

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

**FORM 10-Q/A**  
**(Amendment No. 1)**

QUARTERLY REPORT UNDER SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the quarterly period ended September 30, 2001**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

Commission File Number 000-23186

**BIOCRYST PHARMACEUTICALS, INC.**  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

62-1413174  
(I.R.S. employer identification no.)

2190 Parkway Lake Drive; Birmingham, Alabama 35244  
(Address and zip code of principal executive offices)

(205) 444-4600  
(Registrant's telephone number, including area code)

NONE  
(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 17,592,160 shares of the Company's Common Stock, \$.01 par value, were outstanding as of October 31, 2001.

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**Explanatory Note**

**This amendment to the Form 10-Q for the quarterly period ended September 30, 2001, is being filed solely to amend Part II, Item 6(a), Exhibit 10.9, the Termination Agreement between the Registrant and The R. W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc., dated September 21, 2001 (with certain confidential information deleted). Section 4 of the Termination Agreement includes the name "peramivir" as the adopted name for the neuraminidase inhibitor RWJ-270201, for which confidential treatment was requested in the original 10-Q of the Registrant.**

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**PART II. OTHER INFORMATION**

**Item 6. Exhibits and Reports on Form 8-K:**

a. Exhibits:

Number	Description
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- 3.1\* Composite Certificate of Incorporation of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
- 3.2\* Bylaws of Registrant. Incorporated by reference to Exhibit 3.1 to the Company's Form 10-Q for the second quarter ending June 30, 1995 dated August 11, 1995.
- 4.1\* See Exhibits 3.1 and 3.2 for provisions of the Composite Certificate of Incorporation and Bylaws of the Registrant defining rights of holders of Common Stock of the Registrant.
- 10.1\* 1991 Stock Option Plan, as amended and restated as of March 6, 2000. Incorporated by reference to Exhibit 99.1 to the Company's Form S-8 Registration Statement dated June 16, 2000 (Registration No. 333-39484).
- 10.2\* Employment Agreement dated December 27, 1999 between the Registrant and Charles E. Bugg, Ph.D. Incorporated by reference to Exhibit 10.10 to the Company's Form 10-K for the year ending December 31, 1999 dated March 24, 2000.
- 10.3\* License Agreement dated April 15, 1993 between Ciba-Geigy Corporation (now merged into Novartis) and the Registrant. Incorporated by reference to Exhibit 10.40 to the Company's Form S-1 Registration Statement (Registration No. 33-73868).
- 10.4\* Employee Stock Purchase Plan. Incorporated by reference to Exhibit 99.4 to the Company's Form S-8 Registration Statement (Registration No. 33-95062).
- 10.5\* License Agreement dated as of September 14, 1998 between Registrant and The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc. Incorporated by reference to Exhibit 10.23 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 10.6\* Stock Purchase Agreement dated as of September 14, 1998 between Registrant and Johnson & Johnson Development Corporation. Incorporated by reference to Exhibit 10.24 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 10.7\* Stockholder's Agreement dated as of September 14, 1998 between Registrant and Johnson & Johnson Development Corporation. Incorporated by reference to Exhibit 10.25 to the Company's Form 10-Q for the third quarter ending September 30, 1998 dated November 10, 1998.
- 10.8\* Warehouse Lease dated July 12, 2000 between RBP, LLC an Alabama Limited Liability Company and the Registrant for office/warehouse space. Incorporated by reference to Exhibit 10.8 to the Company's Form 10-Q for the second quarter ending June 30, 2000 dated August 8, 2000.
- 10.9 Termination Agreement dated as of September 21, 2001 between Registrant and The R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical, Inc. (with certain confidential information deleted).

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\* Previously filed.

b. Reports on Form 8-K:  
None

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## SIGNATURES

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

BIOCRYST PHARMACEUTICALS, INC.

Date: January 15, 2002

/s/ W. Randall Pittman

W. Randall Pittman  
Chief Financial Officer and  
Chief Accounting Officer

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**EXHIBIT 10.9**

**CONFIDENTIAL TREATMENT HAS BEEN REQUESTED FOR PORTIONS OF THIS EXHIBIT  
PURSUANT TO 17 C.F.R. §§ 200.80(b)(4), 200.83, 230.406 and 240.24b-2.**

**THIS TERMINATION AGREEMENT** (the "Agreement"), dated as of September 21, 2001 (the "Effective Date"), is hereby entered into by and between BIOCRYST PHARMACEUTICALS, INC., a Delaware corporation having its principal place of business at 2190 Parkway Lake Drive, Birmingham, Alabama 35244 (hereinafter referred to as "BIOCRYST") and ORTHO-McNEIL PHARMACEUTICAL, INC., a Delaware corporation having its principal office at U.S. Route 202, Raritan, NJ 08869 and THE R. W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, a division of ORTHO-McNEIL PHARMACEUTICAL, INC., having its principal place of business at U.S. Route 202, Raritan, NJ 08869 (hereinafter collectively referred to as "ORTHO"). BIOCRYST and ORTHO are sometimes referred to herein individually as a "Party" and collectively as the "Parties" and all references to BIOCRYST and ORTHO shall include their respective Affiliates (hereinafter defined), where appropriate under the terms of this Agreement.

**WITNESSETH**

**WHEREAS**, BIOCRYST and ORTHO previously entered into a license agreement dated September 14, 1998 (the "License Agreement");

**WHEREAS**, On April 27, 2001 pursuant to Section 12.1 of the License Agreement, ORTHO provided notice to BIOCRYST of its election to terminate the License Agreement, with such termination effective as of the August 27, 2001, and the parties, by letter agreement, subsequently extended the effective date of termination until the Effective Date; and,

**WHEREAS**, the Parties desire to clarify the rights and responsibilities of each Party in respect of such termination in order to facilitate and expedite the transfer to BIOCRYST of all activities under the License Agreement related to the development, manufacture and marketing of a Neuraminidase Inhibitor Product (collectively, the "Development Program").

**NOW, THEREFORE**, in consideration of the foregoing premises, and the mutual promises, covenants and agreement hereinafter set forth, the receipt and sufficiency of which is hereby acknowledged, both Parties to this Agreement hereby mutually agree as follows:

**SECTION 1. DEFINITIONS**

Capitalized terms used in this Agreement shall have the meanings set forth in the License Agreement unless otherwise defined in this Agreement or unless the context clearly indicates to the contrary:

1.1 "Agreement" shall mean this Termination Agreement.

1.2 "Clinical and Clinical Support Studies" shall mean any and all scientific evaluations of neuraminidase inhibitors, including Neuraminidase Inhibitor Products, performed in connection with the Development Program, and all related contracts, data and materials arising in connection therewith, including but not limited to the clinical trials, clinical support studies and the other items set forth on Schedule A, attached hereto.

1.3 "Contracts" shall mean the contracts set forth on Schedule B, attached hereto.

1.4 "Data" shall mean all data, notes, databases and information in any tangible or intangible form, including but not limited to paper, electronic and magnetic media, arising out of or related to the Development Program, including but not limited to that (i) arising out of or related to Clinical and Clinical Support Studies, (ii) underlying or supporting the Regulatory Filings; (iii) required in order to maintain the integrity of New Drug Application files as required by law, rule or regulation, and (iv) which is set forth on Schedule D, attached hereto.

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1.5 “Domain Names” shall mean the Internet domain names set forth in the Trademark Assignment Agreement, attached hereto as Schedule F.

1.6 “Drug Substance” shall mean the approximately [\*\*\*]<sup>1</sup> of GMP grade neuraminidase inhibitor drug substance (manufactured and maintained in accordance with GMP requirements), approximately [\*\*\*] of which has been manufactured according to the final synthesis method, all of which has been manufactured by ORTHO during the term of the License Agreement and which is being stored at ORTHO’s facilities in Spring House, Pennsylvania as of the Effective Date.

1.7 “Drug Tablets” shall mean the drug tablets specified in Schedule C, attached hereto, including both placebos and tablets comprised of the neuraminidase inhibitor manufactured by ORTHO or its Affiliates.

1.8 “License Agreement Effective Date” shall mean the effective date of the License Agreement, September 14, 1998.

1.9 “Materials” shall mean those tangible materials generated by, purchased by or allocated to the Development Program by ORTHO, its contractors and agents as set forth on Schedule C.

1.10 “Purchase Order” shall have the meaning set forth in Section 9.2.

1.11 “Regulatory Filings” shall mean all filings with regulatory agencies, departments, bureaus or other government entities, made in connection with the Development Program by ORTHO, its agent and contractors in order to allow ORTHO to market or sell a Neuraminidase Inhibitor Product anywhere in the world, including but not limited to those regulatory filings set forth on Schedule E, attached hereto.

1.12 “Trademarks” shall mean the trademarks set forth in the Trademark Assignment Agreement, attached hereto as Schedule F.

## **SECTION 2. TERMINATION OF LICENSE AGREEMENT**

2.1 The Parties hereby confirm that the License Agreement is hereby terminated in its entirety pursuant to Section 12.1 of the License Agreement, with such termination effective as of the Effective Date.

2.2 The Parties hereby confirm and agree that all provisions, rights and obligations which survive termination of the License Agreement pursuant to the terms of the License Agreement shall continue to survive, except for Article 26 of the License Agreement which the Parties hereby agree shall not survive. All surviving provisions in the License Agreement are hereby supplemented by the terms of this Agreement.

## **SECTION 3. PATENTS AND INVENTIONS**

3.1 ORTHO hereby acknowledges and agrees that (i) all of its rights to the Existing Know-How, Improvements, Existing Patents, and Improvement Patents which arose by virtue of the License Agreement are terminated; and (ii) BIOCRYST is and shall be the exclusive owner of all right, title and interest in and to the Existing Know-How, Improvements, Existing Patents, and Improvement Patents. To the extent necessary to effectuate the foregoing, ORTHO hereby assigns to BIOCRYST any and all right, title and interest throughout the world that ORTHO may have in and to the Existing Know-How, Improvements, Existing Patents, and Improvement Patents.

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<sup>1\*\*\*</sup> Information omitted and filed separately with the Commission pursuant to 17 C.F.R. §§ 200.80(b)(4), 200.83, 230.406, and 240.24b-2.

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3.2 ORTHO hereby acknowledges and agrees that (i) all of its rights to the Joint Inventions and Joint Patents by virtue of the License Agreement are terminated; and (ii) BIOCRYST is and shall be the exclusive owner of all right, title and interest in and to the Joint Inventions and Joint Patents. To the extent necessary to effectuate the foregoing, ORTHO hereby assigns to BIOCRYST all of ORTHO’s right, title and interest throughout the world in and to the Joint Inventions and the Joint Patents, including but not limited to the Joint Inventions and Joint Patents set forth on Schedule G, attached hereto.

3.3 BIOCRYST hereby grants to ORTHO a royalty-free, perpetual, non-sublicenseable, non-transferable, fully paid-up limited license to use the manufacturing process claimed in the patent application PCT/US00/15969, all national filings thereof, and any continuations or divisionals reissues or re-examinations of the foregoing, solely for ORTHO’s internal business purposes. For purposes of clarity, internal business purposes shall not include performance of such processes for any third party or supply of the product of the process to any third party; however, internal purposes shall include sale of ORTHO products which are derived from the use of the processes, but which are materially changed from the product of the process.

## **SECTION 4. TRADEMARKS, DOMAIN NAMES AND GENERIC NAME**

4.1 The Parties hereby acknowledge that as of the Effective Date and pursuant to the assignment agreement attached hereto as Schedule F (the “Trademark Assignment”), ORTHO has assigned to BIOCRYST, at

BIOCRYST's expense, all right, title and interest in and to the Trademarks and Domain Names and the applications or registrations therefor, together with the goodwill of the business symbolized by the Trademarks and Domain Names. The Trademark Assignment includes the right to sue and recover damages for past and future infringements of ORTHO's rights in the Trademarks and the Domain Names and to bring any proceeding in the United States Patent and Trademark Office or any equivalent agency in any other country for cancellation or opposition or other proceeding in connection with the Trademarks and the Domain Names. The right, title and interest is to be held and enjoyed by BIOCRYST and BIOCRYST's successors and assigns as fully and exclusively as it would have been held and enjoyed by ORTHO had this assignment not been made.

4.2 The Parties acknowledge that the USAN Council has adopted "peramivir" as the United States Adopted Name for the neuraminidase inhibitor RWJ-270201 for publication in the USP Dictionary of USAN and International Nonproprietary Names. ORTHO agrees to provide BIOCRYST with reasonable assistance in updating such publication, or as other otherwise reasonably requested by BIOCRYST in relation to the use and maintenance of peramivir as a nonproprietary name. BIOCRYST agrees to bear ORTHO's reasonable and actual out-of-pocket costs related thereto.

## **SECTION 5. CONTRACTS**

Excepting only the Excluded Contract Liabilities (defined below), ORTHO hereby assigns and transfers to BIOCRYST all of ORTHO's right, title and interest in and to, and obligations under, the Contracts. BIOCRYST hereby assumes all of the obligations of ORTHO under the Contracts arising from and after the Effective Date, and agrees to make any payments, perform all covenants, stipulations, agreements, and obligations under the Contracts accruing after the Effective Date. In no event, however, shall BIOCRYST be deemed to have assumed, with respect to the Contracts, (i) any obligation to perform which accrued prior to the Effective Date, (ii) any financial obligations, including obligations to make payments or reimburse expenses, which accrued prior to the Effective Date; (iii) any liabilities arising out of the actions or inactions of ORTHO, its agents and contractors; or (iv) any liability or obligation attributable to ORTHO's (or its agents' or contractors') breach of any provision of the Contracts or any other agreements with any third parties, ((i) through (iv) shall be collectively referred to as the "Excluded Contract Liabilities").

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## **SECTION 6. CLINICAL AND CLINICAL SUPPORT STUDIES, DATA AND MATERIALS**

Excepting only the Excluded Development Program Liabilities (defined below), ORTHO hereby assigns to BIOCRYST any and all right, title and interest throughout the world that ORTHO may have in and to the Clinical and Clinical Support Studies, Data and Materials. In no event, however, shall BIOCRYST be deemed to have assumed, with respect to the Clinical and Clinical Support Studies, Data and Materials, (i) any obligation to perform which accrued prior to the Effective Date, (ii) any financial obligations, including obligations to make payments or reimburse expenses, which accrued prior to the Effective Date; (iii) any liabilities arising out of the actions or inactions of ORTHO its agents and contractors or arising out of the infringement of any third party intellectual property rights by ORTHO, its agents and contractors; or (iv) any liability or obligation attributable to ORTHO's (or its agents' or contractors') breach of any agreements with any third parties, ((i) through (iv) shall be collectively referred to as the "Excluded Development Program Liabilities").

## **SECTION 7. REGULATORY FILINGS**

Excepting only the Excluded Regulatory Liabilities (defined below), ORTHO hereby assigns to BIOCRYST any and all right, title and interest throughout the world that ORTHO may have in and to the Regulatory Filings. In no event, however, shall BIOCRYST be deemed to have assumed, with respect to the Regulatory Filings, (i) any obligation to perform which accrued prior to the Effective Date, (ii) any financial obligations, including obligations to make payments or reimburse expenses, which accrued prior to the Effective Date; (iii) any liabilities arising out of the actions or inactions of ORTHO, its agents and contractors or arising out of the infringement of any third party intellectual property rights by ORTHO, its agents and contractors; or (iv) any liability or obligation attributable to ORTHO's (or its agents' or contractors') breach of any agreements with any third parties; or (v) any liabilities attributable to any failure of ORTHO (or its agents or contractors) to comply with any applicable laws, regulations or rules, (collectively, the "Excluded Regulatory Liabilities").

## **SECTION 8. CONFIDENTIALITY**

8.1 The Confidentiality provisions set forth in Article 6 of the License Agreement are hereby incorporated into this Agreement by reference as if fully set forth herein, and are hereby extended to cover all information transmitted by either Party to the other in furtherance of either Party's obligations under this Agreement. The parties hereby agree that for confidential information transmitted pursuant to this Agreement the Parties' confidentiality obligations shall remain in effect for five (5) years from the date of each such transmission.

8.2 The Parties hereby understand and agree that ORTHO may keep copies of the Data, Materials and Regulatory Filings and such items reasonably related thereto, solely for archival and regulatory or legal compliance purposes.

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## SECTION 9. DRUG SUBSTANCE

9.1 ORTHO hereby agrees to maintain the Drug Substance, as specified in Schedule C, and to sell to BIOCRYST or its agents or designee(s) (BIOCRYST, its agents and designees shall be collectively referred to in this Section 9 as "BIOCRYST") Drug Substance as requested by BIOCRYST upon the terms and conditions set forth herein. The provisions of this Section 9 shall apply until the earlier of (i) such time that all Drug Substance has been purchased from ORTHO or (ii) August 31, 2002. ORTHO shall not otherwise use the Drug Substance for itself or on behalf of a Third Party, nor shall it sell the Drug Substance to any Third Party.

9.2 ORTHO agrees to supply BIOCRYST with such quantities of Drug Substance as BIOCRYST may order by issuing a "Purchase Order" to ORTHO. ORTHO shall comply with the terms set forth on each Purchase Order. Each Purchase Order will be substantially in the form of Schedule H, attached hereto, which further sets forth the terms and conditions that shall govern the purchases of Drug Substance. In the event of a conflict between the terms of the Purchase Order and the terms of this Agreement, this Agreement shall prevail. Purchase Orders shall be delivered to ORTHO via fax, electronically or by any other mutually agreeable method. ORTHO hereby agrees to fully cooperate with BIOCRYST in supplying such Drug Substance to BIOCRYST, and agrees to promptly notify BIOCRYST of any deficiencies in a Purchase Order and of any and all events that would prevent ORTHO from timely or completely fulfilling any Purchase Order.

9.3 Until the earlier of (a) such time that all Drug Substance has been purchased from ORTHO or (b) August 31, 2002, ORTHO agrees to store the Drug Substance in its facilities located in Springhouse, PA in a controlled environment (with respect to temperature, humidity and otherwise) so as to prevent degradation and contamination of the Drug Substance to the fullest extent possible and as otherwise required by the FDA or other law, rule, regulation or standards.

9.4 BIOCRYST shall pay to ORTHO [\*\*\*]<sup>2</sup> per kilogram of Drug Substance delivered by ORTHO pursuant to a Purchase Order. ORTHO's right to payment for delivery of Drug Substance pursuant to a Purchase Order shall accrue upon delivery of the Drug Substance, however, BIOCRYST shall not be required to make payment in respect of such delivered Drug Substance unless and until BIOCRYST enters into an agreement with a third party for such third party to develop and market a Neuraminidase Inhibitor Product, at which time all accrued amounts shall become due and payable within 60 days. Thereafter, accrued payments shall be due and payable within thirty (30) days of receipt by BIOCRYST of a correct and undisputed invoice from ORTHO. BIOCRYST agrees to provide ORTHO with prompt notice of its entering into an agreement with a third party for such third party to develop and market a Neuraminidase Inhibitor Product.

9.5 BIOCRYST shall have the right to credit its out-of-pocket expenses related to testing of the Drug Substance transferred or to be transferred to BIOCRYST pursuant to this Agreement against the amounts payable to ORTHO pursuant to Section 9.4, above.

9.6 BIOCRYST agrees to bear the reasonable costs of shipping Drug Substance from storage to BIOCRYST. BIOCRYST agrees to pay any sales tax or other state, city or Federal taxes related to the purchase of Drug Substance, other than taxes based on the income or real property of ORTHO. Such shipping costs and taxes shall be set forth on each invoice and shall be due and payable as set forth in Section 9.4, above.

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<sup>2</sup>\*\*\* Information omitted and filed separately with the Commission pursuant to 17 C.F.R. §§ 200.80(b)(4), 200.83, 230.406, and 240.24b-2.

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9.7 Notwithstanding anything to the Contrary in this Agreement, ORTHO agrees to provide BIOCRYST, free of charge and promptly upon BIOCRYST's request with:

(a) such amounts of Drug Substance as BIOCRYST deems reasonably necessary in order to complete the clinical studies with the designations PHI 026, PHI 030, and TX003 and such amounts of the Drug Substance for carcinogenicity studies, animal studies and QA as referred to in item number 19 of Schedule C-5: and,

(b) reasonable amount of Drug Substance for BIOCRYST'S own use as laboratory reference material and for BIOCRYST'S internal research purposes.

## SECTION 10. PAYMENT PROVISIONS

The parties acknowledge and agree that as of the Effective Date, each Party is in complete satisfaction of all of its financial obligations to the other in connection with the termination of the License Agreement and the transfer to BIOCRYST of the Development Program. Except as explicitly provided for in this Agreement, neither Party shall be entitled to seek any further fees, expenses or reimbursements from the other in connection with the termination of the License Agreement and the transfer to BIOCRYST of the Development Program including, but not limited to, all inventions, patents, trademarks, clinical trials and support studies, data, materials, contracts and regulatory filings.

## SECTION 11. REPRESENTATIONS AND WARRANTIES

11.1 Each Party hereby represents and warrants that it is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware and has full organizational power and authority to enter into and perform this Agreement, and to carry out the transactions contemplated under this Agreement.

11.2 ORTHO hereby represents and warrants that (i) the execution, delivery and performance by ORTHO of this Agreement, and the consummation by ORTHO of the transactions contemplated herein, have been duly authorized by all requisite organizational action; (ii) this Agreement and all of the obligations entered into and undertaken in connection with the transactions contemplated herein to which ORTHO is a party constitute, or will constitute upon the execution of such agreements, the valid and binding obligations of ORTHO enforceable in accordance with their respective terms, and (iii) the execution of and performance of the transactions contemplated by this Agreement and compliance with its provisions by ORTHO will not violate any provision of applicable law and will not conflict with or result in any breach of any of the terms, conditions or provisions of, or constitute a default under, or require a consent or waiver under, ORTHO's organizational documents or any indenture, lease, agreement or other instrument to which ORTHO is a party or by which it or any of its properties is bound, or any decree, judgment, order, statute, rule or regulation applicable to ORTHO.

11.3 ORTHO hereby represents and warrants that: (i) it has made diligent efforts to transfer to BIOCRYST (and will in the future) all Regulatory Filings, Clinical and Clinical Support Studies, Data and Materials, according to the time schedules set forth in Schedules E, A, D and C, respectively and should additional items related to the foregoing be discovered by ORTHO or otherwise, ORTHO will use diligent efforts to transfer such items to BIOCRYST and otherwise assist BIOCRYST in connection therewith; (ii) it has filed all letters and other documents with the FDA (and all foreign equivalents) in order to effect a transfer of the Regulatory Filings to BIOCRYST; (iii) the Regulatory Filings, Clinical and Clinical Support Studies, Data and Materials transferred to BIOCRYST include all Regulatory Filings, Clinical and Clinical Support Studies, Data and Materials initiated, conducted or generated in the Development Program; and, (iv) it has or will otherwise fully comply with Article 14 of the License Agreement together with all related time schedules set forth in this Agreement and the Schedules hereto.

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11.4 ORTHO hereby represents and warrants that it has the full power and authority to assign to BIOCRYST all right title and interest in and to, and obligations under, the Regulatory Filings, Clinical and Clinical Support Studies, Data and Materials.

11.5 ORTHO hereby represents and warrants that, to the best of its knowledge, and except for the interests of BIOCRYST, it has the full power and authority to assign to BIOCRYST all right title and interest in and to the Joint Inventions, Joint Patents, Existing Know-How, Existing Patents, Improvements and Improvement Patents free and clear of all liens, claims and encumbrances of any nature. ORTHO further represents and warrants that it has not granted and will not grant any right to any Third Party in or to the Joint Inventions, Joint Patents, Existing Know-How, Existing Patents, Improvements and Improvement Patents.

11.6 ORTHO hereby represents and warrants (i) that it has the full power and authority to assign to BIOCRYST all right, title and interest in and to, and obligations under, the Contracts, (ii) that it has satisfied all financial obligations under, and all liabilities arising out of, the Contracts which accrued prior to the Effective Date, and (iii) that it is not in breach of any of the Contracts.

11.7 ORTHO hereby represents and warrants that it has complied and in the future will continue to comply with all applicable laws, rules and regulations in connection with its, or its agents and contractors, conduct of the Development Program.

11.8 ORTHO hereby represents and warrants that there is no threatened or pending litigation related to the Development Program including but not limited to the Licensed Products, the Contracts and the Clinical and Clinical Support Studies.

11.9 ORTHO hereby represents that all Drug Substance and other drug materials transferred to BIOCRYST hereunder and in connection with the termination of the License Agreement and the transfer to BIOCRYST of the Development Program at the time of transfer to BIOCRYST that are labeled for use in human clinical trials, pursuant to Schedule C, and not labeled for laboratory use or otherwise shipped under quarantine pursuant to Schedule C, met (or will meet) all applicable FDA requirements and were approved to be administered to humans in connection with clinical trials. However, it is understood that, pursuant to Schedule C some Drug Substance may be shipped to BIOCRYST in quarantine status.

11.10 THE EXPRESS REPRESENTATIONS AND WARRANTIES STATED IN THIS ARTICLE 11 ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

## **SECTION 12. INDEMNIFICATION**

12.1 BIOCRYST agrees to indemnify, defend and hold ORTHO and its directors, officers, employees and agents (the "ORTHO Indemnites") harmless from and against any losses, costs, claims, damages, liabilities or expenses (including without limitation, fees and disbursements of counsel incurred by ORTHO Indemnites in any action or proceeding between ORTHO and ORTHO Indemnites and ORTHO Indemnites and any third party or otherwise) (collectively, "Liabilities") arising out of, or in connection with Third Party claims relating to: (i) any

breach by BIOCRYST of the confidentiality provisions of this Agreement, (ii) personal injury or other liability, which occurs after the Effective Date, to a participant in any clinical trial conducted by BIOCRYST of a neuraminidase inhibitor which was the subject of the Development Program; (iii) Liabilities, accruing after the Effective Date based upon BIOCRYST'S or its agents or contractor's, use, sale, distribution or marketing of any neuraminidase inhibitor which was the subject of the Development Program; (iv) BIOCRYST's failure to comply with any law, regulation or rule; and, (v) the gross negligence or intentional misconduct of BIOCRYST.

12.2 ORTHO agrees to indemnify, defend and hold BIOCRYST and its directors, officers, employees and agents (the "BIOCRYST Indemnitees") harmless from and against any losses, costs, claims, damages, liabilities or expense (including without limitation, fees and disbursements of counsel incurred by BIOCRYST Indemnitees in any action or proceeding between ORTHO and BIOCRYST Indemnitees and BIOCRYST Indemnitees and any third party or otherwise) (collectively, "Liabilities") arising out of, or in connection with Third Party claims relating to: (i) the Development Program prior to the Effective Date; (ii) any breach by ORTHO of its representations and warranties under this Agreement; (iii) any breach by ORTHO of the confidentiality provisions of this Agreement, (iv) any breach by ORTHO in the performance or observation of any covenant, agreement, obligation or provision in any of the Contracts to be performed or observed by ORTHO, (v) the Clinical and Clinical Support Studies prior to the Effective Date, (vi) ORTHO's failure to comply with any law, regulation or rule, (vii) the administration of Drug Tablets, Drug Substance or any other drug tablets manufactured by ORTHO from Drug Substance, to humans, to the extent that such Liabilities are attributable to any failure of ORTHO in properly manufacturing or storing the foregoing, or any failure of ORTHO to meet any and all requirements of the FDA with respect to manufacture or storage of the foregoing, and (viii) the negligence or intentional misconduct of ORTHO.

12.3 An indemnitee that intends to claim indemnification under this Agreement shall promptly notify indemnifying party of any claim, demand, action or other proceeding for which the Indemnitee intends to claim such indemnification, and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, to assume sole control of the defense thereof with counsel selected by the indemnifying party; provided, however, that the Indemnitee shall have the absolute right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee. The indemnity obligations under this Agreement shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the indemnifying party, which consent shall not be unreasonably withheld or delayed. The Indemnitee, its employees and agents, shall cooperate fully with the indemnifying party and its legal representatives in the investigation of any action, claim or liability covered by an indemnification from the indemnifying party. The Indemnifying party shall not, without the prior written consent of the Indemnitee, effect any settlement of any pending or threatened action, suit or proceeding in respect of which any Indemnitee is or could have been a party and indemnity could have been sought hereunder by such Indemnitee, unless such settlement includes an unconditional release of such Indemnitee from all liability on claims that are the subject matter of such action, suit or proceeding.

### **SECTION 13. FURTHER ASSURANCES**

13.1 In addition to the actions specifically provided for elsewhere in this Agreement, from and after the Effective Date, each of the parties hereto shall take, or cause to be taken, all actions, and to do, or cause to be done, all things reasonably necessary, proper or advisable under applicable laws, regulations and agreements to consummate and make effective the transactions contemplated by this Agreement and to reasonably aid BIOCRYST in its assumption and continuation of the Development Program, including the execution and delivery of instruments of conveyance, assignment and transfer, cooperation in all filings with, and to obtain all consents, approvals or authorizations of, any governmental authority or any other person under any permit, license, agreement, indenture or other instrument, at the expense of the requesting party.

13.2 In the event that following the Effective Date ORTHO discovers any document, data, contract, invention, patent, or any other item related to the Development Program, which has not been transferred to BIOCRYST but which ORTHO is obligated to transfer and/or assign to BIOCRYST pursuant to the License Agreement, or makes any invention that would be characterized as a Joint Invention under the License Agreement, ORTHO shall promptly notify BIOCRYST and assign and transfer the foregoing to BIOCRYST.

13.3 In the event that ORTHO is contacted by any third party (including for example, the FDA), in any fashion regarding the subject matter of the Development Program, ORTHO shall promptly notify BIOCRYST of the of the nature and substance of such contact or inquiry and shall comply with its confidentiality obligations set forth herein.

### **SECTION 14. INTERPRETATION**

The construction, validity and performance of this Agreement shall be governed in all respects by the laws of the State of New York, without giving effect to principles of conflict of laws.

### **SECTION 15. DISPUTE RESOLUTION**

The Dispute Resolution provisions set forth in Article 19 of the License Agreement are hereby incorporated into this Agreement by reference, and shall apply to this Agreement as if fully set forth herein.

## **SECTION 16. NOTICES**

16.1 Any notice required or permitted to be given under this Agreement shall be mailed by registered or certified mail, postage prepaid, addressed to the Party to be notified at its address stated below, or at such other address as may hereafter be furnished in writing to the notifying Party or by telefax (with confirmation sent by mail) to the numbers set forth below or to such changed telefax numbers as may thereafter be furnished.

If to BIOCRYST:

BIOCRYST Pharmaceuticals, Inc.  
2190 Parkway Lake Drive  
Birmingham, Alabama 35244  
Telefax No.: (205) 444-4640  
Attention: Chief Executive Officer

If to ORTHO:

President  
ORTHO-McNeil Pharmaceutical, Inc.  
U.S. Route 202 South  
Raritan, NJ 08869-0602  
Telefax No.: (908) 218-1416

Any such notice shall be deemed to have been received when it has been delivered in the ordinary course of post or received by telefax.

## **SECTION 17. WAIVER**

The failure on the part of BIOCRYST or ORTHO to exercise or enforce any rights conferred upon it hereunder shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

## **SECTION 18. ENTIRE AGREEMENT**

This Agreement constitutes the entire agreement between the Parties hereto concerning the subject matter hereof and any representation, promise or condition in connection therewith, not incorporated herein, shall not be binding upon either Party.

## **SECTION 19. ASSIGNMENT**

This Agreement, and all rights and obligations hereunder, is personal to ORTHO and shall not be assigned in whole or in part by ORTHO to any other person or company (other than Affiliates of ORTHO) without the prior written consent of BIOCRYST. When assigned as permitted herein this Agreement shall be binding on each Party's successors and assigns.

## **SECTION 20. TITLES**

It is agreed that the marginal headings appearing at the beginning of the numbered Articles hereof have been inserted for convenience only and do not constitute any part of this Agreement.

## **SECTION 21. UNENFORCEABLE PROVISIONS**

Any provision hereof which is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof or affecting the validity or enforceability of such provisions in any other jurisdiction.

## **SECTION 22. OTHERS**

As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by fact or context.

## **SECTION 23. EXECUTION**

This Agreement shall be executed in two (2) counterparts each of which shall for all purposes be deemed an original.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their respective duly authorized officers or representatives as of the day and year first above written.

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BIOCRIST PHARMACEUTICALS, INC.

WITNESS \_\_\_\_\_

By: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

ORTHO-McNEIL PHARMACEUTICAL, INC.

WITNESS \_\_\_\_\_

By: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

R.W. JOHNSON PHARMACEUTICAL RESEARCH  
INSTITUTE, DIVISION OF ORTHO-McNEIL  
PHARMACEUTICAL, INC.

WITNESS \_\_\_\_\_

By: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

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