



**ORTEC INTERNATIONAL, INC.**

**ANNUAL REPORT**



## ORTEC INTERNATIONAL, INC.

### Letter to Our Shareholders

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The momentum established through the successes achieved in 2001 and through mid 2002, i.e., FDA approval of OrCel™ for the treatment of donor sites in burn patients, initiating commercial sales, establishing reimbursement codes, completing pilot studies for both the venous and diabetic leg ulcer trials, was undermined by the events of September 11<sup>th</sup>, the corresponding economic slowdown and the implosion of the equity markets. We expended significant time and energy in 2002 securing capital. Despite the dreadful conditions of the equity markets, we were successful in raising \$8.5 million from new and existing institutional investors.

However the new realities of the capital markets required us to modify our business plan. In June 2002, accordingly, we halted the commercial sale of OrCel for the donor site burn market, implemented a significant reduction in our work force, reduced our overhead costs, focused on debt management, which included the short-term deferral of past due rent for our office, research and production facilities. Those payments for our North Brunswick facility were deferred until the latter part of January 2003. The past due rent obligation for our New York City facility will be required to be paid by us in thirteen monthly installments beginning March 1, 2003. Our remaining resources have been dedicated to the completion of our venous leg ulcer (VLU) pivotal trial, Ortec's most significant near term value building event. Our immediate task is to secure additional financing in the first three months of 2003 to enable us to continue our operations.

In establishing the business plan which we plan to implement during the coming year, we were ever so mindful of avoiding the pitfalls and challenges which our two primary competitors experienced and, which we believe, contributed heavily to both of them filing for bankruptcy protection. Accordingly, in contrast, when establishing a sales and marketing partnership, we will seek to retain a percentage of sales revenue which allows us to achieve profitability at a significantly lower sales threshold and gives proper recognition to our product being a late stage, near-term commercial product. Second, investment in manufacturing capacity and overhead will only be made upon our attaining sales levels which warrant that investment. As an interim step, among other options, we are evaluating the use of existing third party manufacturers skilled in cell manufacturing and scale-up, thereby avoiding significant up front investments which otherwise would be required. We are currently engaged in discussions with such manufacturers.

In contrast to our competitors, we believe that successfully executing both of these components of our business plan will provide us with the ability to be cash flow positive upon achieving approximately \$30 million in sales, a sales threshold already achieved by one of those competitors.

I would like to share with you the other parts of our business plan and our goals and milestones for the next 12 months:

- ❖ Complete the pivotal venous leg ulcer trial  
We have 13 active centers and expect to enroll an additional 20 patients per month in January and February to complete the required enrollment.
- ❖ File the PMA (Pre-Market Approval) with the FDA and publish the results of our VLU trial  
We expect to file sections of the PMA in the first quarter of 2003. This allows the FDA to initiate its review and potentially accelerate the review process.

❖ Receive FDA approval for Venous Leg Ulcers

In August 2001, the FDA gave approval for the use of OrCel in treatment of donor sites in burn patients within 6 months of our donor site PMA filing. We are hopeful that our prior approvals and constant interaction with the FDA will allow for a similar approval timeline for the use of our OrCel to treat venous leg ulcers. In addition, we continue to be very optimistic about securing FDA approval. Our previously published results of our pilot trial for VLU, to our knowledge, continues to be unmatched by any competitive product and demonstrates the strength of our product. We believe that the results of the pivotal VLU trial will be consistent with that of our pilot trial. Our pilot data showed statistical significance at 6 months in that OrCel closed the ulcers completely of 71% of the patients treated versus 37% with standard of care. At three months, 53% of OrCel treated patients had complete closure versus 26% with standard of care. Based on the strength of this data, the FDA approved a reduction in the number of the patients required for our pivotal VLU trial by half.

❖ Establish a corporate partnership for sales and marketing

We continue to negotiate with potential sales and marketing partners for the US licensing rights to OrCel. We are in varying stages in those discussions and negotiations. It is our expectation that prior to the filing of our VLU PMA, we will have consummated a sales and marketing agreement.

❖ Reinitiate commercial sales of OrCel


Depending on the timing of the completion of the sales and marketing agreement and the financial resources we can obtain from that transaction or from other sources, we believe we can achieve between \$4-6 million in sales in 2003 and with the FDA approval for treating VLU with OrCel, sales could achieve \$15-20 million in 2004. During the period in 2002 when we made OrCel commercially available, we reached sales of \$16,000 per week with only a very targeted and limited sales effort. With a sales and marketing partner with a presence in the wound care arena, we believe our sales targets are modest.

❖ Increase Existing Manufacturing Capacity and Reduce Per Unit Cost

With the focus on profitability, we expect to implement a range of cost reduction programs which we believe will have a dramatic impact on the per unit manufacturing cost of OrCel and allow for greater manufacturing efficiency, thereby increasing our current plant capacity. These cost reduction programs will be implemented during the course of 2003 and 2004.

In order to achieve the above goals and implement our business plan we estimate that we will need to raise approximately \$9 million during 2003 and approximately \$6 million additional financing during 2004. These funds, we believe, can be secured from a combination of sources including a sales and marketing agreement for US marketing rights, private placements, sales of additional future royalty rights, consummating a sales and marketing agreement for Europe, and out licensing of future applications of the OrCel technology.

While 2002 was a very challenging year, 2003 presents the opportunity for considerable value building. We are excited about those prospects, yet ever mindful of the challenges that lay ahead. With your support, we will continue to persevere and prevail.



Steven Katz, Ph.D.  
Chairman and CEO

You can get updated information about Ortec either through the internet at the SEC's website - <http://www.sec.gov>, or from us by calling us at (212) 740-6999, Extension 261. Our Form 10-QA for the quarter ended September 30, 2002, will provide you with our unaudited financial statements for the nine months ended September 30, 2002.

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-K, 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, FOR THE COMPANY'S MOST RECENT FISCAL YEAR. SUCH WRITTEN REQUESTS SHALL BE SENT TO THE COMPANY, 3960 BROADWAY, NEW YORK, NEW YORK 10032, ATTENTION: RON LIPSTEIN, SECRETARY.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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.

##### Forward Looking Information

This Report on Form 10-K contains certain forward looking statements and information relating to Ortec, that are based on the beliefs of management, as well as assumptions made by management, utilizing currently available information. When used in this document, the words "anticipate," "believe," "estimate," and "expect" and similar expressions, as they relate to Ortec, are intended to identify forward looking statements. Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions, including those described in this discussion and elsewhere in this Form 10-K Report. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those described herein as anticipated, believed, estimated or expected. We do not intend to update these forward looking statements.

The following discussion should be read in conjunction with our financial statements and notes thereto.

##### General

Since Ortec's inception we have been principally engaged in the research and development of our tissue engineered skin regeneration product, for use in the treatment of chronic and acute wounds, such as venous and diabetic skin ulcers, and autograft donor site wounds for burn victims. We call our product OrCel™ and in June 2001 we filed a trademark application for such name with the United States Patent and Trademark Office.

In February 2001 Ortec received FDA approval to make commercial sales of OrCel for use on patients with recessive dystrophic epidermolysis bullosa, followed by FDA approval in September 2001 for use of the product in the treatment of donor site wounds in burn patients. With these approvals, though Ortec is still a development stage enterprise, in December 2001 we began our first commercial shipment of product, realizing sales revenues of approximately \$22,000.

From inception to date, we have incurred cumulative net losses of approximately \$59.2 million. We expect to continue to incur substantial losses until at least 2003, due to continued spending on research and development programs, the funding of clinical trials and regulatory activities and the increased personnel costs of manufacturing, marketing and sales, distribution and administrative activities.

We are currently conducting pivotal clinical trials of OrCel in the treatment of venous stasis and diabetic foot ulcers. Venous stasis ulcers are open lesions on the legs, which result from the poor circulation of blood returning from the legs to the heart. Diabetic ulcers are open sores that remain after the destruction of surface tissue. Ortec expects to complete the venous stasis clinical trials by the end of 2002, with submission of the FDA filing by the first quarter of 2003. We expect to complete the diabetic ulcers pivotal clinical trials early in 2003, with submission to the FDA anticipated by the end of the second quarter 2003. We anticipate obtaining FDA approval in 2003 for the use of our OrCel product in the treatment of both these medical conditions.

We anticipate that future revenues and results of operations may continue to fluctuate significantly depending on, among other factors, the timing and outcome of applications for additional regulatory approvals, our ability to successfully manufacture, market and distribute OrCel and/or the establishment of collaborative arrangements for the manufacturing, marketing and distribution of our product. We anticipate that our operating activities will result in substantial net losses until at least 2003.

##### Critical Accounting Policies

**Revenue Recognition.** Revenues from sales are recognized upon shipment of product to customers. In December 2001 Ortec made its first commercial sales of product to customers. We account for our Revenue Interest Assignment Agreement in a manner similar to that of debt and provide for interest to reflect the estimated cost of the funds received. Interest is imputed at 30% per annum, which is the minimum return under the agreement. Interest may range from 20% to 35% per annum depending on our sales and the ultimate term of the Agreement.

##### Results of Operations

Year Ended December 31, 2001, and December 31, 2000.

##### Revenues

Ortec made its first commercial shipments of OrCel to customers in December 2001, earning revenues from operations of approximately \$22,000.

##### Expenses

Expenses increased by approximately \$3.4 million in 2001 from approximately \$12.7 million in 2000 to approximately \$16.1 million in 2001.

**Personnel.** Personnel costs increased by approximately \$1.8 million to \$6.6 million in 2001, compared with \$4.8

million in 2000. This increased expense resulted from the additional personnel required to conduct and manage the clinical trial programs, to manufacture the product required by our clinical trial programs and other research and development activities, to prepare for manufacturing scale-up and marketing and an increase in corporate and administrative expenses. During 2001, we conducted two pilot clinical trials, concluded a pivotal clinical trial and the relevant FDA submissions. Based on these trials and submissions, Ortec was granted two FDA approvals in 2001.

Consulting. These fees increased by \$.6 million from \$.8 million in 2000 to \$1.4 million in 2001, primarily due to costs incurred in conducting the clinical trials and FDA submissions, noted above, the development of a new cryopreserved product and in hiring a marketing consultant.

Research and Development. These expenses increased by approximately \$.1 million to \$4.3 million in 2001, compared with \$4.2 million in 2000. The increase in research and development expenses was primarily due to the costs of conducting the venous and diabetic ulcers clinical trials, as well as research work performed in the areas of cryopreservation and production cost reduction.

General and Administrative. These expenses increased by \$.4 million from \$2.3 million in 2000 to \$2.7 million in 2001, due to increased marketing and legal expenses incurred, as Ortec prepares for commercial sales of its product and continues its financing activities. During 2001, the Company worked on and entered into several significant agreements, including the Paul Capital Revenue Interest Assignment agreement, the GE Capital Asset Financing agreement and the Technology Center of New Jersey Lease agreement. We also investigated and evaluated several potential corporate investment partners.

Interest Expense. Ortec incurred increased interest expense of \$.4 million in 2001, compared with the expense incurred in 2000. On August 29, 2001, Ortec entered into a Royalty Revenue Interest Assignment agreement with Paul Capital and as part of this agreement, was entitled to receive \$10.0 million in 2001. \$6.0 million of this amount was received in 2001 and the remaining \$4.0 million was received in January 2002. Upon the achievement of certain milestones, Ortec may be entitled to receive another \$5.0 million and may incrementally receive an additional \$10.0 million, but only upon the mutual agreement of both the Company and Paul Capital. Management anticipates that the effective cost of these funds based on the anticipated revenue stream, over the term of this agreement, which terminates in December 2011, will range between 20% to 35% per annum and as such, approximately \$455,000 in interest expense has been accrued in 2001. We have provided for interest at 30% per annum which represents the minimum return to Paul Capital assuming that we do not early terminate the agreement. Interest Income. Interest income declined by approximately \$395,000 from \$587,000 in 2000 to approximately \$192,000 in 2001, primarily due to the smaller average cash balances outstanding during 2001 compared with 2000. Year Ended December 31, 2000, and December 31, 1999.

#### Revenues

There were no revenues from commercial sales in 2000 and 1999.

#### Expenses

Research and Development. Expenses for the year ended December 31, 2000 increased to \$4.2 million from \$3.1 million for the year ended December 31, 1999, which amounts do not include consulting expenses, a significant portion of which was paid for research and development projects. Such consulting expenses for research and development amounted to approximately \$838,000 in 2000 and \$834,000 in 1999. The increase in research and development expenses relate primarily to the costs associated with the increased clinical trial activity, cryopreservation research and for enhancement and other applications of Ortel.

General and Administrative. This expense amounted to \$2.3 million for the year ended December 31, 2000 and \$2.2 million for 1999.

Personnel. Personnel expenses for the year ended December 31, 2000 increased to \$4.8 million from \$3.7 million for the year ended December 31, 1999. This increase resulted from the larger number of persons employed because of increased research and product development, to conduct our clinical trials, to prepare for manufacturing scale-up in anticipation of marketing our product, and for additional administrative personnel required as a result of such increased staffing levels.

Rent. This expense increased to \$535,000 in 2000 from \$473,000 for the year ended December 31, 1999. This resulted from the increased space occupied at Columbia University's Audubon Biomedical Science and Technology Park in New York City for additional research and development laboratories and to accommodate the increased staffing in 2000.

Interest Income. Interest income increased by approximately \$218,000 from approximately \$369,000 in 1999 to approximately \$587,000 in 2000, because of larger cash and cash equivalent balances in 2000 that resulted from sales of common stock.

#### Liquidity and Capital Resources

Since inception (March 12, 1991) through December 31, 2001, Ortec has accumulated a deficit of approximately \$59.2 million and we expect to continue to incur substantial operating losses until at least 2003. We have financed our operations primarily through private placements of our common stock, our initial public offering and the exercise of our publicly traded Class A warrants at the end of 1997. From inception to December 31, 2001, we received cash proceeds from the sale of equity securities, net of share issuance expenses, of approximately \$49.9 million, and in 2001, we received \$6 million from the sale of a percentage interest in our future revenues from the sale of our product in North America.

For the year ended December 31, 2001, we used net cash for operating activities of approximately \$13.0 million. Cash used in operating activities resulted primarily from our net loss of \$15.9 million, offset by non cash depreciation and amortization of approximately \$737,000, approximately \$188,000 of non cash stock

compensation and an increase in accounts payable and accrued expenses of approximately \$2.1 million.

In 2001 we invested approximately \$620,000 in property, plant, equipment and patent application costs and made deposits and advances of \$105,000 toward certain agreements. Additionally, we paid down \$132,000 on our loans payable during 2001. We did not receive any cash from the sale of our common stock, but we did receive \$6.0 million under our agreement with Paul Capital Royalty Acquisition Fund, L.P.

In December 2001 we entered into a ten-year lease with New Jersey Economic Development Authority to lease approximately 58,000 square feet of manufacturing and office space located in North Brunswick, New Jersey. The leased premises will be completed and will be available to us in two phases. The initial space, consisting of approximately 26,000 square feet, is in an existing building, which will be renovated to our specifications. The additional space, adjoining the existing building and consisting of 32,000 square feet, will be constructed to our specifications. The landlord is responsible for the completion of the renovations and construction of the building and is contributing up to \$1,300,000 for the renovations and \$3,200,000 for the construction of the new building. Any additional renovation or construction costs will be borne by us.

We expect to move to the new facility and to be fully operational at that site in 2003. We believe that the move into the existing building will provide us with the anticipated manufacturing capacity required through 2004, sufficient to generate sales revenues in excess of \$50.0 million. Accordingly, we believe that initially no additional manufacturing build-out costs will be necessary in the building to be constructed. That second move into the newly constructed building will allow us to consolidate our manufacturing, marketing and sales, research and administrative operations in one location, facilitate future growth and afford us the ability to increase our manufacturing capacity at such time as the manufacturing capacity in the existing building is fully utilized.

On August 29, 2001, we entered into a Revenue Interests Assignment Agreement with Paul Capital. During 2001, Ortec was eligible to receive \$10.0 million under this agreement. We received \$6.0 million in 2001 and the remaining \$4.0 million balance in January 2002. Upon completion of additional milestones, we may be eligible to receive another \$5.0 million. In addition, we may incrementally receive another \$10.0 million, but only upon mutual agreement by both Ortec and Paul Capital.

In consideration for the first \$10.0 million received by us, Paul Capital will receive a minimum of 3 1/3% of end user revenues from the sale of our products in the United States, Canada and Mexico, which percentage will be proportionately increased by the additional amounts paid by Paul Capital to us under the August 29, 2001 agreement. These percentage payments may be further adjusted upward or downward, based on the volume of net sales to end users of our products in those three countries. We anticipate that our effective cost for the amounts we receive from Paul Capital will range between 20% to 35% per annum. Beginning on January 1, 2003, Paul Capital will be entitled to receive each year the first proceeds to us from end user sales of our products in those three countries. Such annual amounts Paul Capital will be able to draw in advance will range from \$1.5 million in 2003 to \$7.5 million in 2005 and thereafter. The agreement provides for quarterly and annual accountings between Paul Capital and us for those advance payments.

In the event of a change in control of Ortec or upon the occurrence of certain other events as defined in the agreement, Paul Capital has the option to put its revenue interest back to us for an amount as provided in the agreement. Ortec also has the option to repurchase Paul Capital's interest upon the occurrence of a change in control of Ortec or a complete divestiture by us of our products, for an amount provided in the agreement.

We have granted Paul Capital a security interest in our United States and Canadian patents and trademarks relating to our technology for our product, to secure payments we are required to make to Paul Capital.

The agreement terminates on December 31, 2011, unless terminated earlier by either party, as permitted by the terms of the agreement.

In January 2002 we received a \$1,300,000 line of credit from GE Capital for equipment lease financing. These proceeds will be utilized in financing manufacturing equipment purchases in 2002.

Our capital funding requirements will depend on numerous factors, including the progress and magnitude of our research and development programs, preclinical testing and clinical trials, the time involved in obtaining regulatory approvals for commercial sale of our product to treat venous stasis and diabetic foot ulcers, the cost involved in filing and maintaining patent claims, technological advances, competitive and market conditions, our ability to establish and maintain collaborative arrangements, our cost of manufacturing scale up and the cost and effectiveness of commercialization activities and arrangements.

We require substantial funding to continue our research and development activities, clinical trials, manufacturing scale up, marketing, sales, distribution, and administrative activities. Our cash and cash equivalents on hand at December 31, 2001, (approximately \$0.9 million), and the additional \$4.0 million which was due from Paul Capital and was received in January 2002, will enable us to continue our operations until April 30, 2002.

We have raised funds in the past through the public or private sale of securities and through the agreement with Paul Capital. Even after the remaining \$4.0 million received from Paul Capital in January 2002, we will need to raise additional funds in the future through public or private financings, collaborative arrangements or from other sources. The success of such efforts will depend in large part upon continuing developments in our clinical trials and upon market conditions.

On March 27, 2002, we engaged H.C. Wainwright & Co., Inc., an investment banking firm, to act as our financial advisor in connection with raising capital for the Company through debt and/or equity financing. While we can give no assurance that any equity financing will be secured, Wainwright is assisting us in raising equity

financing of \$12,000,000, which we believe will enable us to continue our operations for the next 12 months.

If received, we will use the above proceeds primarily to complete our clinical trials for use of OrCel in the treatment of venous stasis and diabetic ulcers and to submit the results of those trials to the FDA for approval to market OrCel for treatment of those medical conditions. We expect that the anticipated financing will allow us to do this. Based upon our current schedule for completion of the clinical trials and submission to the FDA, we believe that we can obtain FDA approval for the use of our product in treating both venous stasis and diabetic ulcers patients in 2003.

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 manufacturing, marketing, distribution or other rights to our product. However, we can give no assurance 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 financing will be available to us on acceptable terms, if at all. Further, we can give no assurance that any arrangements resulting from these discussions will successfully reduce our funding requirements. If additional funding is not available to us when needed, we may not be able to continue operations.

Ortec International, Inc.  
(a development stage enterprise)

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