SECURITIES AND EXCHANGE COMMISSION

# FORM 8-K

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### **FILER**

#### **BIOVEST INTERNATIONAL INC**

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## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 16, 2008

# **BIOVEST INTERNATIONAL, INC.**

(Exact name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of

incorporation or organization)

0-11480

(Commission File Number)

41-1412084 (I.R.S. Employer Identification No.)

377 Plantation Street Worcester, Massachusetts 01605 (Address of Principal Executive Offices; Zip Code)

Registrant's telephone number, including area code: (508) 793-0001

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2-(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### **BIOVEST INTERNATIONAL, INC.**

#### FORM 8-K

#### Item 1.01. Entry Into a Material Definitive Agreement.

On January 16, 2008, Biovest International, Inc. (the "Company") entered into a sublicense agreement (the "Sublicense Agreement") with Revimmune, LLC ("Revimmune") under which the Company was granted the exclusive worldwide rights to Revimmune<sup>™</sup>, a patent-pending pharmaceutical treatment in late-stage development for the treatment of and prevention of transplant rejection including rejection following a bone marrow transplant. The pharmaceutical treatment uses an already-approved active pharmaceutical in a novel, ultra-high dose, pulsed administration.

The Sublicense Agreement is attached as Exhibit 10.1 to this Current Report on Form 8-K.

Other material terms and conditions of the Sublicense Agreement are as follows:

The Company is obligated to pay to Revimmune a royalty of 6% on net sales, and in the event of a sublicense by the Company, to pay 20% of sublicense consideration received. The Company did not pay an upfront fee in connection with the Sublicense but upon the approval of the sublicensed treatment in the U.S. for each sublicensed indication, the Company is required to issue to Revimmune vested warrants to purchase 2,000,000 shares of the Company's common stock. Each such warrant which will be granted at the approval of each successive Sublicensed Product will have an exercise price of \$1.10 per share or, at the discretion of Company, at a price equal to the fair market value of the Company's common stock on the date of the grant of such warrant.

The Company assumed certain obligations under Revimmune's license with Johns Hopkins University related to the sublicensed technology, including the payment of all royalty obligations due Johns Hopkins University for the sublicensed products which includes a 4% royalty on licensed products and services and a 20% royalty on sublicense consideration.

The Company will be responsible, at its sole cost and expense, for the development, clinical trial(s), promotion, marketing, sales and commercialization of the sublicensed products.

Revimmune, LLC is affiliated with Dr. Frank O' Donnell who is a director of the Company.

The offers, sale, and issuance of the Company's warrants in the above-described transactions were made pursuant to the exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, as they were made without any form of general solicitation to sophisticated parties with full access to all material information relating to the securities issued.

#### Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information included in Item 1.01 of this Form 8-K is hereby incorporated by reference into this Item 2.03.

#### Item 3.02. Unregistered Sales of Equity Securities.

The information included in Item 1.01 of this Form 8-K is hereby incorporated by reference into this Item 3.02.

#### Item 7.01. Regulation FD Disclosure.

The following information is being furnished under Item 7.01 of Form 8-K: Press release dated January 22, 2008 announcing that the Company has entered into a sublicense agreement with Revimmune, LLC. A copy of this press release is attached as Exhibit 99.1 to this Form 8-K.

This Current Report on Form 8-K sets forth statements that are not strictly historical in nature and such statements are referred to as "forward-looking statements." The forward-looking statements in this Form 8-K include statements about our product development programs, clinical trials for our BiovaxID<sup>M</sup> and or Revimmune<sup>M</sup> product and potential future market opportunity. Such forward-looking statements are subject to known and unknown risks, uncertainties, and other factors that may cause our actual results to be materially different from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of Biovest' s clinical trials and product development programs. All forward looking statements in this Form 8-K are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this Current Report on Form 8-K to reflect events or circumstances after the date hereof.

#### Item 9.01. Financial Statements and Exhibits.

See the Exhibit Index set forth below for a list of exhibits included with this Form 8-K.

#### Signature

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunder duly authorized.

BIOVEST INTERNATIONAL, INC.

By:

/s/ Alan M. Pearce Alan M. Pearce Chief Financial Officer

Date: January 22, 2008

#### EXHIBIT INDEX

Exhibit	
Number	Description
10.1	Sublicense Agreement between Revimmune, LLC and Biovest International, Inc. dated January 16, 2008

<sup>99.1</sup> Press Release dated January 22, 2008 titled "Biovest Secures Worldwide Exclusive License to Late-Stage Technology for the Elimination of Transplant Rejection"

#### SUBLICENSE AGREEMENT BETWEEN REVIMMUNE, LLC AND BIOVEST INTERNATIONAL, INC.

This Sublicense Agreement (this "Agreement or "Sublicense Agreement") effective as of January 16, 2008, by and between **REVIMMUNE**, **LLC**, a Florida limited liability company, ("REVIMMUNE"), and **BIOVEST INTERNATIONAL**, **INC.**, a Delaware corporation, ("BIOVEST") (collectively the "Parties").

#### WITNESSETH:

Whereas, REVIMMUNE has received an exclusive worldwide license to certain rights arising from U.S. Provisional Patent Applications Serial No. 60/742,172, filed on December 2nd, 2005, entitled "*Use of High-dose Oxazaphosphorine Drugs for Treating Immune Disorders*", along with associated know-how, as specifically defined in the License Agreement from Johns Hopkins University (the "JHU License") attached hereto as Exhibit A (the "Revimmune Licensed Rights");

Whereas, the founders of REVIMMUNE began negotiating with various personnel at JHU for the potential acquisition of the Revimmune Licensed Rights in 2003;

Whereas, the founder of REVIMMUNE obtained a Notice of Allowance for the trade name "REVIMMUNE" ON March 25, 2003;

Whereas, REVIMMUNE was organized as a limited liability company by filing articles of organization with the State of Florida on January 16, 2006;

Whereas, BIOVEST recognizes that the REVIMMUNE Licensed Rights are valuable for drug development, use and/or sale in the treatment or prevention of human diseases;

Whereas, BIOVEST wishes to enter into an agreement to obtain an exclusive sublicense to the Sublicensed Products from REVIMMUNE in order to develop, promote, market and commercialize prophylactic and/or therapeutic products or treatments for the prevention of transplant rejection including rejection following a bone marrow transplant.

Whereas, the Revimmune License names BIOVEST as an affiliate of REVIMMUNE for all purposes under the Revimmune License; and

WHEREAS, REVIMMUNE is willing to grant such sublicense to BIOVEST under the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

#### **ARTICLE 1-DEFINITIONS**

Capitalized terms, not otherwise defined herein shall have the meaning assigned to them in the JHU License. For purposes of this Agreement, the following terms shall have the meanings set forth below:

- 1.1 "Effective Date" shall mean the date first written above.
- 1.2 "Territory" shall mean worldwide.
- 1.3 "Field" shall mean the treatment of and prevention of transplant rejection including rejection following a bone marrow transplant and specifically shall not include indications for any other diseases or treatments.
- 1.4 "Sublicensed Rights" shall mean the Revimmune Licensed Rights plus any intellectual property rights acquired by REVIMMUNE either prior to the date of this Agreement or hereafter during the term of this Agreement (whether acquired from JHU, another third party, or through internal development activities) specifically limited to the Field and the Sublicensed Indications.
- 1.5 "Sublicensed Products" shall mean any materials, compositions, drugs, or other products, methods or services which are in material part first identified, discovered, made, or commercialized by practicing one or more valid claims included in the patents that are part of the Sublicensed Rights specifically limited to the Field and the Sublicensed Indications.
- 1.6 "Sublicense Indications" shall mean the treatment of and prevention of transplant rejection including rejection following a bone marrow transplant and specifically shall not include indications for other diseases or treatments. For clarification, treatments for all forms of autoimmunity, including but not limited to MS, are excluded from the definition of Sublicense Indications.
- 1.7 "Sublicensed Royalty" shall have the meaning set forth in Article 4 hereof.
- 1.8 "Revimmune Licensed Rights" shall mean the rights granted to REVIMMUNE in the JHU License.
- 1.9 "JHU License" shall mean the License Agreement between Johns Hopkins University and REVIMMUNE attached hereto as Exhibit A.
- 1.10 "JHU" shall mean John Hopkins University.
- 1.11 "Affiliate" shall mean, with respect to a specified person or entity, any other person or entity that controls, is controlled by, or is under common control (whether through equity ownership, contract, or otherwise) the specified person or entity.



#### ARTICLE 2-REPRESENTATIONS AND WARRANTIES; RESPONSIBILITIES OF THE PARTIES

2.1 <u>Representations and Warranties of Both Parties</u>. Each Party represents and warrants to the other Party that: (i) it is free to enter into this Sublicense Agreement; (ii) in so doing, it will not violate any other agreement to which it is a party; and (iii) it has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement.

2.2 <u>Representations and Warranties of REVIMMUNE</u>. REVIMMUNE hereby represents and warrants that:

(a) The JHU License is in full force and effect, and REVIMMUNE has the right to grant the sublicense there under without the consent or approval of any third party;

(b) To the best of REVIMMUNE's knowledge, all the REVIMMUNE Licensed Rights listed in the JHU License attached as Exhibit A are in full force and effect and have been maintained to date;

(c) REVIMMUNE is not aware of any asserted or unasserted claim or demand against the REVIMMUNE Licensed Rights;

(d) None of the REVIMMUNE Licensed Rights infringes upon any patent or other proprietary rights of any third party; and

(e) REVIMMUNE has not entered into any agreement with any other entity which is in conflict with the rights granted to BIOVEST pursuant to this Sublicense Agreement.

2.3 <u>Representations and Warranties of BIOVEST</u>. BIOVEST hereby represents and warrants that:

(a) BIOVEST has the right to enter into this Sublicense Agreement without the consent of any third party;

(b) BIOVEST will exercise reasonable efforts to develop, promote, market, sell and commercialize the Sublicensed Rights for all Sublicense Indications;

(c) BIOVEST has no right in or to the JHU License or the Licensed Products except only those rights and interest expressly granted hereunder and

(d) BIOVEST has acknowledged and waived any and all conflicts of interest rising from or related in any fashion to this Sublicense Agreement including but not limited to the ownership and management of Revimmune.

- 2.4 <u>Employee Agreements</u>. Each Party warrants that it has, and covenants that it will have, entered into a proprietary information and inventions agreement with each of its employees prior to the time that any such employee shall receive confidential information from a disclosing party under this Agreement or begin work related to this Agreement. Such agreement shall minimally set forth employee obligations to assign inventions to the inventing Party and to maintain confidentiality of confidential information consistent with the terms of this Agreement.
- 2.5 <u>REVIMMUNE Responsibilities</u>. REVIMMUNE will be responsible to maintain the JHU License in full force and effect.

#### 2.6 BIOVEST Responsibilities.

(a) BIOVEST will be responsible, at its sole cost and expense, for the development, promotion, marketing, sales and commercialization of the Sublicensed Rights in connection with each of the Sublicense Indications.

(b) BIOVEST will during the term of this Sublicense Agreement use commercially reasonable efforts to continuously develop, promote, sale, market and commercialize the Sublicensed Products for each of the Sublicense Indications.

(c) Subject to Section 3.3 and Article 6 hereof, BIOVEST shall share with REVIMMUNE all proprietary and clinical data and information related to the Sublicensed Products, Sublicensed Rights and any related clinical trial which data and information may be used by REVIMMUNE in support of the development and commercialization of products for indications other than the Sublicense Indications.

(d) BIOVEST shall maintain all information and data related to the Sublicensed Products and Sublicensed Rights confidential.

(e) BIOVEST shall not develop or commercialize any product or treatment that could reasonably be considered to be in competition with Revimmune Licensed Rights for indications other than the Sublicense Indications.

(f) BIOVEST shall promptly pay all Royalties required by this Sublicense Agreement.

(g) BIOVEST shall maintain insurance pursuant to Article 7 and shall cause such insurance to name REVIMMUNE as a coinsured.

#### **ARTICLE 3-LICENSE GRANT**

#### 3.1

<u>Grant of License</u>. Subject to the terms and conditions of this Agreement, REVIMMUNE hereby grants to BIOVEST an exclusive (including to the exclusion of REVIMMUNE), perpetual sublicense to the Sublicensed Rights throughout the Territory, with the right to grant further sublicenses, to develop, promote, market, sell, make, have made, use, import, offer for sale, and commercialize the Sublicensed Products for the Sublicense Indications in the Field and Territory. For clarification, BIOVEST shall have no rights under this Agreement to develop, promote, market, sell, make, have made, use, import, offer for sale or commercialize any product based on or using the Sublicensed Rights for

the treatment of any disease, or for use in connection with, any indication other than the Sublicense Indications. The license grants in this paragraph shall apply to BIOVEST and any of its Affiliates, and if any Affiliate of BIOVEST exercises rights under this Agreement, such Affiliate shall be bound by all the terms and payments, which shall apply to the exercise of the rights, to the same extent as would apply had this Agreement been directly entered into between REVIMMUNE and such Affiliate.

- Right to Grant Sublicenses. BIOVEST shall have the right to sublicense the Sublicensed Rights in the Territory with the prior written 3.2 approval of REVIMMUNE, which approval may not be unreasonably withheld, provided; (i) the sublicensee agrees to be bound by all terms and conditions of this Sublicense Agreement as amended, including, but not limited to, the payment of all royalties to REVIMMUNE as provided in Article 4 as though BIOVEST itself had sold the Licensed Product (ii) BIOVEST guarantees the performance of all material provisions of this Sublicense Agreement by its sublicense; (iii) at the time of the sublicense, BIOVEST is not in breach or non-compliance with any material provision of this Sublicense Agreement, (iv) JHU consents in writing to the sublicense; (v) the sublicensee, in REVIMMUNE's reasonable judgment, is reasonably capable of developing, promoting, marketing, selling and commercializing the Sublicensed Products; (vi) the sublicensee, in REVIMMUNE's reasonable judgment, is not a competitor of the Revimmune Licensed Rights; (vii) upon termination of this Sublicense Agreement for any reason, the sublicense granted by BIOVEST shall revert directly to REVIMMUNE, which may at its election recognize or disaffirm such sublicense and (viii) all fees in connection with or resulting from the sublicense required by the JHU License and by this Sublicense Agreement are paid by Biovest. Each sublicense granted by BIOVEST pursuant to this Agreement shall be consistent the provisions of this Agreement and the JHU License. Prior to the grant of each sublicense hereunder, BIOVEST shall provide REVIMMUNE a copy of the sublicense. BIOVEST shall not grant any paid-up license or accept equity in consideration, directly or indirectly, for such sublicenses without REVIMMUNE's written approval.
- 3.3 Intellectual Property. Title to any and all New Intellectual Property developed solely through the efforts of the employees, agents, independent contractors, or joint venture partners of one Party shall vest solely and exclusively in such Party, provided that any such New Intellectual Property owned by REVIMMUNE will become subject to the licenses granted in this Agreement and any such New Intellectual Property owned by Biovest shall be licensed back to Revimmune on a royalty-free basis and exclusively for non-transplant rejection disease indications throughout the Territory. Any New Intellectual Property developed through the joint efforts of the employees, agents, independent contractors, or joint venture partners of both Parties shall be owned jointly by the Parties, provided that any such jointly owned New Intellectual Property shall be subject to the licenses granted in this Agreement and any such New jointly owned Intellectual Property shall be licensed back to Revimmune on a royalty-free basis and exclusively for non-transplant rejection disease indications throughout the Territory. "New Intellectual Property eveloped through the joint efforts, provided that any such jointly owned New Intellectual Property shall be subject to the licenses granted in this Agreement and any such New jointly owned Intellectual Property shall be licensed back to Revimmune on a royalty-free basis and exclusively for non-transplant rejection disease indications throughout the Territory. "New Intellectual Property" shall mean any and all inventions, know-how, developments, methods, processes, improvements, and other information relating to the Revimmune Licensed Rights, Sublicensed Rights, or Sublicensed Products in any form, technical or economic, patentable or unpatentable, confidential or otherwise to the extent they are first conceived or developed by either Party or by both Parties after the date of this Agreement.
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3.4 <u>Rights of REVIMMUNE</u>. REVIMMUNE shall, during the term of this Sublicense Agreement, have the absolute right, without notice to or consent from BIOVEST or its sublicensees, to: (i) sublicense, assign, develop, promote, sell, market, commercialize or otherwise deal with the Licensed Rights for any or all indications or diseases other than the Sublicense Indications and (ii) enter into any amendment, modification or restatement of the License Agreement between REVIMMUNE and JHU including an amendment or modification to the Revimmune License Rights, provided that none of the actions in foregoing clauses (i) or (ii) shall adversely affect the rights of BIOVEST without BIOVEST's prior written consent.

#### ARTICLE 4-ROYALTY AND OTHER PAYMENTS AND REPORTS

- 4.1 <u>License Fee</u>. As consideration for entering into this Agreement, BIOVEST shall pay to REVIMMUNE ten (10) dollars within thirty (30) days of the Effective Date.
- 4.2 Royalties.

(a) As consideration for the license rights granted BIOVEST under this agreement, BIOVEST will pay REVIMMUNE a Fixed Royalty equal to six percent (6%) of Net Sales (as defined in the JHU License) of any Sublicensed Product (the "Sublicensed Royalty") by BIOVEST, its affiliates or sublicensees. The Fixed Royalty will not be payable on sales by BIOVEST to its Affiliates and will instead be applied to the sale of Sublicensed Products by such Affiliates.

(b) Royalty Stacking. In the event that a royalty is obligated to a third party, Biovest shall assume the full responsibility for any such royalty.

- 4.3 <u>Sublicense Fee. Upon a sublicense by BIOVEST</u>, BIOVEST shall pay to REVIMMUNE an amount equal to 20% of the consideration received by BIOVEST for the sublicense (other than sublicenses to Affiliates of BIOVEST). This fee shall not reduce the on going Royalty obligation under Section 4.2 above, which shall continue after the date of sublicense. This sublicense fee is in addition to the sublicense fee required to be paid to JHU under the JHU License.
- 4.4 <u>Fee at Product Approval</u>. Upon FDA approval of each Sublicensed Product for sale or use in the U.S., BIOVEST shall issue to REVIMMUNE a vested warrant to purchase 2,000,000 shares of BIOVEST common stock at an exercise price of \$1.10 per share (or, if higher, the fair market value of a share of BIOVEST common stock on the date of the issuance of the warrant, as determined by BIOVEST's Board of Directors in its reasonable judgment) subject to customary adjustment in the event of a stock dividend, stock split or other similar event for a term of seven years. For clarification, a separate warrant will be granted for each Sublicensed Product approved by the FDA for sale or use in the US.

- 4.5 <u>Relationship to JHU License and Payment of Royalties to JHU</u>. The Parties acknowledge that, notwithstanding any terminology used in this Agreement to the contrary, BIOVEST is a primary licensee (and not a sublicense) under the JHU License by virtue of the last two sentences of Section 2.1 of the JHU License. In addition to (and not in reduction of or in off-set of) BIOVEST's obligations to Revimmune set forth in this Article IV and Section 4.2 and Section 4.3, BIOVEST shall be responsible to pay (or reimburse Revimmune if Revimmune directly pays JHU) for all royalties resulting from sales or activities under this Sublicense Agreement that are required to be paid to JHU under the License Agreement between Revimmune and JHU. BIOVEST's obligations to pay royalties to JHU shall be in addition to BIOVEST's obligations to pay Royalties and Sublicense Fees to Revimmune.
- 4.6 <u>Term of Royalty Obligations</u>. The Sublicensed Royalty specified herein continue as to each Sublicensed Product in the Territory for the term of this Sublicense Agreement, including any Extension Term hereof.
- 4.7 <u>Date and Place of Sale</u>. Sublicensed Products shall be considered sold when BIOVEST, an Affiliate or Sublicensee is paid by a purchaser for a Sublicensed Product.
- 4.8 <u>Monthly Report</u>. On or before the tenth day of each calendar month commencing with the first to occur of the sale of any Sublicensed Product or the receipt by BIOVEST of any Net Sale, BIOVEST shall provide a written Report of Sales reflecting the unit sales and Net Sales for each Sublicensed Product for each calendar month.
- 4.9 <u>Payments by BIOVEST</u>. Payments shall be made to REVIMMUNE on a monthly basis no later than thirty (30) days following the end of the month during which such payments accrued.
- 4.10 <u>Place of Payment</u>. All payments due shall be payable in United States dollars by wire transfer to a bank account designated by each Party from time to time.
- 4.11 Taxation of Payments.

(a) Insofar as any payment that is due under this Agreement is subject to any tax, duty, levy, or other government imposition, the Party receiving the payment agrees to bear any and all such taxes, duties, levies or impositions. Each Party hereby authorizes the other Party to withhold such taxes, duties, levies or impositions from the payments in accordance with this Agreement if BIOVEST or REVIMMUNE is required to do so under the laws of the United States. Whenever a Party deducts such tax, duty, levy or imposition from any payments due, then it shall furnish the other Party with a certificate showing the payment of thereof to the United States.

(b) In the event any payments which are due to under this Agreement are subject to value added taxation by any government, then the Party receiving the payment shall bear such value added tax in full and the Party making the payment shall be reimbursed therefore. If appropriate, the Party receiving payment may add such value

added taxes to its royalty accounts, provided such value added taxes are credited against the other Party's value added tax debt and the other Party is reimbursed in full with respect thereto. Notwithstanding anything herein to the contrary, the Party making the payment shall have no liability for any value added tax directly or indirectly relating to thereto.

(c) In the event any payment is subject to a withholding or other income tax in the Territory, promptly following becoming aware of the applicability of any such tax, the Party making the payment shall so advise the other Party. The Party receiving the payment shall have the right to contest with the appropriate governmental body any such proposed withholding and the other Party shall provide, at receiving Party's expense, reasonable cooperation in any such contest. The Parties shall provide each other with such receipts or other evidence of any tax withheld as is necessary to claim any credit or deduction available to it in other jurisdictions. Payments shall only be reduced for withholding taxes imposed by the jurisdiction out of which the payment is directly made.

- 4.12 <u>Interest</u>. All payments due hereunder that are not paid when due and payable as specified in this agreement shall bear interest at an annual rate equal to the prime rate ("Prime Rate") for U.S. dollar deposits in effect from time to time, as published daily in the Wall Street Journal plus 2%, compounded monthly from the date due until paid, or at such lower rate of interest as shall then be the maximum rate permitted by applicable law.
- 4.13 <u>Right to Documentation</u>. Upon request, REVIMMUNE shall have the right to request reasonable documentation of BIOVEST's Sublicensed Royalty calculations to determine BIOVEST's Net Sales and/or Sublicensee Net Sales for the Sublicensed Products and to request discussion of such calculations with appropriate representatives of BIOVEST.
- 4.14 <u>Records Retention</u>. BIOVEST, its Sublicensee shall keep complete and accurate records pertaining to the sale of Sublicensed Products in the Territory and covering all transactions which Net Sales are derived for a period of three (3) calendar years after the year in which such sales occurred, and in sufficient detail to permit REVIMMUNE to confirm the accuracy of royalty calculations hereunder. Such records shall be available at all reasonable times for inspection by REVIMMUNE or its representatives for verification of royalty payments or compliance with other aspects of this Agreement.

#### 4.15

<u>Audit Request</u>. At the request of REVIMMUNE, BIOVEST, its Affiliates and Sublicensees shall permit an independent, certified public accountant appointed by REVIMMUNE acceptable to BIOVEST, at reasonable times and upon reasonable notice, to examine those records and all other material documents relating to or relevant to Net Sales and Sublicensed Royalties in the possession or control of BIOVEST or Sublicensees, for a period of three (3) years after such Sublicensed Royalties have accrued, as may be necessary to: (i) determine the correctness of any report or payment made under this Agreement; or (ii) obtain information as to the Sublicensed Royalties payable for any calendar quarter in the case of BIOVEST's or sublicense's failure to

report or pay pursuant to this Agreement. Said accountant shall not disclose to REVIMMUNE any information other than information relating to said reports, royalties, and payments. Results of any such examination shall be made available to both Parties. REVIMMUNE shall bear the full cost of the performance of any such audit, unless such audit demonstrates underpayment of royalties by BIOVEST of more than ten percent (10%) from the amount of the original royalty payment made by BIOVEST. In such event, BIOVEST shall bear the full cost of the performance of such audit.

#### **ARTICLE 5-PATENT PROSECUTION; ENFORCEMENT; INFRINGEMENT**

5.1 Patent Prosecution and Maintenance.

(a) <u>Responsibility</u>. The Parties hereby covenant, acknowledge and agree that the rights and responsibilities to prosecute and maintain any Patents licensed to REVIMMUNE pursuant to the JHU License shall be governed by the terms of the JHU License. Biovest hereby assumes fifty percent of the cost and responsibility for patent prosecution of the licensed claims of Revimmune including but not limited to the Sublicensed Rights.

(b) <u>Cooperation</u>. Each Party agrees to cooperate with the other Party to execute any documents necessary or desirable to secure and perfect the other Party's legal rights and worldwide ownership in the other Party's intellectual property, including, but not limited to documents relating to patent, trademark and copyright applications. Each Party agrees to take actions reasonably necessary to diligently prosecute and maintain its intellectual property in major commercial markets where viable protection is available. Each party or its representatives shall be entitled to meet and confer with the other Party and their patent counsel at reasonable times and places.

- 5.2 <u>Limitations on Publications</u>. The Parties agree that no one Party shall publish the results of any studies, whether conducted by its own employees or in conjunction with a third party, carried out pursuant to this Agreement or confidential information received from the other Party that is relating to a Sublicensed Product, without the prior written approval of the other Party. Each Party agrees to provide the other Party with a copy of any proposed abstracts, presentations, manuscripts, or any other disclosure which discloses clinical study results pursuant to this Agreement or confidential information received from the other Party at least sixty (60) days prior to their intended submission for publication and agrees not to submit or present such disclosure until the Party not seeking to disclose such information provides its prior written approval. Such written approval will not be unreasonably withheld unless such proposed disclosure could reasonably harm or impair a Party's intellectual property assets or may reasonably cause commercial harm to a Party.
- 5.3 <u>Notification of Infringement</u>. If either Party learns of an infringement or threatened infringement by a third party of any Sublicensed Rights granted hereunder within the Territory, such Party shall promptly notify the other Party and shall provide such other Party with available evidence of such infringement. Section 5.4 shall then be applicable.

5.4 Patent Enforcement. REVIMMUNE shall have the first right, but not the duty, to institute patent infringement actions against third parties based on any Sublicensed Rights under this Agreement. If REVIMMUNE does not institute an infringement proceeding against an offending third party within ninety (90) days after receipt of notice from BIOVEST, BIOVEST shall have the right, but not the duty, to institute such an action. The costs and expenses of any such action (including fees of attorneys and other professionals) shall be borne by the Party instituting the action, or, if the Parties elect to cooperate in instituting and maintaining such action, such costs and expenses shall be borne by the Parties in such proportions as they may agree in writing. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to institute and prosecute such infringement actions. Any award paid by third parties as a result of such an infringement action (whether by way of settlement or otherwise) shall be paid to the Party who instituted and maintained such action, or, if both Parties instituted and maintained such action, such award shall be allocated among the Parties in proportion to their respective contributions to the costs and expenses incurred in such action.

#### 5.5 Infringement Action by Third Parties.

(a) <u>Claim or Suit Against BIOVEST</u>. In the event of the institution of any claim or suit by a third party against BIOVEST for patent infringement involving the manufacture, use, or sale of any Sublicensed Product in the Territory, BIOVEST shall promptly notify REVIMMUNE in writing of such claim or suit, However, BIOVEST shall have the right to defend such claim or suit at its own expense and REVIMMUNE hereby agrees to assist and cooperate with BIOVEST to the extent necessary in the defense of such claim or suit. During the pendency of such claim or suit, BIOVEST shall continue to make all payments due under this Agreement, but shall have a credit against Sublicensed Royalty payments otherwise payable hereunder for the full amount of all reasonable costs and expenses incurred by BIOVEST in defending against such claim or suit; provided, however, that in applying the credit against any royalty payments, the amount of such payment shall not be reduced by more than 50% and any remaining credit shall be applied against subsequent royalty payments. The cost and expense of any such claim or suit including but not limited to the cost of defense shall be shared equally by Revimmune and Biovest.

(b) <u>Claim or Suit Against REVIMMUNE</u>. In the event of the institution of any claim or suit by a third party against REVIMMUNE for patent infringement involving the manufacture, use, or sale of any Sublicensed Product in the Territory covered by this Sublicense Agreement, REVIMMUNE shall promptly notify BIOVEST in writing of such claim or suit. REVIMMUNE shall have the right but not the obligation to defend such claim or suit at its own expense and BIOVEST hereby agrees to assist and cooperate with REVIMMUNE, at BIOVEST's own expense (provided that Revimmune shall reimburse BIOVEST for its out-of-pocket expenses), to the extent necessary in the defense of such claim or suit.

#### **ARTICLE 6-CONFIDENTIALITY**

- 6.1 <u>Use of Name</u>. REVIMMUNE agrees not to use directly or indirectly BIOVEST's name without BIOVEST's prior written consent. BIOVEST agrees not to use directly or indirectly REVIMMUNE's name or information without REVIMMUNE's prior written consent. Notwithstanding the foregoing, BIOVEST and REVIMMUNE may include an accurate description of the terms of this Agreement to the extent required under federal or state securities laws or other disclosure; and BIOVEST may use REVIMMUNE's names in various documents used by BIOVEST for capital raising and financing purposes.
- 6.2 <u>Confidentiality; Exceptions</u>. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for the longer of three (3) years thereafter or the termination of the JHU License, the receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose other than proper performance hereunder any information furnished to it by the other Party pursuant to this Agreement, except to the extent that it can be established by the receiving Party by competent proof that such information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) was independently developed by or for the receiving Party by persons not having access to such information, as determined by the written records of such party.

6.3. <u>Obligations of Employees and Consultants.</u> The Parties each represent that all of its employees and the employees of its Affiliates, and any collaborators or consultants to such Party or its Affiliates, who shall have access to confidential information of the Parties are bound by written obligations to maintain such information in confidence and not to use such information except as expressly permitted herein. Each Party agrees to enforce confidentiality obligations to which its employees and consultants (and those of its Affiliates) are obligated.

#### **ARTICLE 7-INDEMNIFICATION**

- 7.1 Indemnification by BIOVEST. BIOVEST shall defend, indemnify and hold REVIMMUNE and JHU, their respective officers, directors, employees and consultants harmless from and against any and all third party claims, suits or demands, threatened or filed, ("Claims") for liability, damages, losses, costs and expenses (including the costs and expenses of attorneys and other professionals), at both trial and appellate levels, relating to the distribution, testing, manufacture, use, sale, consumption on or application of Sublicensed Products by BIOVEST, its Affiliates or its sublicensees pursuant to this Sublicense Agreement, including, without limitation, claims for any loss, damage, or injury to persons or property, or loss of life, relating to the promotion and advertising of Sublicensed Products and/or interactions and communications with governmental authorities, physicians or other third parties relating to the Sublicensed Products. The foregoing indemnification shall not apply to any third party Claims to the extent are caused by the gross negligence of REVIMMUNE or, in the case of indemnification of JHU by JHU, and the foregoing indemnification shall also not apply to any Claims that would give rise to a REVIMMUNE indemnification obligations pursuant to Section 7.1 below or pursuant to any other provision of this Agreement.
- 7.2 Indemnification by REVIMMUNE. REVIMMUNE shall defend, indemnify and hold BIOVEST, its officers, directors, employees and consultants harmless from and against any and all third party Claims for liability, damages, losses, costs and expenses (including the costs and expenses of attorneys and other professionals), at both trial and appellate levels, relating to REVIMMUNE's activities contemplated under this Agreement, including, but not limited to, (a) breach of the representations, warranties and obligations of REVIMMUNE hereunder, or (b) any tax, duty, levy or government imposition on any sums payable by BIOVEST to REVIMMUNE hereunder. The foregoing indemnification shall not apply to any Claims to the extent caused by the gross negligence of BIOVEST.
- 7.3 <u>Notice</u>. In the event that either Party seeks indemnification under Sections 7.1 or 7.2, the Party seeking indemnification agrees to (i) promptly inform the other Party of the Third party Claim, (ii) permit the other Party to assume direction and control of the defense or claims resulting there from (including the right to settle it at the sole discretion of that Party), and (iii) cooperate as reasonably requested (at the expense of that Party) in the defense of the Claim.
- 7.4 Insurance. Prior to the use of any Sublicensed Product in connection with a clinical trial or the first sale of a Sublicensed Product which ever occurs first, BIOVEST shall obtain and maintain broad form comprehensive general liability insurance and products liability insurance with a reputable and financially secure insurance carrier, subject to approval by REVIMMUNE' s primary insurance broker, to cover such activities of BIOVEST and BIOVEST's contractual indemnity under this Agreement. Such insurance shall provide minimum annual limits of liability of \$3,000,000 per occurrence and \$5,000,000 in the aggregate with respect to all occurrences being indemnified under this Agreement. Such insurance policy shall name REVIMMUNE as an additional insured and shall be purchased and kept in force for the period of five (5) years after the cessation of sales of all Sublicensed Products under this Agreement.

#### **ARTICLE 8-TERM; TERMINATION**

- 8.1 Term. Unless earlier terminated under Section 8.2 hereof, this Agreement and the Sublicense granted hereby shall commence as of the Effective Date and, unless sooner terminated as provided hereunder, shall have an initial term (the "Initial Term") that shall terminate on the last to occur of: (i) Ten (10) years from the date hereof, (ii) the termination of the JHU License, or (iii) the expiration of the last-to-expire of the patent claims included in the Sublicensed Rights. The Term shall be automatically extended by successive extension terms (the "Extension Terms") of one (1) year each unless either party gives written notice of its election not to extend the term at least ninety (90) days prior to the expiration of the Initial Term or of any Extension Term. Notwithstanding the forgoing, the Sublicense shall terminate upon the filing of a petition in bankruptcy by or against Biovest or the filing of any lien or security interest in the Sublicense or any interest under the Sublicense without the prior written consent of REVIMMUNE. Further, the Sublicense shall terminate in the event that BIOVEST does not file an IND which is accepted for filing by the Food and Drug Administration for an indication which upon approval will result in royalties being paid to Revimmune under this Sublicense within two (2) years from the date hereof.
- 8.2 <u>Breach</u>. Failure by either Party to comply with any of the material obligations contained in this Agreement shall entitle the other Party to give to the Party in default notice specifying the nature of the default and requiring it to cure such default. If such default is not cured within one hundred twenty (120) days after the receipt of such notice (or, if such default cannot be cured within such 120 day period, if the Party in default does not commence and diligently continue actions to cure such default), the notifying Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, in addition to any other remedies available to it by law or in equity, to terminate this Agreement by giving written notice to take effect within thirty (30) days after such notice unless the defaulting Party shall cure such default within said thirty (30) days. The right of either Party to terminate this Agreement, as hereinabove provided, shall not be affected in any way by its waiver or failure to take action with respect to any previous default.
- 8.3 <u>Termination of Sublicenses</u>. Upon any termination of this Agreement, all sublicenses granted by BIOVEST under this Agreement shall terminate simultaneously, subject, nevertheless, to Section 8.4.
- 8.4 <u>Effect of Termination</u>. Upon the termination of this Sublicense Agreement, BIOVEST and its sublicensees shall promptly: (i) return to REVIMMUNE all relevant records, materials or confidential information of REVIMMUNE concerning the REVIMMUNE Licensed Rights relating to such Sublicensed Product in the possession or control of BIOVEST or its sublicensees; (ii) assign to REVIMMUNE, or REVIMMUNE's designee, its registrations with governmental health authorities, licensees, and approvals of such Sublicensed Product in the Territory and (iii) cease and desist from developing, promoting, marketing, selling or commercializing any Sublicensed Product (except to the extent reasonably necessary to liquidate existing inventories and fulfill then-existing orders and obligations).

- 8.5 <u>Surviving Rights</u>. Termination of this Agreement shall not terminate BIOVEST's obligation to comply with Articles 4, 5, 6 and 7 hereunder.
- 8.6 <u>Accrued Rights, Surviving Obligations</u>. Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party under this Agreement prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

#### **ARTICLE 9-MISCELLANEOUS PROVISIONS**

- 9.1 <u>Relationship of Parties</u>. Nothing in this Agreement is or shall be deemed to constitute a partnership, agency, employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 9.2 <u>Inter-relationships</u>. REVIMMUNE and BIOVEST each acknowledge that a Hopkins Capital Group, LLC entity owns an equity interest in both REVIMMUNE and BIOVEST and that Frank O' Donnell, MD is an affiliate and founder of the Hopkins Capital Group, LLC entities, REVIMMUNE and BIOVEST. BIOVEST represents that its Audit Committee and independent directors have been fully advised of these inter-relationships.
- 9.3 <u>Assignment</u>. Except as otherwise provided herein, neither this Agreement nor any interest hereunder shall be assignable by BIOVEST without the prior written consent of REVIMMUNE; provided, however, that either Party may assign this Agreement to any wholly-owned subsidiary or to any successor by merger or sale of substantially all of its assets to which this Sublicense Agreement relates in a manner such that the assignor shall remain liable and responsible for the performance and observance of all its duties and obligations hereunder. This Sublicense Agreement shall be binding upon the successors and permitted assigns of the parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 10.3 shall be void. Biovest shall not pledge or permit any lien or security interest to be placed against the Sublicense or any interest hereunder without the prior written consent of REVIMMUNE. Any pledge, lien or security interest not in accordance with this Section 10.3 shall be void.
- 9.4 <u>Further Actions</u>. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

9.5

<u>Force Majeure</u>. Neither Party shall be liable to the other for loss or damages nor shall have any right to terminate this Agreement for any default or delay attributable to any act of God, flood, fire, explosion, strike, lockout, labor dispute, shortage of raw materials, casualty, accident, war, revolution, civil commotion, act of public enemies, blockage or embargo, injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or subdivision, authority or representative of any such government, or any other cause beyond the reasonable control of such Party, if the Party

affected shall give prompt notice of any such cause to the other Party. The Party giving such notice shall thereupon be excused from such of its obligations hereunder as it is thereby disabled from performing for so long as it is so disabled and for thirty (30) days thereafter. Notwithstanding the foregoing, nothing in this Section 10.5 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

- 9.6 <u>No Trademark Rights</u>. Except as otherwise provided herein, no right, express or implied, is granted by this Agreement to use in any manner the name "BIOVEST" or "REVIMMUNE" or any other trade name or trademark of the other party in connection with the performance of this Agreement.
- 9.7 <u>Public Announcements</u>. Except as required by law, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other. In the event of a legally-required public announcement, the Party making such announcement shall provide the other with a copy of the proposed text prior to such announcement.
- 9.8 Notices. Any notice required or permitted to be given or delivered hereunder or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been properly served if: (a) delivered personally, (b) delivered by a recognized overnight courier service instructed to provide next-day delivery, (c) sent by certified or registered mail, return receipt requested and first class postage prepaid, or (d) sent by facsimile transmission followed by confirmation copy delivered by a recognized overnight courier service the next day. Such notices, demands and other communications shall be sent to the addresses set forth below, or to such other addresses or to the attention of such other person as the recipient Party has specified by prior written notice to the sending Party. Date of service of such notice shall be: (i) the date such notice is personally delivered or sent by facsimile transmission (with issuance by the transmitting machine of confirmation of successful transmission), (ii) three days after the date of mailing if sent by certified or registered mail, or (iii) one day after date of delivery to the overnight courier if sent by overnight courier. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:
  - (a) If to REVIMMUNE, addressed to:

REVIMMUNE, LLC 324 South Hyde Park Avenue Suite 350 Tampa, FL 33606 Attn: Managing Member

(b) If to BIOVEST, addressed to:

BIOVEST INTERNATIONAL, INC. 324 South Hyde Park Avenue Suite 350 Tampa, FL 33606 Attn: CEO

- 9.9 <u>Amendment</u>. No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party. This Agreement may be executed in a series of counterparts, all of which, when taken together, shall constitute one and the same instrument.
- 9.10 <u>Waiver</u>. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by the waiving Party.
- 9.11 Dispute Resolution.

(a) <u>Senior Officials</u>. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement which relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated senior officials are as follows:

For BIOVEST:	Chairman of the Audit Committee
For REVIMMUNE:	Francis E. O' Donnell, Jr., M.D. Managing Member

In the event the designated senior officials are not able to resolve such dispute within the thirty (30) day period, either Party may invoke the provisions of Section 10.11(b).

(b) <u>Arbitration</u>. In the event of any dispute, difference or question arising between the Parties in connection with this Agreement, the construction thereof, or the rights, duties or liabilities of either Party, and which dispute cannot be amicably resolved by the good faith efforts of both Parties, then such dispute shall be resolved by binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association. The arbitration panel shall be composed of three arbitrators, one of whom shall be chosen by REVIMMUNE, one by BIOVEST, and the third by the two so chosen. If both or either of BIOVEST or REVIMMUNE fails to choose an arbitrator or arbitrators within fourteen (14) days after receiving notice of commencement of arbitration or if the two arbitrators fail to choose a third arbitrator within fourteen (14) days after their appointment, the then President of the American Arbitrators required to complete the board or, if he shall decline or fail to do

so, such arbitrator or arbitrators shall be appointed by the American Arbitration Association. The decision of the arbitrators shall be by majority vote and, at the request of either Party; the arbitrators shall issue a written opinion of findings of fact and conclusions of law. Costs shall be borne as determined by the arbitrators. Unless the Parties to the arbitration shall otherwise agree to a place of arbitration, the place of arbitration shall be at Tampa, Florida, U.S.A. The arbitration award shall be final and binding upon the Parties to such arbitration and may be entered in any court having jurisdiction.

- 9.12 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of FLORIDA.
- 9.13 <u>Severability</u>. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.
- 9.14 <u>Entire Agreement of the Parties</u>. This Agreement constitutes and contains the entire understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof.

#### [NEXT PAGE IS THE SIGNATURE PAGE]

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IN WITNESS WHEREOF, each of the Parties has caused this Agreement to be executed by its duly authorized officer as of the day and year first above written.

#### **REVIMMUNE LLC**

By:

/s/ Francis E. O' Donnell, Jr.

Name:

Francis E. O' Donnell, Jr., M.D.

Title:

Manager

#### **BIOVEST INTERNATIONAL, INC.**

By:

/s/ Steven Arikian

#### Name:

Steven Arikian, M.D.

#### Title:

Chairman and CEO

#### EXHIBIT A

Johns Hopkins University License Agreement



### Biovest Secures Worldwide Exclusive License to Late-Stage Technology for Elimination of Transplant Rejection

Published Study Shows Revimmune<sup>™</sup> Reduces the Incidence of Chronic Bone Marrow Transplant Rejection of Host by Approximately 85%, Enabling Bone Marrow Transplant Usage to Cure Chronic Illnesses Such as Sickle Cell Anemia

TAMPA, FLORIDA - January 22, 2008 - Biovest International, Inc. (OTCBB: BVTI), a majority-owned subsidiary of Accentia Biopharmaceuticals, Inc. (NASDAQ: ABPI), announced today that it has secured the worldwide, exclusive license to Revimmune<sup>™</sup> for the treatment and prevention of transplant rejection including rejection following a bone marrow transplant. As an initial indication, the Company intends to submit an Investigational New Drug (IND) application seeking Food and Drug Administration (FDA) permission to enter a Phase 3 clinical trial of Revimmune usage in bone marrow transplants to treat and possibly cure sickle cell anemia, an inherited disease that is chronic and lifelong, leading to painful crises, organ failure, and strokes. The average lifespan of an individual with sickle cell anemia is approximately 42 years.

Revimmune is a patent-pending pharmaceutical treatment in late-stage development for the prevention of transplant rejection, with applications to bone marrow transplants for a wide variety of indications including elimination of sickle cell anemia, and other hereditary hemoglobinopathies such as thalassemia.

According to Biovest's Chairman and CEO, Dr. Steven Arikian, "Rejection is frequent in bone marrow transplants, as the transplanted immune system from the donor attacks the organs of the transplant recipient, and many life-threatening complications occur. With the acquisition of Revimmune for transplant rejection, we obtain a product that we believe can improve the percentage of successful transplants, as evidenced by its ability to dramatically reduce the incidence of chronic Graft-Versus-Host Disease (GVHD) in bone marrow transplants." GVHD is a particularly severe type of transplant rejection characterized by the donor marrow (graft) producing immune cells that attack multiple organs of the recipient (host).

In clinical studies at Johns Hopkins University Medial Center for treatment and prevention of transplant rejection including rejection following a bone marrow transplant, more than 200 patients have been treated with Revimmune. In a group of over 46 bone marrow transplant patients<sup>(1)</sup>, the use of Revimmune is associated with a reduction in the incidence of chronic bone marrow transplant rejection of the recipient by approximately 85%. In particular, transplant patients who received Revimmune had an incidence of just 11% of chronic GVHD, in contrast to an incidence of 75% in patients engrafted without Revimmune. Accordingly,

Revimmune has the potential to be the first effective treatment of this life-threatening complication.

Dr. Arikian explained another key reason why Revimmune may be ideal for use in bone marrow transplants to cure sickle cell anemia, "While bone marrow transplant offers the only potential cure for sickle cell anemia, very few people have a suitable donor for transplant. Another expected advantage of Revimmune is that its use expands the potential pool of transplant donors by reducing the requirement for tissue matching, overcoming a major obstacle of treatment."

The technology is being licensed to Biovest for transplant rejection from Revimmune, LLC, a Hopkins Capital Group II LLC (HCG II) portfolio company, which holds the exclusive license for the technology from the Johns Hopkins University. Revimmune, LLC has previously licensed the exclusive, worldwide rights to Revimmune for treatment of all autoimmune diseases to Accentia Biopharmaceuticals. Dr. Frank E. O' Donnell Jr. is a managing partner of HCG II. More details of the license can be found in the Company's 8-K filing. HCG II is not affiliated with the Johns Hopkins University.

#### **REVIMMUNE FOR PREVENTION OF GRAFT-VERSUS-HOST DISEASE**

The principal investigator for the ongoing Revimmune study in bone marrow transplant patients at Johns Hopkins University School of Medicine is Dr. Richard Jones. Dr. Jones and Dr. Leo Luznik, and colleagues presented results of the study<sup>(1)</sup> at a recent meeting on bone marrow transplantation entitled: Post-Transplantation High-Dose Cyclophosphamide (Cy) Is Effective Single Agent GVHD Prophylaxis That Permits Prompt Immune Reconstitution after Myeloablative HLA Matched Related and Unrelated Bone Marrow Transplantation (BMT).

Dr. Jones and Dr. Luznik concluded that the results of the study indicate that post-transplantation Revimmune (high-dose cyclophosphamide) is effective as a single agent strategy for limiting acute and chronic GVHD after myeloablative HLA-matched related and unrelated allografting; this approach also limits the need for prolonged immunosuppression, resulting in favorable immunoreconstitution with few opportunistic infections in this unfavorable group of patients.

Graft-versus-host disease is a common complication of allogeneic bone marrow transplantation in which functional immune cells in the transplanted marrow recognize the recipient as "foreign" and mount an immunologic attack.

After bone marrow transplantation, T cells present in the graft, either as contaminants or intentionally introduced into the host, attack the tissues of the transplant recipient after perceiving host tissues as antigenically foreign. The T cells produce an excess of cytokines, including TNF alpha and interferon-gamma (IFNg). A wide range of host antigens can initiate graft-versus-host disease, among them the human leukocyte antigens (HLAs). However, graft-versus-host disease can occur even when HLA-identical siblings are the donors.

While donor T cells are undesirable as effector cells of graft-versus-host-disease, they are valuable for engraftment by preventing the recipient's residual immune system from rejecting the bone marrow graft (host-versus-graft). Additionally, as bone marrow transplantation is frequently used to cure cancer, mainly leukamias, donor T-cells have proven to have a valuable graft-versus-tumor effect.

#### BACKGROUND ON SICKLE CELL ANEMIA

**Sickle-cell anemia and disease (SS)** is a group of genetic disorders caused by sickle hemoglobin (Hgb S or Hb S). In many forms of the disease, the red blood cells change shape upon deoxygenation because of polymerization of the abnormal sickle hemoglobin; the hemoglobin proteins stick to each other, causing the cell to get a rigid surface and sickle shape. This process damages the red blood cell membrane, and can cause the cells to become stuck in blood vessels. This deprives the downstream tissues of oxygen and causes ischemia and infarction, which may cause organ damage, such as stroke. The disease is chronic and lifelong. Individuals are most often well, but their lives are punctuated by periodic painful attacks.

#### **BACKGROUND ON REVIMMUNE**

Developed by Dr. Richard Jones, Dr. Robert Brodsky, and colleagues at Johns Hopkins University School of Medicine, Revimmune uses an already-approved active pharmaceutical (cyclophosphamide) in a novel, ultra-high dose, pulsed administration to eliminate unwanted immune reactions in a new patent-pending method for the treatment and prevention of a broad range of diseases including transplant rejection and rejection following a bone marrow transplant, which has been licensed to Biovest. Revimmune holds the potential to be the first effective treatment to protect against certain life-threatening complications associated with transplants, including the prevention of Graft-Versus-Host Disease. Revimmune includes a risk management program to enhance patient safety by ensuring appropriate patient selection, supportive care, and tracking of outcomes data.

#### **References:**

<sup>(1)</sup> Post-Transplantation High-Dose Cyclophosphamide (Cy) Is Effective Single Agent GVHD Prophylaxis That Permits Prompt Immune Reconstitution after Myeloablative HLA Matched Related and Unrelated Bone Marrow Transplantation (BMT). Session Type: ASH Poster Session, Board #120-III. Luznik Leo, Chen R. Allen, Kaup Michele, Bright C. Emilie, Bolanos-Meade Javier, Thorburn J. Christopher, Kos Ferdynand, Hess D. Allan, Jones J. Richard, Fuchs J. Ephraim (Intr. by Leo Luznik) Division of Hematologic Malignancies, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD, USA.

#### About Biovest International, Inc.

Biovest International, Inc. (OTCBB: BVTI) is a pioneer in the development of advanced individualized immunotherapies for life-threatening cancers of the blood system. Biovest is a majority-owned subsidiary of Accentia Biopharmaceuticals, Inc., (NASDAQ:ABPI) with its remaining shares publicly traded. Biovest has a foundation in the manufacture of biologics for research and clinical trials. In addition, Biovest develops, manufactures and markets patented cell culture systems,

including the innovative AutovaxID<sup> $\mathbb{N}$ </sup>, which is being marketed as an automated vaccine manufacturing instrument and for production of cellbased materials and therapeutics. Biovest is currently conducting a pivotal Phase 3 clinical trial for BiovaxID<sup> $\mathbb{N}$ </sup>, which is a patient-specific anticancer vaccine focusing on the treatment of follicular non-Hodgkin's lymphoma. BiovaxID<sup> $\mathbb{N}$ </sup> has been granted Fast Track status by the FDA.

#### For further information, visit the Company Web site at: www.biovest.com

#### **Biovest International, Inc. Corporate Contacts:**

Douglas Calder, Director of Investor Relations & Public Relations Phone: (813) 864-2554, ext.258 / Email: <u>dwcalder@accentia.net</u> or

Susan Bonitz, Ph.D., Director, Program Coordination Phone: (813) 864-2554, ext.277 / Email: <u>sbonitz@accentia.net</u>

#### **Forward-Looking Statements:**

Statements in this release that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements about Revimmune(TM), BiovaxID(TM), AutovaxID(TM), and any other statements relating to products, product candidates, product development programs, the FDA or clinical study process including the commencement, process, or completion of clinical trials or the regulatory process. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions, and other statements identified by words such as "may," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the actual results of Biovest to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval for product candidates; competition from other pharmaceutical or biotechnology companies; and the additional risks discussed in filings with the Securities and Exchange Commission. All forward-looking statements are qualified in their entirety by this cautionary statement, and Biovest undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. The product names used in this statement are for identification purposes only. All trademarks and registered trademarks are the property of their respective owners.