AGREEMENT  
 AGREEMENT entered into this 26th day of September 2007 by and between Lonza Walkersville, Inc., a Delaware corporation formerly known as Cambrex Bio Science Walkersville, Inc. (“Lonza”), and Ortec International, Inc., a Delaware corporation (“Ortec”), (each of Lonza and Ortec a “Party” and together the “Parties”).  
R E C I T A L S:  
 A. Lonza and Ortec have heretofore entered into the following agreements, all of which are dated October 18, 2004, except for the Cell Therapy Manufacturing Agreement which is dated October 29, 2003 (the “Manufacturing Agreement”):  
 1.  
Manufacturing Agreement,  
 2.  
Amendment No. 1 to the Manufacturing Agreement,  
 3.  
Sales Agency Agreement,  
 4.  
License Agreement and  
 5.  
Security Agreement  
 B. Lonza and Xxxx Royalty Fund LP (“PRF”) entered into the Consent and Agreement also dated October 18, 2004, which defines the relative rights of Lonza and PRF to the proceeds Ortec receives from the sales of Ortec’s OrCel product. Orcel LLC, a Delaware limited liability company (“Orcel”) and a wholly-owned subsidiary of Ortec, is also a party to the License Agreement and to the Security Agreement.  
 C. Lonza and Ortec have reached certain agreements to cancel all of the foregoing agreements except the Manufacturing Agreement and Amendment No. 1 thereto, and to modify the terms of the Manufacturing Agreement and Amendment No. 1 thereto, as provided herein.  
   
 NOW THEREFORE, in consideration of the foregoing and the mutual promises and covenants hereinafter set forth, Lonza and Ortec, intending to be legally bound, hereby agree as follows.  
 1. Definitions. Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in the Manufacturing Agreement.  
2. Cancellation of Agreements. The Parties hereto agree that the following agreements between Lonza and Ortec, all dated October 18, 2004, are cancelled effective upon the execution of this Agreement:  
 (a)  
Sales Agency Agreement,  
 (b)  
License Agreement and the  
 (c)  
Security Agreement  
 Orcel, by its execution of this Agreement, agrees to the cancellation of the License Agreement and of the Security Agreement. As a result of the cancellation of the Sales Agency Agreement and the Security Agreement, Lonza acknowledges that it will no longer have any security interest in any Collateral, as that term is defined in the Security Agreement, and therefore agrees to use its best efforts to cancel the Consent and Agreement between it and PRF pursuant to a separate agreement with PRF.  
3.  
Payments by Ortec.  
 (a)  
The Parties agree that the amount Ortec owes to Lonza as of the date of the execution of this Agreement is $1,250,000. Lonza shall, upon the execution of this Agreement, apply the $100,000 deposited by Ortec with Lonza pursuant to the Manufacturing Agreement to reduce such  
   
obligation to $1,150,000 and Ortec shall no longer have any right to all or any portion of such $100,000 for any reason.  
 (b)  
Ortec shall, no later than September 28, 2007, pay Lonza $750,000.  
 (c)  
Lonza agrees to perform for Ortec the work described in Section 4 of this Agreement (“Lonza’s Work”) and shall be paid at the rates and in the manner described in Section 5 of this Agreement.  
 (d)  
Ortec intends to raise capital through the sale of its equity securities in the first quarter of 2008. Ortec shall, no later than March 31, 2008, pay to Lonza from the net proceeds (net after payment by Ortec of finder’s fees and broker’s commissions and legal fees in connection with such capital raise) received by Ortec from such capital raise, the lesser of (i) 25% of such net proceeds in reduction of all outstanding amounts owed to Lonza, including for work performed under this Agreement through March 31, 2008 and remaining debt (collectively, the “Resulting Obligation”) or (ii) the Resulting Obligation.  
 (e)  
Notwithstanding the foregoing, the Resulting Obligation shall be due no later than July 1, 2008. If the Resulting Obligation is not paid by July 1, 2008, Lonza shall have the right to terminate this Agreement or bring any appropriate action for breach of such payment.  
 4. Lonza’s Work. In connection with Ortec’s submission to the United States Food and Drug Administration (the “FDA”) of Ortec’s application for Pre-Market Approval (the “PMA”) seeking FDA clearance for the commercial sale of Ortec’s OrCel® product (“OrCel”) for the treatment of venous stasis ulcers, which submission will include the results of Ortec’s confirmatory clinical trial on 60 additional patients, Lonza will perform and support the following work in a production suite with a clean room as well as in other laboratory and work areas in its multi-client production facility at 0000 Xxxxx Xxxx Xxxx, Xxxxxxxxxxxx, Xxxxxxxx  
   
00000, and will use its reasonable efforts to comply with the times set forth in Schedule A hereto.  
 (a)  
Order all raw materials, supplies and packaging materials needed for the work to be performed by Lonza as provided in this Section 4.  
 (b)  
With Ortec’s assistance, train Lonza’s personnel in all analytical methodology required for in-process and release testing of incoming raw materials and finished OrCel product including, but not limited to, histotechnology and histomorphometric evaluation of OrCel histological specimens for use in the release testing of (i) components and raw materials used to manufacture OrCel and (ii) of the lots of OrCel manufactured by Lonza.  
 (c)  
With Ortec’s assistance, train Lonza’s personnel to manufacture OrCel, including the production of a training lot.  
 (d)  
Perform aseptic process validation of key OrCel production process operations to make certain that Lonza’s work can be performed under aseptic conditions and meet FDA standards for a production environment sufficient to maintain product sterility.  
 (e)  
Perform at least one full scale engineering run for the production of an OrCel lot to demonstrate the ability to manufacture approvable material.  
 (f)  
Perform up to five validation runs in the production suite to show that Lonza can produce full scale lots of OrCel, the results of which validation runs are to be submitted to the FDA as part of Ortec’s PMA application.  
 (g)  
Thereafter perform up to three production runs, subject to FDA pre-approval inspection, for the purpose of receiving FDA certification that Lonza’s production facility meets the FDA’s GMP requirements so that the facility can be used to manufacture OrCel units for commercial sale.  
 5. Charges for Lonza’s Work. For Lonza’s Work, including the use of Lonza’s clean room, other facilities and personnel, Ortec shall pay to Lonza either  
 (a)  
$50,000 per month plus one hundred seventy five dollars ($175) per hour for the time spent by Lonza personnel in such month performing Lonza’s Work in the clean room and one hundred twenty five dollars  
   
($125) per hour for time spent by Lonza personnel in performing Lonza’s Work other than in the clean room or  
 (b)  
Four hundred dollars ($400) per hour for the time spent by Lonza personnel in such month performing Lonza’s Work in the clean room and one hundred twenty five dollars ($125) per hour for time spent by Lonza personnel in performing Lonza’s Work other than in the clean room.  
 For Lonza’s Work performed in October and November 2007, Ortec shall pay Lonza in accordance with Section 5(b) above but beginning December 1, 2007 Ortec shall pay for Lonza’s Work in accordance with Section 5(a) above. Beginning January 1, 2008, Ortec, at its option, may at one time during the remaining term of this Agreement (the “Remaining Term”), elect to change its payments for Lonza’s Work from Section 5(a) to Section 5(b), effective only on the first day of a month and provided that Ortec gives Lonza 30 days prior written notice of Ortec’s election to make such change. Such notice by Ortec shall be provided to Lonza in the manner for notice provided in Section 8 below. For the removal of doubt, Ortec shall only be permitted to change the manner in which it is charged for Lonza’s Work one time during the Remaining Term of the Agreement.  
Lonza shall provide Ortec with statements not less frequently than once a month on the 10th day of the month, showing what portion of Lonza’s Work was performed through the end of the month immediately preceding the date such statement is required to be provided to Ortec. Such statement shall provide detailed information as to how such an amount is calculated. For example, such monthly statement shall provide time records for the personnel used in accordance with Lonza’s time keeping system then in effect and the charge for each hour of use.  
6. Turnover of Records of Sales Efforts. Within thirty days after the execution of this Agreement, Lonza will, except as limited by court orders and/or by confidentiality agreements by which Lonza is bound, turn over to Ortec all of its (a) records of its marketing activity, including without limitations, sales calls, recruitment of salesmen, contacts with potential salesmen and potential purchasers of Ortec’s OrCel product, (b) all sales promotion and  
   
sales material which Lonza produced for use in selling OrCel and (c) information and records as to the development of a website page to be used to market OrCel.  
7. Manufacturing Agreement Not Cancelled. The Manufacturing Agreement between Ortec and Lonza, as amended by the provisions of Amendment No. 1 thereto which survive the cancellation of the Sales Agency Agreement, is not cancelled although performance thereof by Lonza and Ortec, and any payments required to be made pursuant to the provisions thereof, are suspended until, and if, Ortec receives FDA clearance for the commercial sales of OrCel for the treatment of venous stasis ulcers. Until then the work to be done by Lonza for Ortec, and the payments to be made by Ortec to Lonza, are those provided in this Agreement. Ortec and Lonza will, in the period before receipt of such FDA clearance for commercial sale of OrCel for the treatment of venous stasis ulcers, seek to negotiate a per unit price that Ortec will pay to Lonza for Lonza’s manufacture of OrCel, in lieu of the payments Ortec is required to make to Lonza pursuant to the Manufacturing Agreement (including, without limitation, as provided in Schedule 11.1 to the Manufacturing Agreement). Absent such agreement between Lonza and Ortec establishing such per unit price, when, and if, the FDA clears the commercial sale of OrCel for the treatment of venous stasis ulcers, Lonza and Ortec shall continue to be bound by all of the provisions of the Manufacturing Agreement as amended by the surviving provisions of Amendment No. 1 thereto, including, without limitation, the payment terms thereof. Anything in Section 13 of Amendment No. 1 to the Manufacturing Agreement to the contrary notwithstanding, the provisions of Section 3.3.2 of such Amendment No. 1 shall survive the termination of the Sales Agency Agreement so that the maximum contribution Ortec shall be required to make for construction of the Custom Production Suite to be used in Phase II shall continue to be $1,000,000.  
8. Notices. All notices (including those of Ortec’s exercise of its options, set forth in Section 5 above, to elect the method of calculating Lonza’s charges), consents, waivers and other communications under this Agreement and under the Manufacturing Agreement, as amended, must be in writing and will be deemed to have been given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by fax or e-mail, provided that a copy is mailed by U.S.  
   
registered mail, return receipt requested, or (iii) when received by the addressee, if sent by a nationally recognized overnight delivery service (receipt requested), in each case to the appropriate address and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate to the other Party):  
If to Lonza, to:  
 Lonza Walkersville, Inc.  
 0000 Xxxxx Xxxx Xxxx  
 Xxxxxxxxxxxx, Xxxxxxxx 00000  
 Fax (000) 000-0000  
 Attention: Xxxxx X. Xxxxx, Business Director, Cell Therapy  
E-mail: Xxxxx.Xxxxx@Xxxxx.xxx  
 With a copy to:  
 Lonza Inc.  
 00 Xxxxxxxx Xxxxx  
 Xxxxxxxxx, XX 00000  
 Fax: (000) 000-0000  
 Attention: Xxxxxxx X. Xxxxx, Esq.  
E-mail: xxxxxxx.xxxxx@xxxxx.xxx  
 and  
 If to Ortec, to:  
 Ortec International, Inc.  
 0000 Xxxxxxxx  
 Xxx Xxxx, Xxx Xxxx 00000  
 Fax: (000) 000-0000  
 Attention: Costa Papastephanou, CEO, and Xxxx X. Xxxxxxxxxx, CFO  
E-mail:  
xxxxx.xxxxxxxxxxxxx@xxxxxxxxxxxxxxxxxx.xxx and  
 xxxxxxxxxxx@xxxxxxxxxxxxxxxxxx.xxx  
   
 With a copy to:  
 Xxxxx Xxxxxxxxx Xxxxxxxx Xxxxx Xxxxx Bass & Rhine, LLP  
000 Xxxxxxxxx Xxxxxx, 00xx Xxxxx  
 Xxx Xxxx, XX 00000  
 Fax: (000) 000-0000  
 Attention: Xxxxxxx Xxxxxxxxx, Esq.  
 E-mail: xxxx@xxxxxx.xxx  
 9. Entire Agreement. This agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof. The recitals hereto are hereby incorporated by reference.  
10. Governing Law and Jurisdiction. This Agreement will be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to any conflicts of laws provisions thereof that would cause the application of the laws of a different jurisdiction.  
11. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.  
12. Amendments. This Agreement may not be amended or modified, and no provisions hereof may be waived, without the written consent of the Parties.  
13. Severability. Each provision of this Agreement will be treated as a separate and independent clause, and the unenforceability of any one clause will in no way impair the enforceability of any of the other clauses herein. If one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to scope, activity, subject or otherwise, so as to be unenforceable at law, such provision or provisions will be construed by the appropriate judicial body by limiting or reducing it or them so as to be enforceable to the maximum extent compatible with the applicable law as it will then appear.  
   
 14. Titles. The titles used in this Agreement are for convenience only and are not to be considered in construing or interpreting any term or provision of this Agreement.  
15. Assignment. Neither Party will assign this Agreement, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that Lonza will be permitted to assign its rights and obligations hereunder to one or more of its affiliates. Any purported assignment not permitted under this Section 15 will be null, void, and of no effect. Any permitted assignment shall not release the assignor from liability hereunder if such assignor’s obligations hereunder are not performed by its assignee.  
16. Waiver. The failure of any Party at any time or times to require performance of any provision of this Agreement will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of the breach of any term contained in this Agreement, whether by conduct or otherwise, in any one or more instances, will be deemed to be construed as a further or continuing waiver of any such breach or the breach of any other term of this Agreement.  
17. WAIVER OF JURY TRIAL. THE PARTIES HERETO HEREBY EACH WAIVE TRIAL BY JURY IN ANY SUIT BROUGHT BY EITHER OF THEM AGAINST THE OTHER OR ON ANY COUNTERCLAIM IN RESPECT THEREOF ON ANY MATTERS, WHATSOEVER, ARISING OUT OF, OR IN ANY WAY IN CONNECTION WITH, THIS AGREEMENT.  
18. No Presumption Against Drafter. For purposes of this Agreement, each Party hereby waives any rule of construction that requires that ambiguities in this Agreement be construed against the drafter.  
   
 19. Non-Solicitation. Each Party agrees not to employ or solicit for employment (or for use as an independent contractor), any employee of the other Party or its affiliates during the term of this Agreement and for a period of two years thereafter, except with such other Party’s prior written consent.  
IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year first above written:  
 WITNESS:  
ORTEC INTERNATIONAL, INC.  
 /s/ Xxxx Xxxxxxxxxx  
By: /s/ Costa Papastephanou  
 Xxxx X. Xxxxxxxxxx,  
Costa Papastephanou,  
 Chief Financial Officer  
Chief Executive Officer  
 WITNESS:  
LONZA WALKERSVILLE, INC.  
 /s/ Xxxxx X. Xxxxx  
By: /s/ Xxxxxxx X. Xxxxxxxx  
 Print Name: Xxxxx X. Xxxxx  
Print Name: Xxxxxxx X. Xxxxxxxx  
Title: VP: Cell Therapy  
Title: Business Sector Controller  
   
 The undersigned, Orcel LLC, agrees to the cancellation of the License Agreement and of the Security Agreement as provided in Section 2 of the foregoing agreement.  
 ORCEL LLC  
 By:  
ORTEC INTERNATIONAL, INC.,  
 its only member  
 WITNESS:  
 /s/ Xxxx Xxxxxxxxxx  
By: /s/ Costa Papastephanou  
 Xxxx X. Xxxxxxxxxx  
Costa Papastephanou  
 Chief Financial Officer  
Chief Executive Officer  
 Dated: September 26, 2007  
Dated: September 26, 2007  
   
 Schedule A  
 ID  
 Task  
Name  
 Duration  
 Start  
 Finish  
 Predecessors  
 Qtr 4, 2007  
Oct / Nov / Dec  
 Qtr.1, 2008  
Jan / Feb / Mar  
 Qtr. 2, 2008  
Apr / May / Jun  
1  
Section 4 – LONZA’S WORK  
175  
days  
Mon  
10/1/07  
Fri  
5/30/08  
 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  
2  
Section 4a  
(Raw Materials & Packaging)  
10  
wks  
Mon  
10/1/07  
Fri  
12/7/07  
 \_\_\_\_\_\_\_\_\_\_  
3  
Section 4b  
(Analytical Methodology)  
13  
wks  
Mon  
10/1/07  
Fri  
12/28/07  
 \_\_\_\_\_\_\_\_\_\_\_\_\_  
4  
Section 4c  
(OrCel Training & Training Lot)  
4  
wks  
Mon  
11/5/07  
Fri  
11/30/07  
 \_\_\_\_  
5  
Section 4d  
(Aseptic Processing Validation)  
4  
wks  
Wed  
10/10/07  
Tue  
11/6/07  
 \_\_\_\_\_  
6  
Section 4e  
(Full Scale Engineering Run)  
4  
wks  
Mon  
12/3/07  
Fri  
12/28/07  
 4  
\_\_\_\_  
7  
Section 4f  
(5 OrCel Process Validation Runs)  
12  
wks  
Mon  
12/31/07  
Fri  
3/21/08  
 6  
\_\_\_\_\_\_\_\_\_\_\_  
8  
Section 4g  
(3 OrCel Production Runs)  
4  
wks  
Mon  
4/7/08  
Fri  
5/2/08  
 7FS+2 wks  
\_\_\_\_\_  
9  
Section 4h  
(FDA Approval of Lonza Facility)  
8  
wks  
Mon  
4/7/08  
Fri  
5/30/08  
 8SS  
\_\_\_\_\_\_\_\_\_\_  
   
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