PRF, including a director designated by PRF, as a majority of our Board of Directors.

In consideration for the \$10,000,000, PRF will receive a minimum of 3.33% of the first \$100,000,000 of annual sales plus 1.99% of annual sales in excess of \$100,000,000 of ORCEL in the United States, Canada and Mexico. Such percentage may be further adjusted upward or downward, based on the volume of net sales to end users of our products in those three countries. Beginning on January 1, 2003, PRF was entitled to receive each year the first proceeds to us from end user sales of our products in North America. The annual amounts that PRF will be able to draw in advance against the end user sales of our products are: \$600,000 in 2003, \$1,000,000 in 2004, and \$7,500,000 in 2005 through 2011. The agreement provides for quarterly and annual accountings between PRF and us for those advance payments. The purpose of these accountings is to reconcile the advances paid against the actual amount we are required to pay computed on the basis of the aforementioned percentages of sales volume. Based on this reconciliation of the actual calculated amounts versus the advances paid, we will either be required to pay additional amounts or receive a refund of all or a portion of the advances we paid to PRF. We have not paid PRF any advances, as there were no sales during 2003 and 2004. The amounts received from PRF have been classified as debt in accordance with our interpretation of Emerging Issues Task Force (EITF) Issues No. 88-18, "Sales of Future Revenue". PRF bears the risk of revenue interest paid being significantly less than the current revenue interest obligation, as well as the reward of revenue interest paid to it being significantly greater than the current revenue interest obligation. Therefore we are under no obligation to make any other payments to PRF in the scenario when no repurchase right (as defined) is triggered and no significant interest payments are made. Conversely, we will be obligated to continue to make revenue interest payments in the scenario where sales are sufficiently high to result in amounts due under the Revenue Interest Assignment Agreement being in excess of the current revenue interest obligation.

We granted PRF a security interest in our United States and Canadian patents and trademarks relating to our technology for our ORCEL product (collectively, the "Pledged Assets"), to secure payments required to be made by us to PRF under this agreement. Pursuant to the default provisions under the agreement PRF may require us to repurchase their revenue interest at the put option exercise price which is defined as a price which would yield an internal rate of return to PRF of 30%.

The events that could require us to repurchase our revenue interest include:

- any change of control of our company;
- a transfer of substantially all of our assets;
- a transfer of our interests in our products;
- a judicial decision that has a material adverse effect on our business, operations, assets, or financial condition;
- the occurrence of any event that has a material adverse effect on our ability to perform our obligations to repurchase the revenue interest obligation;
- the acceleration of our obligations or the exercise of default remedies by a secured lender under certain debt instruments; a funding termination event (as defined) such as a bankruptcy event (as defined);
- our insolvency (as defined);
- the breach of representation, warranty or certification made by us in the agreements with PRF that, individually or in the aggregate, would reasonably be expected to have a material adverse effect on our business, operations, assets or financial condition, and such breach is not cured within 30 days after notice thereof from PRF.

Additionally we agreed not to issue any new debt or equity securities that contain mandatory cash dividend or redemption provisions through the revenue interest period, or December 31, 2011.

On December 13, 2004 PRF entered into a forbearance agreement with us agreeing that they cannot exercise their right to compel us to repurchase their interest in our revenues because of our insolvency prior to July 1, 2006 (which is defined as (a) our liabilities, excluding our revenue interest assignment obligation, exceeding the fair market value of our assets or (b) our inability to pay our debts as they become due). In accordance with EITF No. 86-30, "Classification of Obligations When a Violation is Waived by the Creditor", we have classified our revenue interest assignment obligation as a noncurrent liability as a result of the forbearance.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

As defined in our agreement with PRF we are currently insolvent. As a result of this insolvency our obligation under the revenue interest assignment is stated at \$22,738,110, the amount PRF could compel us to repurchase their interest in our revenues at December 31, 2004, had they not entered into a forbearance agreement with us. This amount represents the amount that would give PRF a 30% internal rate of return on their \$10,000,000 from the dates of their original investments. Should we continue to be insolvent we will need to continue to incur non-cash interest charges for this obligation. At such time when the default provisions are no longer applicable, the effective interest rate imputed on the obligation will be determined using the interest method and payments to PRF will be recorded as a reduction of our obligation under the revenue interest assignment.

In accordance with accounting promulgated by Statements of Financial Accounting Standards No. 15, "Accounting by Debtors and Creditors for Troubled Debt Restructurings" (SFAS 15) even if we are no longer insolvent as long as our future cash payments relating to the revenue interest assignment obligation are indeterminate, the revenue interest assignment obligation would remain at the value that achieves the 30% internal rate of return for PRF through the last date of our insolvency. However, we would no longer have to accrue any additional interest to achieve a 30% internal rate of return related to insolvency. That is, we would not reverse the accrual for the insolvency repurchase event even when we are no longer insolvent. At December 31, 2004 the amount attributed to the insolvency is \$12,738,110. Our revenue stream is considered indeterminate since we cannot predict with certainty the payments we will be required to make on this obligation since theoretically our sales are not limited in amount and payments under our agreement with PRF are determined based on future sales. We estimate that we would need to achieve a North American sales level of approximately \$750,000,000 during the approximate remaining six years under the agreement to offset the principal balance of the \$22,738,110 revenue interest obligation.

SFAS 15 allows debtors that can predict with certainty the absolute amounts of future cash flow payments to record an immediate gain if the maximum future cash payments are less than the carrying amount of the obligation. In the case where the future cash payments are indeterminate, as ours are considered, the gain is not recognized until the end of the term of the outstanding debt, December 31, 2011, or upon termination. As such, we believe we will likely record a gain on the revenue interest assignment obligation to PRF in 2011 or upon termination, if sooner.

If we were unable to repurchase the revenue interest upon a repurchase event, PRF could foreclose on the Pledged Assets, and we could be forced into bankruptcy. PRF can also foreclose on the Pledged Assets if we remain insolvent (waived until July 1, 2006) or are involved in a voluntary or involuntary bankruptcy proceeding. No repurchase events or foreclosures have occurred as of December 31, 2004.

We also have the option to repurchase PRF's interest upon the occurrence of a change in control of the Company or a complete divestiture by us of our interests in our products, for an amount of cash flows that will generate a 35% internal rate of return to PRF.

On December 16, 2004, pursuant to a Special Warrant Offer which reduced the exercise prices of a portion of the 50,000 warrants that PRF received in February 2003 to \$1.00 in exchange for the surrender of the balance, warrants to purchase 27,778 shares of our common stock were exercised for which we received \$27,889, and warrants to purchase 22,222 shares of our common stock were surrendered to us. As a result of the Special Warrant Offer PRF was considered to have received a deemed dividend of approximately \$2,500 based on a Black Scholes calculation considering the valuation of the warrants prior to the December 16, 2004 offering and subsequent to the offering (see Note 12).

## **12 - EQUITY TRANSACTIONS**

Each share of our common stock is entitled to one vote.

In September 2001, we, with shareholder approval, increased the authorized amount of our common stock to 35,000,000 shares and authorized the issuance of up to 1,000,000 shares of preferred stock.

In February 2003, we, with shareholder approval, increased the authorized amount of our common stock to 200,000,000 shares.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

On June 24, 2003, we effected a one for ten reverse stock split for each outstanding share of common stock. This reverse stock split was retroactively reflected in the accompanying financial statements and all references to shares are to the new shares with per share amounts appropriately adjusted.

**Founders:** Pursuant to an agreement between Dr. Eisenberg and the other founders (the "Other Founders"), a business relationship was formed by the founders for the manufacture and sale of products derived from the Technology (the "Business Agreement"). Under the terms of the Business Agreement, Dr. Eisenberg, who was the owner of all the capital stock of Ortec (60,000 shares) agreed to license the Technology to Ortec and sell 70% of Ortec's shares for a purchase price of \$1,000,000 to the Skin Group. Dr. Eisenberg was paid \$85,000 in connection with this agreement as reimbursement for his expenses (\$35,000 during the period from inception (March 12, 1991) to December 31, 1991 and \$50,000 during the year ended December 31, 1992). The Other Founders initially owned all of the stock of the Skin Group (95,382 shares). On July 27, 1992, the Skin Group was merged with and into Ortec.

**First private placement:** In March 1991, the Skin Group issued, in a private placement, 21,744 shares for \$65,000. In June and October 1991, the Skin Group issued an aggregate 14,902 shares, to a then director of ours (the "Director") for an aggregate gross proceeds of \$250,000.

**Second private placement:** Commencing in November 1991, the Skin Group issued 7,948 shares under a second private placement for \$750,006. The 7,948 shares consisted of 5,302 shares issued during 1991 and 2,646 issued shares during 1992 for \$500,000 and \$250,006, respectively. Under the second private placement an additional 2,286 of our shares were issued for \$215,467. In addition, the Director was granted warrants to purchase 736 of our shares at \$94.25 per share.

**Stock purchase agreement entered into with the Director:** In June 1992, 5,304 of our shares were sold to the Director for a total purchase price of \$499,998. The purchase price was payable in installments and shares and warrants were issued in installments pro rata with the payment of the purchase price. During the years ended December 31, 1992 and 1993, the Director paid \$299,998 and \$200,000, respectively, and was issued 3,182 and 2,122 shares, respectively. In addition, the Director was granted warrants to purchase 7,957 shares (4,774 and 3,183 of which were granted in 1992 and 1993, respectively) at an exercise price of \$94.25 per share; such warrants were exercised on December 29, 1998.

Further, in connection with the Director's purchase of the 5,304 shares, in 1993, the Other Founders granted to the Director options to purchase from them an aggregate of 7,400 of our shares, at a price of \$50 per share. In 1993, the Director exercised such option in part, and purchased 4,900 shares from the Other Founders at the option price of \$50 per share. The remaining balance of such options expired April 15, 1994.

**Third private placement:** Pursuant to a third private placement that commenced on January 13, 1993, and concluded on March 31, 1993, we sold an aggregate of 10,965 shares at \$100 per share for \$1,096,500. Subsequent to such offering, in 1993, we sold an additional 2,250 shares at \$100 per share for \$225,000. In connection with such purchases, all purchasers received certain registration rights.

**Stock Purchase Agreement with Home Insurance Company dated July 19, 1993:** Pursuant to a Stock Purchase Agreement dated July 19, 1993, by and between us and the Home Insurance Company (Home Insurance), we sold to Home Insurance 11,112 shares of common stock for an aggregate purchase price of \$999,999, or \$90 per share. In connection with such purchase, Home Insurance received certain registration rights.

**Shares issued in exchange for commission:** In 1993, we issued 60 shares to an individual as compensation for commissions in connection with the sale of our shares. Such commissions are included in share issuance expenses. The stock issued was valued at \$100 per share.

In August 1993, the Director entered into a stock option agreement with Dr. Eisenberg and the Other Founders, pursuant to which he received the right to purchase an aggregate of 10,000 shares owned by such persons in various amounts and at various times, at a purchase price of \$100 per share. As of December 31, 1993, the Director had exercised options and purchased 500 shares under such agreement at \$100 per share. The remaining balance of such options has expired.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**Fourth private placement:** Pursuant to a fourth private placement consummated in July 1994, we sold an aggregate of 3,946 shares at between \$100 and \$125 per share for aggregate proceeds of \$397,712.

**Stock Purchase Agreement with Home Insurance dated July 22, 1994:** Pursuant to a Stock Purchase Agreement dated July 22, 1994, between Ortec and Home Insurance, we sold to Home Insurance 5,000 shares of common stock for an aggregate purchase price of \$500,000, or \$100 per share. In connection with such purchase, Home Insurance received certain registration rights and warrants to purchase 1,000 shares of common stock at \$120 per share, which expired on July 21, 1997.

**Rent Forgiveness:** During the year ended December 31, 1995, Dr. Eisenberg's father waived the rights to \$40,740 of unpaid rent which was accounted for as additional paid-in capital.

**Initial Public Offering:** On January 19, 1996, we completed an initial public offering of 120,000 units for aggregate proceeds of \$6,000,000. Each unit consisted of one share of our common stock, one Class A warrant to purchase one share of common stock at \$100 and one Class B warrant to purchase one share of common stock at \$150. As of December 31, 1998, 108,378 Class A warrants were exercised and the balance expired unexercised. The Class B warrants were originally set to expire in January 1999. We extended the expiration date to March 31, 2000. The Class B warrants were subject to redemption by us at \$.10 per warrant. We received gross proceeds of approximately \$1,282,000 and \$10,823,000 and net proceeds of approximately \$1,262,000 and \$10,165,000 as a result of the exercise of warrants in 1998 and 1997, respectively.

**Fifth private placement:** In November 1996, we completed a private placement of our securities from which we received gross proceeds of \$6,220,797 and net proceeds of approximately \$5,733,000 (after deducting approximately \$487,000 in placement fees and other expenses of such private placement). We sold 95,911 shares of common stock in such private placement at average prices of \$64.90 per share. In addition, we granted five-year warrants to placement agents to purchase such number of shares equal to 10% of the number of shares of common stock sold by such placement agents, exercisable at prices equal to 120% of the prices paid for such shares. Pursuant to the purchasers' request, we registered all 95,911 shares.

**Options and warrants issued for services:** During 1992 and 1993, we issued warrants to purchase 666 shares at \$94.25 per share, and during 1995 we issued warrants to purchase 2,000 shares at \$100 per share to members of our Scientific Advisory Board. During 1996 and 1997, we issued warrants to purchase 24,210 shares at \$60 to \$120 per share to the Director and certain others. These warrants expired at various dates through November 2001.

On January 20, 1996, we granted "lock-up warrants" entitling shareholders to purchase an aggregate of 38,905 shares of our common stock at a price of \$10 per share. All unexercised warrants expired on January 18, 2000. At different times during 1996, seven persons exercised such warrants and purchased 3,389 shares of common stock at the \$10 per share exercise price. The issuance of such lock-up warrants was in consideration for such shareholders signing lock-up agreements agreeing not to sell or transfer shares of our common stock purchased at prices of \$90 or more per share until January 20, 1997. At different times during the third quarter of 1997, eight persons exercised such warrants and purchased an aggregate of 2,121 shares of common stock at the \$10 per share exercise price. During 1998, nine persons exercised such warrants and purchased an aggregate of 9,608 shares of common stock at the \$10 per share exercise price. During 1999, five persons exercised such warrants and purchased an aggregate of 1,410 shares of common stock at the \$10 per share exercise price. There were no underwriting discounts or commissions given or paid in connection with any of the foregoing warrant exercises.

During the third quarter of 1997, we granted to one person and its seven designees four-year warrants to purchase an aggregate of 3,750 shares of common stock, at an exercise price of \$120 per share. Such warrants were not exercisable until July 18, 1998 and were granted in consideration for consulting services rendered to us.

During the fourth quarter of 1997, we granted to one person and its six designees four-year warrants to purchase an aggregate of 3,750 shares of common stock, at an exercise price of \$120 per share. Such warrants were not exercisable until July 18, 1998 and were granted in consideration for consulting services rendered to us.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

During 1998, warrants for 1,870 shares, mentioned in the two previous paragraphs, were exercised utilizing the cashless exercise option of the warrant agreement. We issued 620 shares upon this exercise.

During the third quarter of 1997, we granted to one person a one-year warrant to purchase an aggregate of 63 shares of common stock, at an exercise price of \$120 per share. Such warrants were granted in consideration for consulting services rendered to us. The warrant was exercised during 1998.

We recorded consulting expense of approximately \$65,000 as a result of these grants during the year ended December 31, 1998.

During the fourth quarter of 1997, we granted five-year warrants to our three executive officers to purchase an aggregate of 24,000 shares of common stock, at an exercise price of \$120 per share. Such warrants were granted in consideration for services rendered to us. The exercise of such warrants was contingent upon the occurrence of certain events, which were considered probable at December 31, 1997. As of December 31, 1998, five of the six events had occurred so that 18,500 of those warrants became vested. As a result, we recorded compensation expense of approximately \$80,000 in December 1997 and \$1,185,000 for the year ended December 31, 1998. The balance of the warrants became vested upon the exercise of warrants owned by a director in December 1998 in accordance with the terms of certain compensation provisions as approved by our Board of Directors.

In consideration for services rendered by him as our director in the five-year period from 1992 to 1996 for which he never received compensation, we extended by one year to December 31, 1998 the expiration date of warrants owned by a director to purchase an aggregate of 8,693 shares, exercisable at \$94.25 per share. As a result, we recorded compensation expense of approximately \$420,000, during the fourth quarter of 1997. All of these warrants were exercised on December 29, 1998.

During the fourth quarter of 1998, we granted five-year options to our three executive officers to purchase an aggregate of 52,075 shares of common stock, at exercise prices ranging from \$121.30 to \$124.40 per share. The exercise of such options was contingent upon the occurrence of certain events. All of these options became vested upon the exercise of warrants owned by a director in December 1998 in accordance with the terms of certain compensation provisions as approved by our Board of Directors. As a result, we recorded compensation expense of approximately \$495,000 in December 1998.

**Sixth private placement:** In December 1998, we completed a private placement of our securities from which we received proceeds of \$2,000,000. In addition, we granted three-year warrants to the purchaser to purchase 5,000 shares at \$120 per share. We sold 20,000 shares of common stock in such private placement. We allocated the \$2,000,000 proceeds amongst the common stock and warrants based upon the relative fair market value of the stock at the date of issuance and the estimated fair value of the warrants using the Black-Scholes option pricing model. We assigned values to the common stock and warrants issued of \$1,788,698 and \$211,302, respectively.

**Seventh private placement:** In March 1999, we completed a private placement of 38,916 shares of our common stock to twenty investors from which we received proceeds of \$3,405,076. In addition, each investor also received a three-year warrant to purchase 20% of the number of shares of our common stock such investor purchased in such private placement. The prices at which such warrants were exercisable was \$125 per share for one half, and \$145 per share for the other half, of the number of shares issuable upon exercise of such warrants. We allocated the \$3,405,076 proceeds amongst the common stock and warrants based upon the relative fair market value of the stock at the date of issuance and the estimated fair market value of the warrants using the Black-Scholes option pricing model. We assigned values to the common stock and warrants issued to the investors of \$3,168,785 and \$236,291, respectively. Oscar Gruss & Son, Incorporated (Gruss) acted as placement agent in such private placement. For its services as placement agent, we paid Gruss \$272,406 and granted Gruss a five-year warrant to purchase an aggregate of 3,892 shares of our common stock at an exercise price of \$105 per share. The value assigned to the Gruss warrants was \$232,000. Other share issuance costs amounted to \$106,002.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Eighth private placement:** In December 1999, we completed a private placement of 163,637 shares of our common stock to two institutional funds from which we received proceeds of approximately \$9,000,000. Share issuance costs amounted to approximately \$9,500.

**Ninth private placement:** In March 2000, we completed a private placement of 6,667 shares of our common stock to one fund from which we received proceeds of approximately \$1,000,000. In addition, we paid a placement agent who introduced us to the fund a fee of approximately \$43,400 and granted such placement agent a five year warrant to purchase 267 shares of our common stock at an exercise price of \$150 per share. The value assigned to the warrant was \$23,000, which was reflected as share issuance costs. Other share issuance costs amounted to \$3,200.

**Tenth private placement:** In September 2000, we completed a private placement of 124,757 shares of our common stock to ten investors from which we received approximately \$8,421,000. In addition, we paid the placement agent who introduced us to the investors a fee of approximately \$525,400. Other share issuance costs amounted to approximately \$46,500.

**Options issued for services:** In April 2001, we issued options to purchase 6,000 shares of our common stock, at \$69.50 per share, to certain professionals. The estimated fair value of \$188,080 for such options was charged to general and administrative expenses.

During 2002, we completed a private placement with several investors, in which we raised cash proceeds of \$8,200,000, issued convertible preferred shares, issued warrants to purchase common shares and granted common stock as dividends. (See Note 13).

During July 2003, we granted a warrant to purchase 150,000 shares at an exercise price of \$2.00 per share to a vendor in consideration for twelve months of consulting services. In accordance with the agreement, 50% of the shares, or 75,000 shares, vested immediately, with the balance vesting upon the six-month anniversary in January 2004. As a result, we recorded expense of \$87,000 in 2003 and \$94,393 during 2004 representing the value of the additional 75,000 shares which had vested.

**Restricted Share Grant:** During 2003 an allocation of 1,800,000 restricted shares of common stock were granted to officers and certain employees. The issuance of these shares is contingent on our achieving certain milestones and if issued will contain delayed vesting provisions (see Note 21).

**Special Warrant Offer:** On November 16, 2004, we made a Special Warrant Offer (SWO) to all holders of our Series B-1, B-2 and C warrants. Such warrants were originally issued in connection with our Series B and Series C preferred stock financings in November and December 2002 and in February, May and July 2003 (See Note 13). At the time of the SWO there were outstanding and eligible for the SWO: 667,989 and 25,000 Series B-1 warrants exercisable to purchase our common stock at \$4.00 and \$15.00 per common share, respectively; 544,138 and 25,000 Series B-2 warrants exercisable to purchase our common stock at \$5.00 and \$20.00 per common share, respectively, and 1,707,000 Series C warrants to purchase our common stock at \$3.60 per common share. Under the terms of the SWO, the holders were entitled to purchase 1/3 of such shares they could otherwise purchase at a reduced exercise price of \$1.67 per common share. Concurrently with such exercise they would receive 2/9 of such shares they could otherwise purchase at the reduced exercise price of \$0.01 per common share, and they would surrender the right to purchase their remaining 4/9 of such shares they could otherwise purchase. Each warrant holder participating in the SWO received a new warrant to purchase 30% of the common shares acquired by such purchaser in the SWO.

The SWO was concluded December 3, 2004. Holders of 491,791 of our Series B-1 warrants, 431,341 of our Series B-2 warrants, and 1,605,000 of our Series C warrants participated in the SWO.

Participation in the offering resulted in aggregate gross proceeds of \$1,438,019 consisting of cash proceeds of \$1,338,019 and \$100,000 relating to the settlement of an existing promissory note obligation. There were no fees paid to our placement agent in connection with the SWO. We issued 496,981 shares of our common stock and 233,8274 shares of Series D convertible preferred stock, which are equivalent to 935,310 shares of common stock. We also issued

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

five-year Series E warrants to the investors to purchase an additional 429,689 shares of our common stock for \$1.80 per share.

As a result of the SWO, the warrant holders who participated in the offering were considered to have received a deemed dividend aggregating \$1,120,500 based upon a Black Scholes calculation considering the valuation of the warrants prior to the November 16, 2004 offering and subsequent to the offering. We recorded an aggregate deemed dividend of \$1,123,000 inclusive of Paul Royalty Fund's SWO described in Note 11.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes warrant activity during the period from March 12, 1991 (inception) through December 31, 2004 (excluding the Class A and B warrants which were issued during the IPO):

	Price Range (\$)	Warrants
March 12, 1991 (inception)		
Granted	94.25	736
Balance, December 31, 1991	94.25	736
Granted	94.25	5,508
Balance, December 31, 1992	94.25	6,244
Granted	94.25 - 120.00	4,823
Balance, December 31, 1993	94.25 - 120.00	11,067
Granted	120.00	1,000
Balance, December 31, 1994	94.25 - 120.00	12,067
Granted	100.00	400
Expired	94.25	(268)
Balance, December 31, 1995	94.25 - 120.00	12,199
Granted	10.00 - 100.00	51,161
Exercised	100.00	(3,389)
Expired	120.00	(245)
Balance, December 31, 1996	10.00 - 120.00	59,726
Granted	120.00 - 142.50	33,063
Expired	120.00	(1,000)
Balance, December 31, 1997	10.00 - 142.50	91,789
Granted	120.00 - 140.00	7,500
Exercised	10.00 - 120.00	(20,585)
Expired	120.00	(10,843)
Balance, December 31, 1998	10.00 - 142.50	67,861
Granted	125.00 - 145.00	11,674
Exercised	10.00	(1,410)
Expired	60.00 - 94.25	(1,716)
Balance, December 31, 1999	10.00 - 142.50	76,409
Granted	150.00	267
Exercised	120.00	(200)
Expired	10.00 - 100.00	(15,499)
Balance, December 31, 2000	77.00 - 150.00	60,977
Expired	77.00 - 120.00	(21,436)
Balance, December 31, 2001	77.00 - 150.00	39,541
Granted	.01 - 62.48	2,221,015
Exercised	.01	(973,997)
Expired	.01 - 145.00	(169,348)
Balance, December 31, 2002	.01 - 150.00	1,117,211
Granted	.01 - 15.00	2,369,212
Exercised	.01 - 4.00	(398,750)
Expired	140.00	(2,500)
Balance, December 31, 2003	.01 - 120.00	3,085,173
Granted	.01 - 15.00	518,741
Exercised	.01 - 20.00	(1,464,759)
Surrendered	3.60 - 20.00	(1,145,836)
Expired	140.00	(4,716)
Balance, December 31, 2004	2.00 - 120.00	988,603

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes warrant data as of December 31, 2004:

Range of exercise prices	Number outstanding	Weighted Average Remaining contractual Life (years)	Weighted Average Exercise Price	Number exercisable
\$1.80 to \$5.00	984,736	4.20	\$2.80	984,736
\$45.00	3,600	0.42	\$45.00	3,600
\$105.00 to \$120.00	267	0.19	\$120.00	267
	<u>988,603</u>			<u>988,603</u>

**13 - SERIES A, B, C, & D PREFERRED STOCK, 12% CONVERTIBLE DEBENTURES**

**Series A Convertible Preferred Stock:** On June 25, 2002, our board of directors unanimously adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series A convertible preferred stock, and designating the relative rights and preferences of the Series A convertible preferred stock. The stated value, which is also the liquidation preference of the Series A convertible preferred stock, is \$10,000 per share. We were required to pay dividends on the Series A preferred shares, at the rate of 6% per annum of the \$10,000 liquidation preference per share, through June 30, 2003; at the rate of 9% per annum thereafter until June 30, 2004; and thereafter at the rate of 12% per annum. At our option such dividends may be paid in our common stock at the "conversion price" for the conversion of such dividends if such shares of common stock have been registered under the Securities Act of 1933 for sale in the public securities markets. The conversion price is fixed initially at \$15.00 per share of our common stock. There are no shares of Series A convertible preferred stock outstanding. In November 2004, the designation establishing the rights and preferences of the Series A convertible preferred stock was eliminated from our certificate of incorporation so that we are no longer authorized to issue any more Series A convertible preferred stock.

**Series B Convertible Preferred Stock:** On November 7, 2002, our board of directors adopted an amendment to our certificate of incorporation designating 1,200 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series B convertible preferred stock at a stated value of \$10,000 per share. Dividends on the Series B preferred shares are payable at the rate of 12% per annum, in cash or shares of common stock, at our option, except that in the first year, dividends are payable, in advance, in shares of common stock.

The Series B preferred stock is convertible into common shares at any time at the option of the investor, based on a fixed conversion rate of not less than \$3.00, or commencing after February 1, 2003, based on an alternative conversion rate equal to 90% of the average of the five lowest volume weighted average prices for the common stock for the twenty trading days immediately prior to conversion, subject to a floor price of \$2.50.

**Series C Convertible Preferred Stock:** On May 23, 2003, our board of directors adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series C convertible preferred stock at a stated value of \$6,000 per share. Dividends on the Series C preferred shares are payable at the rate of 10% per annum, in cash or shares of common stock, at our option.

The Series C preferred stock is convertible into common shares at any time at the option of the investor, based on a fixed conversion rate of \$2.00 per share.

**Holders Redemption Rights:** Both the Series B and Series C convertible preferred stock have redemption provisions entitling the holders to require us to redeem such preferred shares, including upon the occurrence of the following events:

- the consolidation, merger or other business combination of the Company with or into another entity, except (a) for a migratory merger effected solely for the purpose of changing jurisdiction of incorporation, or (b) if the holders of our voting power prior to such transaction have the ability after the transaction is completed to elect a majority of members of the board of directors of the surviving entity or entities;

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

- in the case of the Series B preferred stock the sale or transfer of more than 20%, and in the case of the Series C preferred stock more than 50%, of our assets other than inventory in the ordinary course of business;
- in the case of the Series B preferred stock acquisition by a third party of more than 30% of our outstanding shares of common stock through a purchase, tender or exchange offer, and in the case of the Series C preferred stock acquisition by a third party of more than 50% of our outstanding shares of common stock.

The redemption price is payable, at our option in cash or common stock. The preferred stock has been presented in shareholders' de ficit as it is our intention to repay any redemption in common stock. All of our outstanding Series B and C preferred stock were exchanged for common stock on January 5, 2005 (see Note 21).

**Series D Convertible Preferred Stock:** On August 19, 2003, our board of directors adopted an amendment to our certificate of incorporation designating 2,000 shares out of the 1,000,000 shares of preferred stock that we are authorized to issue, as Series D convertible preferred stock at a stated value of \$10,000 per share. In the event we declare a cash dividend on our common stock we will be required to pay a dividend on each share of our Series D preferred stock in an amount equal to the cash dividend paid on one share of our common stock multiplied by the number of shares of our common stock into which such one share of our Series D preferred stock can be converted.

Each holder of Series D preferred stock may, at such holder's option, subject to certain limitations, elect to convert all or any portion of the shares of Series D preferred stock held by such holder into a number of fully paid and nonassessable shares of our common stock equal to the quotient of (i) the Series D liquidation preference (\$10,000 per Series D preferred share) divided by (ii) the Series D conversion price of \$2.50 per share. The conversion price is subject to customary adjustments to the Series D conversion price in the event of stock splits, stock combinations, stock dividends, distributions and reclassifications and other corporate events.

**Issuance of 12% Convertible Debentures:** In March 2002, we engaged an investment-banking firm to act as our advisor and to assist in raising capital for us in the form of either debt or equity financing.

On May 13, 2002, we issued \$2,333,000 of 12% convertible debentures, which were convertible into common shares at the lesser of \$3.36 or the price per share of the equity securities to be issued in a subsequent financing. These debentures, payable April 10, 2003, bore interest at the rate of 12% per annum, up to October 10, 2002 and 18% thereafter. We also issued 291,000 stock purchase warrants as part of this May 13, 2002 financing, exercisable at \$4.50 per share for up to five years from the date of grant. The warrants had price protection features whereby the price of the warrants can be reduced to the prices at which common stock or common stock equivalents are thereafter sold by us.

On June 28, 2002, \$600,000 of these debentures sold on May 13, 2002 were converted into Series A preferred stock at 110% of face value. Additionally, on June 28, 2002, we issued an additional \$250,000 of 12% convertible debentures and \$1,200,000 in Series A convertible preferred stock. The total face value of the preferred stock issued was \$1,870,000 which consisted of the \$1,200,000 of cash proceeds received, the \$600,000 face value of converted debentures and the \$70,000 of additional conversion face value. Additionally, the Series A preferred stock was convertible into common shares at a rate of \$1.50 per share. The Series A preferred stock had provisions whereby redemption was out of our control; therefore, the preferred stock was classified as temporary equity.

On June 28, 2002, we also issued 654,624 common stock purchase warrants, at an exercise price of \$1.875 per common share for a five-year period. Of the 654,624, an aggregate of 31,250 warrants were issued with the convertible debentures, with the remainder issued with the Series A preferred stock. The warrants also had similar price protection features, whereby the price of the warrants can be reduced to the prices at which common stock or common stock equivalents are thereafter sold by us.

During the third quarter 2002, we issued \$1,425,000 in convertible debentures, with terms comparable to those issued in the second quarter. Additionally, 178,127 warrants were issued with similar terms to warrants issued on May 13, 2002. In October and November 2002, prior to our Series B preferred stock financing, we issued an additional \$1,900,000 in convertible debentures and 237,503 warrants, with terms comparable to those issued earlier in 2002.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

We deferred the payment of interest due on June 30 and September 30, 2002, pending the completion of our Series B preferred stock financing. These debentures along with the accrued interest were convertible into equity securities if we completed the sale of at least \$5,000,000 in equity securities by July 12, 2002, which date was extended through November 13, 2002. On November 13, 2002, these debentures and accrued interest were converted into Series B preferred stock with the closing of the Series B preferred stock financing. These were converted at the rate of 110% of the debentures plus accrued interest into \$10,000 par value Series B convertible preferred shares.

The relative estimated fair value of the warrants issued in connection with the debentures of \$440,523 was recorded as debt discount, as well as the estimated fair value of the beneficial conversion features of \$1,042,663. Both of these values were being amortized over the remaining life of the convertible debentures, or through April 10, 2003. Upon conversion, the remaining unamortized beneficial conversion features were charged to interest expense.

The relative estimated fair value of the warrants issued in connection with the Series A preferred stock of \$797,919 was recorded as a discount to the preferred stock and was reflected as interest expense, on the date of issuance. Additionally, the estimated fair value of the beneficial conversion feature of \$859,256 has been recorded as an additional discount and reflected as interest expense. The Series A preferred stock had no redemption date, and therefore the charge to interest expense was reflected immediately as the conversion privilege was exercisable immediately.

**First Sale of Series B Convertible Preferred Stock:** In November and December 2002, we issued 938,274 shares of Series B convertible preferred stock to several investors in a private placement, which was funded by an aggregate of \$8,178,000 of financing received, which included \$1,070,000 of new Series B preferred stock and the conversion of the aforementioned convertible debentures and convertible Series A preferred stock. We recorded a loss on extinguishment of debentures and preferred shares of \$1,004,027, principally due to the additional buying power granted to the investors resulting from the difference between the present value of the original debt and the revised present value. The convertible debentures and convertible Series A preferred stock were converted at 110% of face value plus accrued interest. In addition, these investors were granted Series A warrants to purchase 938,275 shares of our common stock at an exercise price of \$.01. These Series A warrants vested immediately and were exercised immediately, upon grant. The investors were also granted Series B-1 and B-2 warrants, which could be used to purchase 542,989 and 469,138 shares of common stock at an exercise price of \$15.00 and \$20.00 per share, respectively. These B-1 warrants were exercisable beginning August 13, 2003 and expire seven years from the date of grant and the B-2 warrants were exercisable beginning November 13, 2003 and expire seven years from date of grant. We assigned values to the Series B preferred stock of \$9,382,742 and the Series A, B-1 and B-2 warrants issued to the investors of \$2,245,206, \$694,447 and \$539,390, or \$3,479,043 in the aggregate, based upon the relative fair market value of the stock at the date of issuance and the estimated fair market value of the warrants, using the Black-Scholes option pricing model.

The warrants issued with the second quarter and third quarter 2003 financings were exchanged for B-1 warrants, issued in the fourth quarter of 2003.

The first year's dividends on the Series B preferred stock were paid in advance in common shares at the rate of 12% upon issue of the preferred shares and were to be paid semiannually in subsequent years, in either cash or common shares, at our election, until the preferred stock is converted to common shares. For the first year's dividends totaling \$1,125,559, paid in common stock, the investors were issued 375,315 shares of common stock, of which 293,489 shares were issued in November 2002 and 81,826 shares in January 2003.

In addition, certain of the investors were given options to purchase, for one year and for amounts ranging from 100% to 200% of their investments, additional shares of the Series B convertible preferred stock at the price paid for such stock by investors on November 13, 2002.

H.C. Wainwright & Company, Inc. (Wainwright) acted as placement agent in this private placement. For its services as placement agent, we paid Wainwright \$601,490. Legal and other professional fees totaled \$155,997. All but \$136,046 of the \$755,487 aggregate costs was amortized to interest expense when the \$5,908,000 convertible debentures and \$1,200,000 of Series A preferred stock were converted to Series B preferred stock. In connection with the Series B

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

conversion, we granted Wainwright and its agents warrants to purchase 800,000 and 500,000 shares of common stock, at an exercise price of \$.01 and \$15.00, respectively, vesting immediately upon issue and August 13, 2003, respectively. These warrants expired on January 31, 2003 and will expire seven years from issue, respectively. In December 2002, we issued 35,273 shares of common stock upon exercise of the \$.01 warrants granted to Wainwright. The fair market value assigned to the Wainwright warrants was \$280,000 and \$24,615, or \$304,615 in the aggregate, for the \$.01 warrants and the \$15.00 warrants, respectively. Total share issuance costs were \$866,612 inclusive of professional fees, the \$136,046 above fees paid to Wainwright, and the fair value of the aforementioned warrants. Issuance costs for the Series B preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock.

**Second Sale of Series B Convertible Preferred Stock:** In February 2003, we received gross proceeds of \$2,000,000 from the sale of our Series B convertible preferred stock. We issued to such investors 200 shares of Series B convertible preferred stock, 292,308 shares of common stock (including 92,308 shares of common stock constituting the first year's dividends on such 200 shares of Series B convertible preferred stock, which dividends were paid in advance, and 200,000 shares of common stock, which were issued upon exercise of Series A warrants, exercised at \$.10 per share) and warrants to purchase an additional 200,000 shares of common stock, of which warrants to purchase 100,000 (the B-1 warrants) shares were exercisable at \$15.00 per share and warrants to purchase the other 100,000 (the B-2 warrants) shares were exercisable at \$20.00 per share. In May and June 2003, in conjunction with the conversion of virtually all of the Series B preferred stock and our reverse stock split, these B-1 and B-2 warrants were amended and restated to provide for exercise prices of \$4.00 and \$5.00, respectively. PRF did not convert its 50 shares of Series B preferred stock on May 23, 2003 and, accordingly, the exercise price of its B-1 and B-2 Warrants were not amended and remained at their original exercise price of \$15.00 and \$20.00, respectively.

Wainwright acted as placement agent in this private placement and in addition to cash compensation, we granted warrants to purchase an aggregate of 37,692 shares of common stock, exercisable at \$0.01 per share, to employees of the placement agent firm. The fair value of these warrants was \$86,692. Total share issuance costs were \$393,488 inclusive of professional and investment banking fees and the fair value of the aforementioned warrants. Issuance costs for the Series B preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock. During 2004 certain of these warrants to purchase 32,460 shares of our common stock were exercised. We received \$325.00.

Dividends are payable in cash or common shares at our option, at the rate of 12% per annum. An accrued dividend of \$50,000 at December 31, 2004 has been provided for within stockholders' equity (deficit), as it is our intent to issue common shares in payment of the dividend.

**Sale of Series C Convertible Preferred Stock:** In May and July 2003, we received gross proceeds of \$5,690,000 from the sale of 948 shares of Series C convertible preferred stock, issuing warrants to purchase 1,707,000 shares of our common stock exercisable at \$3.60 per share. Our Series C preferred stock has a stated value of \$6,000 per share and is convertible into 2,844,999 shares of common stock at \$2.00 per share. In addition, in connection with the Series C financing, investors, other than Paul Royalty Fund, agreed to convert their Series B preferred shares into common shares or their equivalent. As a result, 605,389 shares of Series B preferred stock were converted into 2,421,556 shares of common stock and 482,885 shares of Series B preferred stock were converted into an equal number of shares of Series D preferred stock (with a common stock equivalent of 1,931,540 shares). The Series D convertible preferred stock is non-redeemable and has a stated value of \$10,000 per share. As part of the May 2003 Series C financing, employees of the investment-banking firm which arranged the Series C financing were granted warrants to purchase 149,520 shares of our common stock at an exercise price of \$.01 as part of their compensation. Accordingly, we recorded \$269,000 in Series C preferred share issuance costs related to the warrants issued. Total share issuance costs were \$797,327 inclusive of professional and investment banking fees and the fair value of the aforementioned warrants. Issuance costs for the Series C preferred stock are reflected as a reduction of the proceeds from the sale of the preferred stock.

Dividends were payable in cash or common shares at our option, at the rate of 10% per annum. An accrued dividend of \$563,805 and \$336,550 at December 31, 2004 and 2003, respectively, has been provided for within stockholders' deficit since it was our intent to issue common shares in payment of the dividend.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Deemed Dividend:** In conjunction with these conversions, all Series B-1 and B-2 warrants were amended to provide for revised exercise prices of \$4.00 and \$5.00, respectively. Paul Royalty Fund did not exercise its right to convert its 50 shares of Series B preferred stock into common stock or its equivalent and as such, its B-1 and B-2 warrants were not amended and remained at their original exercise prices of \$15.00 and \$20.00, respectively. As a result of the change in the B-1 and B-2 warrants at May 23, 2003, we recognized a deemed dividend to investors of \$519,000.

Based on the relative fair market value of the preferred stock at the dates of issuance and the estimated fair market value of the warrants, using the Black-Scholes option pricing model, at December 31, 2003, we assigned values to the Series C preferred stock and the Series C warrants of \$4,464,368 and \$1,225,632, respectively. Similarly, we assigned values to the Series D preferred stock, based on values previously assigned to the Series B preferred stock.

Additionally, since the effective conversion price of the Series C preferred stock on the date of issuance was lower than the market value of the common shares on that date, we recognized \$691,000 of additional discounts on the preferred issuances. This conversion feature was charged to retained earnings as accretion of discount.

In August 2003, holders of 483 shares of Series B convertible preferred stock converted their shares into an equal number of shares of Series D convertible preferred stock.

In June and October 2004, a holder of 35.624 shares of Series C preferred stock with a value of \$137,752, converted its shares into 106,872 shares of common stock. Additionally we issued 13,743 shares of our common stock valued at \$30,099 as payment of dividends on the converted Series C preferred stock.

#### **14 - STOCK OPTIONS**

In April 1996, the Board of Directors and stockholders approved the adoption of a stock option plan (the "Plan"). The Plan provides for the grant of options to purchase up to 35,000 shares of our common stock. These options may be granted to employees, our officers, our non-employee directors, consultants, and advisors. The Plan provides for granting of options to purchase our common stock at not less than the fair value of such shares on the date of the grant. Some of the options generally vest ratably over a four-year period, while others vest immediately. The options generally expire after seven years.

In August 1998, the stockholders and Board of Directors ratified and approved an amended and restated 1996 Stock Option Plan increasing the maximum number of shares of our common stock for which stock options may be granted from 35,000 to 155,000 shares. In August 2000, the stockholders and Board of Directors ratified and approved the second amendment to our Amended and Restated 1996 Stock Option Plan increasing the number of shares of our common stock for which options have been or could be granted under the Plan from 155,000 to 300,000 shares.

In February 2003, the stockholders and Board of Directors ratified and approved an amended and restated Stock Option Plan, increasing the maximum number of shares of our common stock for which stock options may be granted from 300,000 to 450,000 shares. As of December 31, 2004, 21,676 options were available for grant under the Plan.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes the stock option activity through December 31, 2004:

	Number	Weighted average exercise price (\$)
Granted - adoption of stock option plan	15,600	70.80
Balance, December 31, 1996	15,600	70.80
Granted	12,300	119.40
Forfeited, expired	(300)	66.30
Balance, December 31, 1997	27,600	92.50
Granted	68,975	121.00
Exercised	(675)	74.20
Forfeited, expired	(1,450)	111.90
Balance, December 31, 1998	94,450	111.70
Granted	39,900	108.70
Forfeited, expired	(22,100)	149.30
Balance, December 31, 1999	112,250	103.30
Granted	44,996	79.60
Exercised	(350)	70.00
Forfeited, expired	(4,485)	82.70
Balance, December 31, 2000	152,411	123.00
Granted	75,650	59.30
Forfeited, expired	(24,730)	74.10
Balance, December 31, 2001	203,331	85.40
Granted	115,511	12.90
Forfeited, expired	(31,630)	76.80
Balance, December 31, 2002	287,212	57.30
Granted	160,861	2.20
Forfeited, expired	(99,874)	84.02
Balance, December 31, 2003	348,199	24.16
Granted	129,500	1.92
Forfeited, expired	(49,375)	20.32
Balance, December 31, 2004	428,324	15.40

The following data has been provided for exercisable options:

	Year ended December 31,		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Number of options	258,574	250,508	223,554
Weighted average exercise price	\$23.04	\$29.98	\$ 65.70
Weighted remaining contractual life	4.18 years	4.79 years	4.26 years

Our Board of Directors or its Stock Option Committee has determined the exercise price for all stock options awarded.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The following table summarizes option data as of December 31, 2004:

Range of exercise prices	Number outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.98 to \$8.75	336,519	5.09	\$ 2.64	171,994	\$ 3.24
\$10.00 to \$35.30	3,950	.85	\$ 35.03	3,725	\$ 35.16
\$47.00 to \$68.00	67,225	3.47	\$ 53.69	62,725	\$ 53.28
\$70.00 to \$99.38	8,055	2.73	\$ 87.06	7,555	\$ 88.14
\$100.00 to \$127.50	<u>12,575</u>	2.82	\$ 100.22	<u>12,575</u>	\$ 100.22
	<u>428,324</u>	4.68	\$ 15.40	<u>258,574</u>	\$ 23.04

We recognized approximately \$1,696,000 of compensation expense for options and warrants issued to officers and our directors in 1998. Such options and warrants were accounted for as variable option grants. Such options and warrants had vested prematurely in December 1998, upon the exercise of warrants owned by one of our directors, in accordance with the terms of certain compensation provisions provided for and approved by our Board of Directors.

During the years ended December 31, 2004 we issued 100,000 options to a director which was not included in the Plan. During the years ended December 31, 2003 and December 31, 2002, we issued 894,400 and 380,000 options, respectively, to senior executives, which were not included in the Plan. These options vested immediately. The following table provides the exercise price for options issued to the director and senior management.

Number Outstanding	Exercise Price	Remaining Contractual Life (years)
380,000	\$ 3.50	4.89
140,000	\$ 2.00	4.96
460,000	\$ 1.80	5.15
276,000	\$ 3.60	5.15
74,000	\$ 2.10	5.42
44,400	\$ 3.60	5.39
<u>1,374,400</u>		

In addition, we recognized approximately \$94,393 and, \$87,000 in consulting expense in 2004 and 2003, respectively, for a warrant granted to an independent consultant for services rendered to us.

**15 - COMMITMENTS AND CONTINGENCIES**

***Cell Therapy Manufacturing Agreement***

In October 29, 2003 we entered into an agreement commencing November 1, 2003 with Cambrex Bio Science Walkersville, Inc., a subsidiary of Cambrex Corporation (Cambrex), for Cambrex to manufacture ORCEL in Cambrex's Walkersville, Maryland facilities. The Cambrex manufacturing facility is required to meet FDA's good manufacturing processes standards. Cambrex is experienced in the manufacture of cell-based medical products such as our ORCEL.

Our agreement with Cambrex requires us to currently pay Cambrex \$128,750 per month, or \$1,545,000 per year, for the use of a production suite in their facility located in Walkersville, Maryland. The payments we will make to Cambrex will increase to \$175,000 monthly, or \$2,100,000 per year, if we require Cambrex to build us a larger production facility to meet

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

our requirements for the production of ORCEL. In 2004 and 2003 we paid \$1,332,500 and \$200,000, respectively, for the use of Cambrex's production facility. These amounts are included in product and laboratory costs. Such annual payments include some services and overhead expenses provided and paid for by Cambrex. These annual payments we are required to make increase 3% per annum on the anniversary of the commencement date. We are required to pay 50% of the cost of the construction of that larger production facility up to \$1,000,000 (up to \$2,500,000 if we terminate our Sales Agency Agreement with Cambrex). However, the amount we contribute to the construction of that larger facility will be repaid to us by credits against a portion of the future annual payments of \$2,100,000 and of certain other payments we are required to make to Cambrex after the larger facility is in use. We are also required to pay specified hourly charges for the Cambrex employees engaged in the production of ORCEL as well as certain other charges. After construction of the larger production facility we are required to acquire from Cambrex virtually all of our requirements for ORCEL that Cambrex can produce. Prior to our election to have Cambrex construct the larger production facility for us, either we or Cambrex may terminate the agreement on six months notice by us and twelve months notice by Cambrex. If we elect to have Cambrex construct the larger production facility for us the agreement will continue for six years after the larger production facility is constructed. However, even after such construction we and Cambrex may elect to scale down over the following three years the portion of our requirements for ORCEL that Cambrex will produce for us. We may elect the scale down period at any time after one year after the larger production facility is constructed and in operation in which event there are additional payments we must make to Cambrex. If we elect the scale down period after one year we must pay Cambrex \$2,625,000 and if we elect the scale down period after two years we must pay Cambrex \$1,050,000. If we elect the scale down periods in either of those two years, we forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against payments we are thereafter required to make to Cambrex. Either Cambrex or we may elect the scale down period later than three years after that facility is in operation and neither of us will be required to make any additional payments to the other because of that election. If after the construction of the larger production facility we breach a material term of our agreement with Cambrex, or elect to terminate the agreement, we will have to pay Cambrex the following amounts:

If termination occurs after the following anniversary of the construction of the larger production facility	Amount of Payment
6 years	\$1,050,000
5 years, but less than 6 years	1,575,000
4 years, but less than 5 years	2,625,000
3 years, but less than 4 years	3,675,000
2 years, but less than 3 years	5,250,000
1 year, but less than 2 years	6,300,000

In addition, upon such termination we will forfeit our right to receive any further credits (up to the amount of our contribution to the cost of the larger production facility) against future payments we may have to make to Cambrex.

***Sales Agency Agreement***

On October 18, 2004 we entered into a Sales Agency Agreement with Cambrex, providing for Cambrex to be the exclusive sales agent in the United States for our ORCEL product or any other future bi-layered cellular matrix product of ours for the treatment of venous stasis ulcers, diabetic foot ulcers or any other therapeutic indication for dermatological chronic or acute wound healing. The agreement is for a period of six years beginning sixty days after we receive clearance from the FDA for the commercial sale of our ORCEL for the treatment of venous stasis ulcer, but the agreement's six year term will not commence before April 1, 2005. The agreement requires us to pay commissions to Cambrex ranging from initially at 40% of net sales and decreasing to 27% of net sales as the amount of sales increases. The agreement requires Cambrex to spend \$4,000,000 for marketing efforts during the sixteen-month period after the FDA clears our sale of ORCEL for the treatment of venous stasis ulcers.

Cambrex has the right to terminate the agreement if (a) we do not receive FDA clearance for commercial sale of ORCEL for the treatment of venous stasis ulcers by April 1, 2005 or (b) if for any period of six consecutive months beginning in 2007, sales are less than 9,000 units. We may terminate the agreement if sales of ORCEL are less in any twelve month period than amounts targeted in the agreement for that period (ranging from 10,000 units in the first twelve month period to 100,000 units in the sixth twelve month period).

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

Concurrent with the Sales Agency Agreement we entered into a License Agreement pursuant to which we licensed certain intellectual property rights to Cambrex. We also entered into a Security Agreement with Cambrex to secure the performance of our obligations under the Manufacturing, License, and Sales Agreement. The secured collateral consists of all accounts, cash, contract rights, payment intangibles, and general intangibles arising out of or in connection with the sale of products pursuant to the sales agreement and/or license agreement, and all supporting obligations, guarantees and other security therefore, whether secured or unsecured, whether now existing or hereafter created. The lien and security interest under this security agreement are subordinate and junior in priority to the perfected lien and security interest granted to Paul Royalty Fund as secured party under the Paul Royalty Security Agreement.

In connection with the Sales Agency Agreement, our manufacturing agreement with Cambrex was modified so that if Cambrex builds us a larger production facility the maximum amount we could be required to contribute to that construction was reduced from \$2,500,000 to \$1,000,000.

***Supply Agreement***

We purchase bovine collagen sponges, a key component of ORCEL, from one supplier who produces the sponges to our specifications. On December 30, 2004 we entered into a two-year supply agreement with this supplier. Under such agreement we agreed to minimum purchase commitments. We agreed to purchase a minimum of 3,500 units of finished collagen sponges within the first twelve-month period. The value of such commitment is approximately \$200,000. We also agreed that subsequent to a written notification from the FDA allowing us to sell ORCEL commercially for treatment of venous stasis ulcers we will provide such supplier projections for one or more subsequent quarters and the parties will be obligated to purchase and sell those projected amounts.

***Government Regulation***

We are subject to extensive government regulation. Products for human treatment are subject to rigorous preclinical and clinical testing procedures as a condition for clearance by the FDA and approval by similar authorities in foreign countries prior to commercial sale. Presently, we are awaiting a response from the FDA for clearance for sale of ORCEL to treat venous stasis ulcers based on our recently concluded clinical trial. It is not possible for us to determine whether the results achieved from that human clinical trial will be sufficient to obtain FDA clearance.

**16 - LEGAL PROCEEDINGS**

In 2002, ClinTrials Networks, LLC (ClinTrials) claimed that we had breached our agreement with them, which provided for ClinTrials to arrange and manage the FDA mandated clinical trials for use of our ORCEL for the treatment of venous stasis ulcers, and for other services. In October 2002, ClinTrials commenced an arbitration proceeding against us, claiming that we owed ClinTrials \$165,936 and during the arbitration hearings ClinTrials increased its claim to approximately \$400,000, plus reimbursement of legal fees. In September 2003, the arbitrator awarded ClinTrials \$93,263 in full settlement of its claim plus interest of 6% per annum from January 1, 2002 until the award is fully paid. Additionally, we were ordered to pay \$61,497 for claimant's attorney's fees and costs, and \$1,438 for arbitration fees. We paid this award in the fourth quarter of 2003.

During the quarter ended September 30, 2002, PDI, Inc. commenced an action against us in the Superior Court of New Jersey, Bergen County, claiming that we owe \$205,000 to PDI for services that they have performed for us. In the second quarter of 2003 we paid PDI \$150,000 in full settlement of its claim against us.

We have successfully defended challenges to our United States and European patents in the past. Advanced Tissue Sciences (ATS) challenged, in the European Patent Office, the grant of our European Patent upon the ground that the patent lacks novelty and is not inventive over prior art. The agency hearing this case is the European Patent Office. The original proceeding began November 5, 1998 and involved ATS as the opposer and Ortec, as the patentee. The first hearing was resolved in our favor. That is, the European Patent Office Tribunal affirmed the grant of the patent, ruling against ATS. ATS seeks cancellation of the patent. ATS has appealed the decision on the patent and the appeal is pending. We expect an oral hearing date for the appeal to be set in a year or later. We cannot predict with any certainty the ultimate outcome of that appeal.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

17 - RELATED PARTY TRANSACTIONS

*Due to Founder*

Pursuant to an amended agreement, we had engaged the services of Dr. Mark Eisenberg, one of our directors, who is also one of our founders, as a consultant through August 31, 2005. During 2003, we terminated our agreement with Dr. Eisenberg and discontinued research activities in Australia. For the period ended December 31, 2003, production and laboratory costs include compensation due to Dr. Eisenberg of \$195,000, respectively, and approximately \$1,029,000 for the period from inception to December 31, 2003. In accordance with the settlement agreement, we recorded consulting expense of \$194,656 for the remainder of the \$304,478 of consulting fees due under the consulting agreement with Dr. Eisenberg. Additionally, we recorded \$28,881 in rent expense that we owed Dr. Eisenberg for the space we occupied in the Australian laboratory. The total amount due Dr. Eisenberg under the settlement agreement aggregated \$398,574 which represents unpaid consulting fees, the rent for the Australian laboratory, and \$65,215 of advances made by Dr. Eisenberg on our behalf. We settled the balance due Dr. Eisenberg in 2004 by issuing 100,000 options to purchase our common stock at an exercise price of \$2.00 per share. We recorded the \$398,574 settlement in 2004 as a contribution of capital given that the settlement was with our director. These options will expire in five years.

*Research Collaboration*

On October 11, 2004 we entered into a collaboration with Hapto Biotech, Inc., a company involved in the field of tissue engineering, for the purpose of further developing promising product leads identified through a research collaboration established in September 2002 between us and Hapto Biotech, utilizing each company's proprietary technologies. The activities of the two entities will be conducted in a new entity, Hapto / Ortec Collaboration, LLC. The collaboration may require an approximate projected capital contribution of \$300,000 from each entity during its first twelve months of operation. The agreement provides for a license agreement to us if the collaboration is successful in developing other technology (as defined) which can be used to treat Hard to Heal Chronic Wounds (as defined). At December 31, 2004 an amount payable to the collaboration of \$68,741 was included in accounts payable.

*Change of Control*

In December 1998, our Board of Directors authorized agreements between us and two of our executive officers and another employee, which state that in the event of a "change of control" certain "special compensation arrangements" will occur. A "change of control" is defined as a change in the ownership or effective control of Ortec or in the ownership of a substantial portion of our assets, but in any event if certain members of our Board of Directors no longer constitute a majority of the Board of Directors. In the event that such change of control occurs, the agreements provide these individuals additional compensation, interest-free loans to exercise their stock options and warrants, and extensions of the expiration dates of all of their then outstanding options and warrants so that none will expire in less than three years from such termination of employment. In addition, for all of the individuals, in the event of a change of control, all unvested options and warrants will vest immediately upon such change of control.

18 - INCOME TAXES

We have deferred start-up costs for income tax purposes and intend to elect to amortize such costs over a period of 60 months, under Section 195(b) of the Internal Revenue Code, when we commence operations.

At December 31, 2004, we had net operating loss carry-forwards of approximately \$26,526,000 for Federal and New York State income tax purposes expiring through 2024. Due to the merger of Skin Group with and into Ortec in July 1992, the net operating losses and other built-in deductions existing at that time were subject to annual limitations pursuant to Internal Revenue Code Section 382. Our ability to utilize net operating losses and other built-in deductions generated after that date may be limited in the future due to additional issuances of our common stock or other changes in control, as defined in the Internal Revenue Code and related regulations.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

For financial statement purposes, a valuation allowance of approximately \$44,047,000 and \$37,588,000 at December 31, 2004 and 2003, respectively, has been recognized to offset entirely our deferred tax assets, which arose primarily from our operating loss carry-forwards and the deferral of start-up expenses for tax purposes, as the realization of such deferred tax assets is uncertain. Components of our deferred tax asset are as follows:

	December 31,	
	2004	2003
Net operating loss carry-forwards	\$ 11,141,000	\$ 8,846,000
Deferral of start-up costs	26,785,000	24,415,000
Interest	5,512,000	3,755,000
Other	609,000	572,000
	44,047,000	37,588,000
Valuation allowance	(44,047,000)	(37,588,000)
Net deferred tax asset	\$ -	\$ -

The following reconciles the income taxes computed at the federal statutory rate to the amounts recorded in our statement of operations:

	Year ended December 31,		Cumulative from
	2004	2003	March 12, 1991 (inception) to December 31, 2004
Income tax benefit at the Statutory rate	\$ (5,233,000)	\$ (5,390,000)	\$ (38,073,000)
State and local income taxes, net of Federal benefit	(1,231,000)	(1,279,000)	(7,134,000)
Permanent difference	5,000	(46,000)	1,160,000
Effect of valuation allowance	6,459,000	6,715,000	44,047,000
	\$ -	\$ -	\$ -

Our net operating loss tax carry-forwards expire as follows:

Year ending December 31,	
2006	\$ 76,000
2007	233,000
2008	511,000
2009	597,000
2010	440,000
2011	677,000
2012	839,000
2018	1,189,000
2019	2,602,000
2020	3,535,000
2021	4,014,000
2022	3,311,000
2023	3,054,000
2024	5,448,000
	\$ 26,526,000

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**19 - FAIR VALUE OF FINANCIAL INSTRUMENTS**

Statement of Financial Accounting Standards No. 107, "Fair Value of Financial Instruments," requires disclosure of the estimated fair value of an entity's financial instrument assets and liabilities. For us, financial instruments consist principally of cash and cash equivalents, loans payable and other long-term obligations.

The following methods and assumptions were used to estimate the fair value of each class of financial instrument for which it is practicable to estimate that value.

*Cash and Cash Equivalents*

The carrying value reasonably approximates fair value because of the short-term maturity of those instruments.

*Loans Payable and Other Long-term Obligations*

Based on borrowing rates currently available to us for other financings with similar terms and maturities, the carrying value of our loans payable, capital lease obligations and other long-term obligations approximate the fair value.

**20 - RETIREMENT PLAN**

The Company maintains a defined contribution 401(k) savings plan (401(k) plan) for the benefit of eligible employees. Under the 401(k) plan, a participant may elect to defer a portion of annual compensation. Contributions to the 401(k) plan are immediately vested in plan participants' accounts. Plan expenses were \$3,255 and \$4,000 for the years ended December 31, 2004 and 2003, respectively.

**21 - SUBSEQUENT EVENTS**

On January 5, 2005 we entered into a number of agreements with institutional and accredited investors (collectively, the "purchase rs") that provided us with:

- Gross aggregate cash proceeds of \$5,403,302 from the sale of our common stock (the "private placement") to former holders of our Series C preferred shares and other purchasers at \$0.833 per share (the "purchase price") with each receiving a five year warrant to purchase one share of common stock at \$1.80 per share for every two shares purchased;
- The exchange of all our outstanding Series C preferred shares at December 31, 2004, or approximately 913 Series C preferred shares, with a liquidation preference of \$5,476,256 plus accrued and unpaid dividends, an aggregate value of \$6,357,104, for shares of our common stock at the \$0.833 per share purchase price and five-year warrants to purchase our common stock at \$1.80 per share. Upon the exchange, the holders of the Series C preferred shares received a warrant to purchase one share of common stock for each two shares of our common stock they received in the exchange. This exchange was offered to Series C preferred shareholders if they participated in the private placement sale of our common stock for an amount equal to 30% of the liquidation preference amounts of their Series C preferred shares exchanged for our common stock. The Series C holders provided gross cash proceeds of \$1,642,877 (30% of \$5,476,256) of the \$5,403,302 aggregate gross proceeds received by us in the private placement. We expect to record a deemed dividend of approximately \$2,126,000 related to the exchange of the Series C preferred shares for common shares.
- As a result of our receipt of over \$5,000,000 in the private placement we elected to repay \$9,626,626 (principal balance outstanding at December 31, 2004) of our outstanding promissory notes, accrued interest of \$674,587 (\$658,776 at December 31, 2004) and an added 20% premium, in all \$12,361,456, by issuing to each noteholder so many shares of common stock equal to the principal, accrued interest and premium of his note divided by the \$0.833 purchase price. Each noteholder also received our five-year warrant to purchase one share of our common stock at \$1.80 per share for each common share received, or approximately 15,000,000

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

warrants. We expect to record a loss on extinguishment of approximately \$10,300,000 in connection with this transaction representing the excess of the fair value of the common stock and warrants issued over the outstanding balance of the promissory notes and accrued interest.

- Purchasers, Series C Holders and holders of the Notes whose participation in these transactions would result in ownership of common stock in excess of 9.99% of our issued and outstanding shares of common stock could elect to receive instead of our common stock, shares of our Series D convertible preferred stock convertible into the same number of shares of our common stock.

We issued an aggregate 17,720,767 shares of common stock, 2,806.37 shares of Series D preferred stock (convertible into 11,225,466 shares of common stock), and five-year Series E warrants to purchase 21,889,989 shares of our common stock at an exercise price of \$1.80 per share, as a result of these transactions.

We have undertaken to register all shares of our common stock referred to above as well as all shares of our common stock issuable upon exercise of all the warrants described above, within 10 days after filing of our Annual Report on Form 10-KSB with the Securities and Exchange Commission, which we are required to file by March 31, 2005. Failure to have the registration statement declared effective within 60 days of filing will subject us to liquidated damages.

We granted each of the purchasers in the \$5,403,302 private placement the right to purchase, within 45 days after the closing date, additional shares of our common stock and our Series E warrants on the same terms as in the private placement in an amount not to exceed 25% of their original cash investment in the private placement. Four investors exercised this right and we received gross proceeds of \$127,719. We issued 153,263 shares and five year warrants to purchase 76,632 shares of our common stock at an exercise price of \$1.80 per share for such additional investments by these four investors. We paid our placement agent 10% of the gross proceeds and will issue a warrant to purchase 22,989 shares of our common stock exercisable at \$0.95 per share.

The Series E Warrants provide that if we sell shares of our common stock at prices below the exercise prices of those warrants, or issue other securities convertible into, or which entitle the holder to purchase, shares of our common stock, which could result in the sale of our common stock at a price which in effect (taking into consideration the price paid for the convertible security or the warrant or the option) is less than the exercise price of the Series E Warrants, then the exercise price of the Series E Warrants is reduced by a portion of the difference between the exercise price and the lower price at which the common stock was, or effectively could be, acquired. That percentage by which the exercise price of the Series E Warrants could be reduced depends not only on the lower price at which our common stock was, or could be, acquired, but also by the ratio that the number of shares of our common stock that were, or could be, so acquired bears to the total number of shares of our common stock that would be outstanding after such sale of our common stock, or the conversion of securities convertible into, or the exercise of such warrants or options to purchase, our common stock.

Commencing 24 months after the Closing Date, subject to a registration statement then being effective with respect to the common stock underlying the warrants, the warrants may be redeemed by us if our common stock closes above \$3.60 for ten consecutive trading days. The warrants contain limited cashless exercise as well as customary anti-dilution provisions.

In connection with these transactions, we paid our placement agent in the transactions commissions consisting of cash equaling 10% of the \$5,403,302 of gross cash proceeds we received from the private placement. The placement agent will receive a warrant to purchase 2,705,387 shares of our common stock exercisable at \$0.95 per share. We paid \$50,000 in legal expenses in connection with the private placement. We will also pay the placement agent cash equal to 6% of the gross proceeds received by us from the exercise, at any time in the next three years, of the warrants issued to the investors who purchased shares of common stock for cash in the private placement. We also entered into an agreement under which the placement agent will provide financial advisory services to us until September 30, 2005, for a fee of \$250,000. The fee will be amortized over the period of service. Payment of such fee, which for a limited time may be payable in common stock at the option of the placement agent, will be deferred until our cash balance exceeds \$10,000,000.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

In accordance with an agreement dated May 23, 2003 amongst the holders of Series B preferred stock which provided for conversion of our outstanding Series B preferred stock should all of the holders of Series C preferred stock convert their preferred shares to common stock (which occurred at the January 5, 2005 closing as described above), Paul Royalty Fund, the sole remaining holder of Series B preferred stock converted their 50 shares of Series B preferred stock into 220,647 shares of common stock, which included common shares for \$51,616 in accrued dividends.

During 2003 an allocation of 1,800,000 restricted shares of common stock were granted to officers and certain employees. The issuance of these shares was contingent on our achieving certain milestones and if issued will contain certain vesting and payout provisions. On January 5, 2005 we issued 1,000,000 and 350,000 of these shares to our chief executive officer and chairman, respectively, for having achieved a milestone of raising in excess of \$15,000,000 over a specified period. Pursuant to our agreements with these individuals these shares will be forfeited if at any time prior to January 1, 2007 we no longer employ them. These shares cannot be sold prior to January 1, 2007, and after January 2007 we have restricted the number of shares that may be sold monthly to 20,000 shares per month by each of them. We expect to record as compensation expense a charge of approximately \$1,284,000 related to this issuance.

On February 2, 2005 we entered into a commercial premium finance agreement with First Insurance Funding Corp. of New York in the amount of \$220,000. The financing agreement bears interest at 7.23% and requires nine monthly payments of \$25,187 beginning March 2005. The financing was utilized to fund the premium payments for our directors and officers insurance policy.

On February 9, 2005 we completed a private placement with one investor from which we received aggregate gross proceeds of \$100,000. We issued to the investor 120,000 shares of our common stock and a five-year warrant to purchase 60,000 shares of our common stock at \$1.80 per share. We paid our placement agent 10% of the gross proceeds and a five-year warrant to purchase 18,000 shares of our common stock exercisable at \$0.95 per share.

ORTEC INTERNATIONAL, INC.  
(A DEVELOPMENT STAGE ENTERPRISE)

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

The unaudited pro forma effect of the aforementioned financings on our December 31, 2004 balance sheet; encompassing the January 5, 2005 placement including the rights exercised to purchase additional shares, the common stock awards issued to our chief executive officer and chairman for meeting their milestones, and the February placement, displayed in a condensed format, is as follows:

	December 31, 2004 <u>(Audited)</u>	First Quarter 2005 <u>Financings</u> <i>dr (cr)</i>	December 31, 2004 <u>(Unaudited)</u> <u>Pro Forma</u>
Cash and cash equivalents	\$ 227,370	5,017,919	\$ 5,245,289
Other current assets	128,938	-	128,938
Total current assets	<u>356,308</u>	<u>5,017,919</u>	<u>5,374,227</u>
Other assets	1,093,048	-	1,093,048
Total assets	<u>\$ 1,449,356</u>	<u>5,017,919</u>	<u>\$ 6,467,275</u>
Promissory notes - investors	\$ 9,626,626	(9,626,626)	-
Other current liabilities	5,325,306	(658,776)	4,666,530
Total current liabilities	<u>14,951,932</u>	<u>(10,285,402)</u>	<u>4,666,530</u>
Long term liabilities	22,853,778	-	22,853,778
Total liabilities	<u>37,805,710</u>	<u>(10,285,402)</u>	<u>27,520,308</u>
Preferred stock			
Series B	270,859	(270,859)	-
Series C	3,529,289	(3,529,289)	-
Series D	3,567,652	9,354,555	12,922,207
Common stock	6,372	19,565	25,937
Additional paid-in capital	76,899,663	23,484,700	100,384,363
Deficit	(120,452,544)	(13,755,351)	(134,207,895)
Treasury stock	(177,645)	-	(177,645)
Total shareholders' equity (deficit)	<u>(36,356,354)</u>	<u>15,303,321</u>	<u>(21,053,033)</u>
Total liabilities and shareholders' deficit	<u>\$ 1,449,356</u>	<u>5,017,919</u>	<u>\$ 6,467,275</u>

(1) Consists of the following:

Loss on extinguishment of promissory notes	\$ 10,344,009
Deemed dividend on Series C warrants	2,125,974
Non-cash stock compensation	1,283,850
Series B preferred dividends	1,518
	<u>\$ 13,755,351</u>