# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

# FORM 8-K/A

Amendment No. 1

# CURRENT REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: November 30, 2005

# **BioCryst Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Charter )

**Delaware** 

(State or other jurisdiction of incorporation)

000-23186

(Commission File Number)

**62-1413174** (IRS Employer Identification #)

# 2190 Parkway Lake Drive, Birmingham, Alabama 35244

(Address of Principal Executive Office)

(205) 444-4600

(Registrant's telephone number, including area code)

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 (see General Instruction A.2 below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 210.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Explanatory Note: This Form 8-K/A amends the Form 8-K filed by BioCryst Pharmaceuticals, Inc. on November 30, 2005 (file no. 000-23186) (the "Form 8-K").

# **TABLE OF CONTENTS**

Item 1.01 Entry Into A Material Definitive Agreement
Item 9.01. Exhibits
SIGNATURES
EXHIBIT INDEX
Development and License Agreement

# **Table of Contents**

# Item 1.01 Entry Into A Material Definitive Agreement.

As disclosed in the Form 8-K, on November 30, 2005, BioCryst Pharmaceuticals, Inc. (the "Company") announced that it entered into a Development and License Agreement dated as of November 29, 2005 (the "Roche Agreement"), with F.Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (collectively "Roche"). The Roche Agreement is a collaboration between the Company and Roche for development of the Company's clinical compound BCX-4208 for transplantation and autoimmune diseases.

The Form 8-K included a description of the material terms of the Roche Agreement. A redacted copy of the Roche Agreement is attached as Exhibit 10.2 to this Form 8-K/A and incorporated herein by reference.

# Item 9.01. Exhibits.

Exhibit No.	Description
10.2	Development and License Agreement dated as of November 29, 2005, by and between BioCryst Pharmaceuticals, Inc. and F.Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (Portions omitted pursuant to request for confidential treatment.)

# **Table of Contents**

# **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 hereunto duly authorized.

Dated: December 22, 2005 BioCryst Pharmaceuticals, Inc.

By: /s/ Michael A. Darwin
Michael A. Darwin
Chief Financial Officer and Chief
Accounting Officer

# **EXHIBIT INDEX**

Exhibit No.

Description

Development and License Agreement dated as of November 29, 2005, by and between BioCryst Pharmaceuticals, Inc. and F.Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. (Portions omitted pursuant to request for confidential treatment.)

Exhibit 10.2

NOTE: THIS DOCUMENT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST PURSUANT TO RULE 24B-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934. PORTIONS OF THIS DOCUMENT FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED HAVE BEEN REDACTED AND ARE MARKED HEREIN BY "\*\*\*". SUCH REDACTED INFORMATION HAS BEEN FILED SEPARATELY WITH THE COMMISSION PURSUANT TO THE CONFIDENTIAL TREATMENT REQUEST.

# **DEVELOPMENT AND LICENSE AGREEMENT**

**BY AND BETWEEN** 

BIOCRYST PHARMACEUTICALS, INC.

**AND** 

F.HOFFMANN-LA ROCHE LTD

**AND** 

HOFFMANN-LA ROCHE INC.

# **TABLE OF CONTENTS**

ARTICLE 1 DEFINITIONS		1
1.1. Activaly Developing		4
1.1 Actively Developing		1
1.2 Adjusted Gross Sales		1
1.3 Affiliate		1
1.4 Autoimmune Indications		2
1.5 Backup Compounds		2
1.6 BioCryst Know-How		2
<ul><li>1.7 BioCryst Patents</li><li>1.8 Calendar Quarter</li></ul>		2 2 2
		2
1.9 Closing Date 1.10 Compound		2 2
1.11 Compound 1.11 Commercially Reasonable	o Efforts	2
1.12 Commercialization	z ciiots	2
1.13 Confidential Information		2 3
1.14 Control		3
1.15 Dermatology		3
1.16 Detail		3
1.17 Develop		3
1.18 Development Costs		4
1.19 Development Plan		4
1.20 Effective Date		4
1.21 Field		4
1.22 First Commercial Sale		4
1.23 Fodosine		4
1.24 Generic Licensed Product	†	4
1.25 IND	•	4
1.26 Insolvency Event		4
1.27 Invoice Price		5
1.28 Joint Development Comm	nittee	5
1.29 Joint Steering Committee		5 5
1.30 Law		5
1.31 Licensed Product		5
1.32 Major Market Countries		5
1.33 NDA Approval		5
1.34 Net Sales		5
1.35 Neurology		5
1.36 Party		5
1.37 Phase II		6
1.38 Phase IIa		6
1.39 Phase IIb		6
1.40 Phase III		6
1.41 Pre-Existing Third Party Li	icense	6
1.42 Promotional Material		6
1.43 Regulatory Authority		6
1.44 Roche Compound		6
1.45 Roche Group		6
1.46 Roche Know-How		6
1.47 Roche Patents		6
1.48 Roche Products		6 7
1.49 ROW Country		7
1.50 Royalty Bearing Products		7
1.51 Sale, Sold or Sell		7

FX	ECL	IT	ION	CO	P\

<ul> <li>1.52 Special Indication Product</li> <li>1.53 Special Indications</li> <li>1.54 Start of Phase IIa</li> <li>1.55 Start of Phase IIb</li> <li>1.56 Start of Phase III or Pivotal Trial</li> <li>1.57 Stem-Cell Transplantation</li> <li>1.58 Sublicensee</li> <li>1.59 Term of the Agreement</li> <li>1.60 Third Party</li> <li>1.61 Transplantation Indications</li> <li>1.62 Valid Claim</li> <li>1.63 Western Europe</li> </ul>	7 7 7 7 7 7 7 7 7 7
ARTICLE 2 GRANT OF RIGHTS	8
<ul> <li>2.1 License Grants</li> <li>2.2 Backup Compounds</li> <li>2.3 First Right of Negotiation of Backup Compounds</li> <li>2.4 Roche Compounds</li> <li>2.5 Fodosine</li> <li>2.6 Pre-Existing Third Party License</li> </ul>	8 9 9 10 10
ARTICLE 3 BIOCRYST RIGHT TO PROMOTE	10
3.1 Co-Promotion	10
ARTICLE 4 GOVERNANCE	10
<ul> <li>4.1 Steering Committee</li> <li>4.2 Development Committee</li> <li>4.3 Committee Membership</li> <li>4.4 Committee Chairs</li> <li>4.5 Committee Meetings</li> <li>4.6 Decision Making</li> <li>4.7 Interactions Between Committees</li> <li>4.8 Performance of Representatives</li> </ul>	10 11 12 12 12 12 13 13
ARTICLE 5 DILIGENCE AND SPECIAL INDICATIONS	13
<ul> <li>5.1 Diligence</li> <li>5.2 Special Indications</li> <li>5.3 Development Plan</li> <li>5.4 Reports</li> <li>5.5 End of Phase IIb</li> <li>5.6 Registration</li> <li>5.7 Sequencing of Licensed Products</li> </ul>	13 13 14 14 14 14 15
ARTICLE 6 CLINICAL TRIALS, REGULATORY MATTERS AND MANUFACTURING	15
<ul><li>6.1 Clinical Trials and Regulatory Matters</li><li>6.2 Adverse Event Reporting</li><li>6.3 Manufacturing and Technical Assistance</li></ul>	15 16 16
ARTICLE 7 CONSIDERATION	17

7.1 Lump Sum Payments 7.2 Development Event Payments 7.3 Commercial Event Payments 7.4 Royalties 7.5 Patent Coverage Adjustment 7.6 Combination Licensed Products 7.7 Payments to Third Parties 7.8 Generic Sales Adjustment 7.9 Royalties Due Once	17 17 19 19 19 20 20 20
ARTICLE 8 PAYMENTS; RECORDS; AUDIT	20
8.1 Payment of Royalties 8.2 Currency 8.3 Payments Nonrefundable 8.4 Roche Records and Audit 8.5 BioCryst Records and Audit 8.6 Withholding Taxes	20 21 21 21 21 21 22
ARTICLE 9 INTELLECTUAL PROPERTY	22
<ul><li>9.1 Prosecution of BioCryst Patent Rights</li><li>9.2 Infringement</li><li>9.3 Hatch-Waxman</li></ul>	22 23 24
ARTICLE 10 CONFIDENTIAL INFORMATION	24
10.1 Non-Use and Non-Disclosure 10.2 Authorized Disclosure	24 24
ARTICLE 11 TERMINATION	25
11.1 Commencement and Term 11.2 Termination for Breach 11.3 Termination by Roche Without Cause 11.4 Consequences of Termination 11.5 Royalty and Payment Obligations	25 25 25 25 25 27
ARTICLE 12 INDEMNIFICATION	27
12.1 Indemnification by BioCryst 12.2 Indemnification by Roche 12.3 Procedure 12.4 Limitation on Damages	27 27 27 28
ARTICLE 13 REPRESENTATIONS AND WARRANTIES	28
13.1 Mutual Representations and Warranties 13.2 BioCryst Representations and Warranties 13.3 Roche Representations and Warranties 13.4 HSR Act and Other Applicable Governmental Filings 13.5 No Debarment 13.6 No PNP Inhibitors 13.7 No Other Representations	28 28 29 29 30 30 30

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ARTICLE 14 CONDITIONS TO CLOSING	30
14.1 Conditions Subsequent	30
ARTICLE 15 DISPUTE RESOLUTIONS AND GOVERNING LAW	30
15.1 Disputes 15.2 Arbitration 15.3 Arbitration Procedure 15.4 Governing Law	30 31 31 31
ARTICLE 16 PUBLICITY	32
16.1 Initial Press Release 16.2 Subsequent Press Releases 16.3 Disclosures Required by Law 16.4 Publications 16.5 Use of Name	32 32 32 32 33
ARTICLE 17 MISCELLANEOUS	33
17.1 Pre-Existing Third Party License 17.2 Extended Benefits 17.3 Survival 17.4 Agency 17.5 Entire Agreement 17.6 Counterparts 17.7 Amendment 17.8 Assignment 17.9 Requirement to Divest 17.10 Notices 17.11 Force Majeure 17.12 Affiliates 17.13 Bankruptcy 17.14 Severability	33 33 33 33 33 33 33 34 34 35 35 35

This Development and License Agreement (this "Agreement") dated as of November 29, 2005 ("Effective Date") is made by and between BioCryst Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware having an office and place of business at 2190 Parkway Lake Drive, Birmingham, Alabama 35244 ("BioCryst"), on one hand, and on the other hand F.Hoffmann-La Roche Ltd, a corporation of Switzerland having its principle office at Grenzacherstrasse 124, CH-4070, Basel, Switzerland ("Roche-Basel") and Hoffmann-La Roche Inc., a New Jersey corporation having its principle place of business at 340 Kingsland Street, Nutley, New Jersey 07110 ("Roche-Nutley") (Roche-Nutley and Roche-Basel are collectively referred to as "Roche").

# **RECITAL**

**WHEREAS**, BioCryst owns or controls patents and know-how related to a series of proprietary compounds which act as purine nucleoside phosphorylase inhibitors ("**PNP Inhibitors**"), including the compound known as BCX-4208.

WHEREAS, Roche has expertise in the discovery, development, manufacture and sale of pharmaceutical products.

WHEREAS, Roche wishes to obtain, and BioCryst wishes to grant, rights and licenses under certain patents and know-how owned or controlled by BioCryst.

NOW, THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement, the parties agree as follows:

#### **ARTICLE 1 DEFINITIONS**

- 1.1 "Actively Developing" means, with respect to a particular indication as of a given time, that (i) Roche is then undertaking active human clinical trials for a Licensed Product in such indication, or (b) the then-current Development Plan indicates that, within two years of such time, active human clinical trials for a Licensed Product in such indication shall be commenced. For the purposes of clarity, Roche shall not be deemed to be Actively Developing a Licensed Product for a particular indication which is then not part of the Development Plan even if the Licensed Product has been previously tested in human clinical trials in such indication.
- **1.2** "Adjusted Gross Sales" means (a) the Invoice Price of Licensed Products multiplied by the quantity of Licensed Products Sold in the Territory, *Iess* (b) without duplication of any of those sales related deductions which are accounted for in the calculation of Net Sales, (i) returns and return reserves (including allowances actually given for spoiled, damaged, out-dated, rejected, returned Licensed Products sold, withdrawals and recalls), (ii) rebates (for example, price reductions, rebates to social and welfare systems, charge backs or reserves for charge backs, cash sales incentives), (iii) government mandated rebates and similar types of rebates (e.g., P.P.R.S, Medicaid), (iv) volume (quantity) discounts, (v) cash discounts and (vi) value added or sales taxes, government mandated exceptional taxes and other taxes directly linked to the gross sales amount (it being understood that income, withholding and capital gains taxes are not the type of taxes contemplated as a deduction in this definition of Adjusted Gross Sales), each of clauses (i) through (vi) as consistently applied by Roche to its products.
- **1.3 "Affiliate"** means (a) an entity that owns directly or indirectly, a controlling interest in a Party, by stock ownership or otherwise, (b) any entity in which a Party owns a controlling interest, by stock ownership or otherwise, or (c) any entity under common control with a Party, directly or indirectly. For purposes of this paragraph, "**controlling interest**" and "**control**" mean ownership of fifty percent (50%) or more of the voting stock permitted to vote for the election of the board of directors or any other arrangement resulting in control of or the right to control the management and the affairs of the entity or Party in question. For purposes of this Agreement, Genentech, Inc., 1 DNA Way, South San Francisco, California shall not be deemed an Affiliate of Roche, unless approved by BioCryst in its sole discretion. For purposes of this Agreement, Chugai Pharmaceutical Co. Ltd., 1-9 Kyobashi 2-chome, Chuo-ku,

Tokyo, 104-8301, Japan ("Chugai"), shall not be deemed an Affiliate of Roche unless Roche provides written notice to BioCryst of its desire to include Chugai as an Affiliate of Roche.

- **1.4 "Autoimmune Indications"** means all indications that involve pathogenic consequences, including tissue injury, produced by autoantibodies or autoreactive T lymphocytes interacting with self epitopes, i.e., autoantigens. Autoimmune Indications shall include, without limitation, asthma, psoriasis, rheumatoid arthritis, systemic lupus erythematosus, scleroderma, juvenile rheumatoid arthritis, polymyositis, ankylosing spondylitis, Type I diabetes, sarcoidosis, Sjogrens syndrome, chronic active non-pathogenic hepatitis, non-infectious uveitis (Behcet's), aplastic anemia, hemolytic anemia, idiopathic thrombocytopenia purpura, vasculitis, Hashimoto's thyroiditis, atopic dermatitis, regional non-pathogenic enteritis (including ulcerative colitis, Crohn's Disease and inflammatory bowel disease), Kawasaki's disease, post-infectious encephalitis, myasthenia gravis, multiple sclerosis, alopecia, and tropic spastic paraparesis.
- 1.5 "Backup Compounds" shall mean any PNP Inhibitor which (i) as of the Effective Date is owned or Controlled by BioCryst, and (ii) has completed Phase IIb related to an indication in the Field during the time period between the Effective Date and the five year anniversary of the Closing Date. Backup Compounds shall exclude (a) the Compound, and (b) Fodosine. For the purposes of this Agreement, in no event shall Fodosine be deemed to be a Backup Compound.
- **1.6 "BioCryst Know-How"** means all knowledge and proprietary information, including trade secrets, owned or Controlled by BioCryst during the Term of this Agreement, directly related to the manufacture, formulation, sale or use of the Compound. BioCryst Know-How includes without limitation materials, samples, chemical manufacturing data, toxicological data, pharmacological data, clinical data, formulations, specifications, quality control testing data, and submissions and correspondence to and from governmental agencies, with regard to Licensed Product.
- 1.7 "BioCryst Patents" means those patents and patent applications or portions thereof that are necessary for the manufacture, use or sale of the Compound or Licensed Product(s) and which are owned or Controlled by BioCryst during the Term of the Agreement, To the extent a BioCryst Patent is necessary for the making, using or selling of the Compound, BioCryst Patents shall include all patents and patent applications based upon or claiming priority to any of the foregoing, and any extensions, supplementary protection certificates, continuations, continuations-in-part, divisions, reissues, re-examinations, additions, substitutions, confirmations, registrations, or re-validations of or to any of the foregoing. Notwithstanding the definition above, BioCryst Patents shall not include any patent rights relating to Fodosine. Exhibit 1.7 lists all BioCryst Patents as of the Effective Date.
- 1.8 "Calendar Quarter" means each three month period beginning on each of January 1, April 1, July 1 and October 1 during the Term of this Agreement.
- **1.9 "Closing Date"** means the date of approval of the transaction by the Federal Trade Commission or the appropriate US anti-trust authorities or the expiration or termination of all applicable waiting periods and requests for information (and any extensions thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act").
- 1.10 "Compound" means the PNP Inhibitor known as BCX-4208 \*\*\*.
- **1.11 "Commercially Reasonable Efforts"** means a level of resources and efforts to Develop and Commercialize a Licensed Product applied by Roche consistent with Roche's practices in pursuing the Development and commercialization of its other pharmaceutical products at a similar stage of product life, safety, efficacy and commercial potential. It is understood that such efforts may change from time to time based upon changing safety, efficacy, scientific, business and commercial considerations.
- **1.12 "Commercialization"** means, with respect to a particular Licensed Product, any and all processes and activities necessary to be conducted to establish and maintain sales for such Licensed

Product, including negotiating and obtaining pricing approvals, offering for sale, Detailing (including launch), promoting, manufacturing, storing, transporting, supporting, distributing, and importing such Licensed Product, and all studies and tests of such Licensed Product, but in all cases excluding Development. "Commercialize" and "Commercializing" shall have their correlative meanings.

1.13 "Confidential Information" means any and all information, data or know-how of a confidential nature (including BioCryst Know-How and Roche Know-How), whether technical or non-technical (such as financial, business and legal information), oral or written, related to Compound or Licensed Product or a Party's business that is disclosed by one Party or its Affiliates ("Disclosing Party") to the other Party or its Affiliates ("Receiving Party"). For the purposes of this Agreement, all information related to BioCryst's licensors and the Pre-Existing Third Party License shall be deemed to be BioCryst Confidential Information.

Confidential Information shall not include any information, data or know-how which:

- (i) either before or after disclosure to the Receiving Party, was or becomes published or generally known to the public through no fault or omission on the part of the Receiving Party or its Affiliates; or
  - (ii) was known or used by the Receiving Party or its Affiliates prior to its disclosure by the Disclosing Party to the Receiving Party; or
  - (iii) either before or after disclosure to the Receiving Party, is provided to the Receiving Party by a Third Party having the legal right to do so;
- (iv) is independently developed by the Receiving Party or its Affiliates without access to our use of the Disclosing Party's Confidential Information; or
- (v) is required to be disclosed by the Receiving Party or its Affiliates to comply with applicable Laws, to defend or prosecute litigation or to comply with governmental regulations, provided that, the Receiving Party provides prior written notice of such disclosure to the Disclosing Party and, to the extent practicable, takes reasonable and lawful actions to minimize the degree of such disclosure.
- **1.14 "Control"** means, with respect to any intellectual property right, that the Party has a license to such intellectual property right and has the ability to grant to the other Party a sublicense to such intellectual property right as provided herein without violating the terms of any agreement or other arrangements with any Third Party existing at the time such Party would be first required hereunder to grant the other Party such sublicense. "**Controlled**" shall have a correlative meaning.
- 1.15 "Dermatology" means the treatment of disorders of the skin in which the skin is the primary site of the disorder (e.g., psoriasis).
- **1.16** "Detail" means, with respect to a particular Licensed Product, a face-to-face presentation (or other means of contact) by a Party's sales representative, to one or several medical professional(s) having prescribing authority in the United States in the Field, as well as to other individuals or entities that have significant impact or influence on prescribing decisions in the United States in the Field, in which the principal objective of such presentation is to emphasize the features and function of such Licensed Product in accordance with Law. For clarity, Detail shall exclude discussions at conventions, tradeshows and similar forums, meetings where only a sample drop or a reminder occurs or other incidental contact. When used as a verb, the terms "Detail" or "Detailing" means to perform a Detail.
- **1.17 "Develop"** means with respect to a particular Licensed Product or Special Indication Product (as the case may be), any and all processes and activities which are necessary to be conducted to obtain NDA Approval for such product, including NDA Approval applications, clinical trial application enabling studies and all other activities conducted thereafter, which may involve preclinical testing, toxicology,

clinical trials, quality of life assessments, pharmacoeconomics, post-marketing studies required to maintain approval of the label, label expansion studies, and further activities related to development of such product to a stage ready for commercialization thereof. "Develop", "Development" and "Developing" shall have their correlative meanings.

- 1.18 "Development Costs" means all out of pocket and internally allocated costs, expenses and liabilities incurred by BioCryst in connection with the Development of a Special Indication Product, including but not limited to (i) fees paid under the Pre-Existing Third Party License (ii) the costs of base salaries and benefits of personnel for the time devoted to, or in furtherance of, the Development of the Special Indication Product, (iii) costs of and in obtaining supplies to be used in conducting the Development of Special Indication Product, and (iv) costs of retaining third party consultants or other independent contractors to assist with the Development of a Special Indication Product.
- **1.19** "Development Plan" means a plan for the Development of Licensed Products in the Field approved from time to time by the JSC pursuant to Section 4.1(a). The initial Development Plan, reflecting the mutual objectives of the Parties with respect to the sequence of events for the Development of the Compound is attached hereto as Exhibit 1.19.
- 1.20 "Effective Date" means the date set forth in the first paragraph of the Agreement.
- 1.21 "Field" means the prevention or treatment of Autoimmune Indications and Transplantation Indications.
- **1.22** "First Commercial Sale" means, for a given country, the first Sale of Licensed Product after NDA Approval in the given country for the Licensed Product (including authorizations for reimbursement).
- **1.23 "Fodosine"** means the compound known as "BCX-1777" (7-((2S,3S,4R,5R)-3,4-dihydroxy-5-hydroxymethyl)pyrrolidin-2-yl)-3H-pyrrolo[3,2-d]pyrimidin-4(5H)-on e hydrochloride)

- 1.24 "Generic Licensed Product" means a product that contains Compound which is offered for sale in a country by a Third Party.
- 1.25 "IND" means Investigational new Drug Applications or corresponding filings in any country in the world.
- 1.26 "Insolvency Event" means, in relation to the Party in question, any of the following: (i) that Party proposes or makes any arrangement or composition with or any assignment for the benefit of its creditors generally; (ii) a petition is filed that is not dismissed within sixty (60) days or a court order is made or a resolution is passed for the bankruptcy, liquidation or winding up of that Party (save for the purposes of a solvent reconstruction the terms of which have been approved in writing by the other Party) or for the appointment of a provisional liquidator or a judicial factor or similar officer in relation to that Party; (iii) an encumbrancer takes possession of or a trustee, receiver, liquidator, provisional liquidator, administrator, manager ad interim, administrative receiver, judicial factor or similar officer is appointed in respect of all or a material part of that Party's intellectual property rights which are the subject of this Agreement and such appointment prejudices the other Party's rights under this Agreement; (iv) that Party is unable to pay its debts as they become due in the ordinary course of business; (v) that Party gives written notice to its creditors that it has ceased to pay its debts in the ordinary course of business; or (vi) that Party does, or

suffers to be done in relation to it, any analogous action or proceeding in any jurisdiction anywhere in the world (including without limitation any actions or proceedings relating to bankruptcy Law of any nature in the United States of America).

- 1.27 "Invoice Price" means, with respect to a Licensed Product, the unit price, without deduction, actually invoiced by the Roche Group for the Sale of such Licensed Product. If any Sales of Licensed Products are made in transactions that are not at arm's length, then the Gross Price for such Licensed Products shall be the amount that would have been invoiced had the transaction been conducted at arm's length. Such amount that would have been invoiced shall be determined, wherever possible, by reference to the average selling price of the Licensed Product in contemporaneous similar transactions which are at arm's length. If, in addition to or in lieu of cash consideration, other consideration is paid in an arm's length transaction to the Roche Group in connection with the Licensed Product or the customer's rights or relationship with the Roche Group in relation thereto, then the amount or fair market value of such other consideration shall be included in the calculation of Invoice Price in the period in which the Sales of Licensed Products occur.
- **1.28 "Joint Development Committee"** or "**JDC"** means that committee comprised of an equal number of representatives of BioCryst and Roche, but not less than three (3) representatives from each company, which shall have the responsibilities set forth in Section 4.2.
- **1.29 "Joint Steering Committee"** or **"JSC"** means that committee comprised of equal number of representatives of BioCryst and Roche, but not less than three (3) representatives from each company, which shall have the responsibilities set forth in Section 4.1.
- 1.30 "Law" means, individually and collectively, any and all laws, ordinances, rules, directives and regulations of any kind whatsoever of any governmental or regulatory authority within the applicable jurisdiction, including any present and future supra-national, national, state and local laws (including rules and regulations having the force of law); requirements under permits; orders, decrees, judgments and directives; requirements of the FDA and other regulatory authorities, including without limitation cGMPs, other requirements imposed under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act, each as amended from time to time, requirements in 21 C.F.R. Part 312, applicable requirements in 21 C.F.R. Parts 600-680 and similar requirements of Regulatory Authorities in countries outside the United States.
- 1.31 "Licensed Product" means any and all pharmaceutical products containing Compound.
- **1.32 "Major Market Countries"** means the United States of America, Western Europe, and with respect to Autoimmune Indications only, also Japan.
- **1.33 "NDA Approval"** means all approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of any national or international or local regulatory authority, department, bureau or other governmental entity, necessary for the Development and Commercialization of Licensed Product in a regulatory jurisdiction.
- **1.34 "Net Sales"** means, for the US, the amount calculated by subtracting from the amount of Adjusted Gross Sales a lump sum deduction of \*\*\*. Notwithstanding the foregoing, amounts received by Roche, its Affiliates and sublicensees for the sale of Licensed Product among Roche, its Affiliates or sublicensees for resale shall not be included in the computation of Adjusted Gross Sales and Net Sales.
- **1.35 "Neurology"** means the treatment of central nervous system autoimmune disorders or diseases wherein the disorder or disease is specific to the central nervous system (e.g., multiple sclerosis).
- 1.36 "Party" means Roche and/or BioCryst, and "Parties" means both Roche and BioCryst,

- **1.37 "Phase II"** means a human clinical trial in the Field performed to evaluate the efficacy of a Licensed Product for a particular indication or indications in patients with the disease or condition under study and/or to determine the common short-term side effects and risks associated with the drug, as described in 21 C.F.R. Part 312, as it may be amended.
- 1.38 "Phase IIa" means a human clinical trial performed to estimate the biologic or clinical effect of a pharmaceutical product in a target population.
- **1.39 "Phase Ilb"** means a placebo or active drug controlled, randomized human clinical trial performed to gain evidence of the efficacy of a pharmaceutical product in a target population, and/or to establish the optimal dosing regimen for such product.
- **1.40 "Phase III"** means a human clinical trial required by the FDA or other equivalent regulatory authority to gain evidence of efficacy in the target population and obtain expanded evidence of safety for Licensed Product, as described in 21 C.F.R. Part 312, as it may be amended.
- **1.41 "Pre-Existing Third Party License"** means the agreement dated June 27, 2000 by and between on the one hand Albert Einstein College of Medicine of Yeshiva University, a division of Yeshiva University and Industrial Research Ltd., and on the other hand BioCryst, as amended from time to time.
- **1.42 "Promotional Material"** means all materials for training commercial personnel and all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, leave behind items, formulary binders, reprints, direct mail, direct-to consumer advertising, Internet postings, broadcast advertisements and sales reminder aids (for example, scratch pads, pens and other like items), in each case created by a Party or on its behalf and used or intended for use in connection with any promotion of a Licensed Product, but excluding Licensed Product labeling.
- **1.43 "Regulatory Authority"** means the United States Food and Drug Administration (**"FDA"**), or in the case of a country other than the United States, such other appropriate regulatory authority with similar responsibilities, including, without limitation, the EMA.
- **1.44 "Roche Compound"** means any PNP Inhibitor other than the Compound which (i) is owned or Controlled by the Roche Group, and (ii) has completed Phase IIb for an indication in the Field during the time period between the Effective Date and the five year anniversary of the Closing Date.
- 1.45 "Roche Group" means, individually and collectively, Roche and its Affiliates.
- **1.46 "Roche Know-How"** means all knowledge and proprietary information, including trade secrets, owned or Controlled by the Roche Group during the Term of this Agreement, which is an improvement on the BioCryst Know-How or which directly relates to the manufacture, formulation or use of the Compound, Licensed Products, Roche Compound or Roche Products. Roche Know-How includes without limitation materials, samples, chemical manufacturing data, toxicological data, pharmacological data, clinical data, formulations, specifications, quality control testing data, and submissions and correspondence to and from governmental agencies.
- **1.47 "Roche Patents"** means all patent applications and patents which claim improvements upon or modification to the inventions and discoveries claimed in any of the BioCryst Patents or which claim inventions directly related to the manufacture, use or sale of Compound, Backup Compound, Roche Compound, Roche Products, or Licensed Products, which patent applications and patents are owned or Controlled by the Roche Group during the Term of this Agreement, and any extensions, supplementary protection certificates, continuations, continuations-in-part, divisions, reissues, re-examinations, additions, substitutions, confirmations, registrations, or re-validations of or to any of the foregoing.
- 1.48 "Roche Products" means any and all pharmaceutical products containing a Roche Compound.

- **1.49 "ROW Country"** shall mean a country which is not included in the Major Market Countries. **"ROW"** means all of the non-Major Market Countries.
- 1.50 "Royalty Bearing Products" means Licensed Products and Roche Products.
- **1.51 "Sale"**, **"Sold" or "Sell"** means the sale, transfer or disposition of a Licensed Product (or Roche Product) for commercial purposes (excluding compassionate use where no consideration is received by the Roche Group) for value to a Third Party (whether an end user, wholesaler or otherwise) by a member of the Roche Group (or, with respect to a Roche Product, sublicensees). For the avoidance of doubt, sales, transfers or dispositions of a Licensed Product among the Roche Group shall not be subject to a royalty, but shall become subject to a royalty when Sold to a Third Party.
- 1.52 "Special Indication Product" means a Licensed Product for Commercialization in a Special Indication.
- **1.53 "Special Indication"** means an Autoimmune Indication with respect to which, at the time BioCryst desires to commence development work pursuant to Section 5.2, Roche is not Actively Developing a Licensed Product for such Autoimmune Indication.
- **1.54 "Start of Phase IIa"** means the date that a patient is first dosed with Royalty-Bearing Product in a Phase IIa clinical trial conducted by or on behalf of the Roche Group.
- 1.55 "Start of Phase IIb" means the date that a patient is first dosed with Royalty-Bearing Product in a Phase IIb clinical trial conducted by or on behalf of the Roche Group
- **1.56 "Start of Phase III or Pivotal Trial"** means the date that a patient is first dosed with Royalty-Bearing Product in a Phase III trial conducted by or on behalf of the Roche Group.
- **1.57 "Stem-Cell Transplantation"** means a procedure in which healthy stem cells are infused to help restore normal bone marrow function.
- 1.58 "Sublicensee" means any Third Party to whom a sublicense has been granted pursuant to Section 2.1(d).
- **1.59 "Term of the Agreement"** means the period commencing upon the Effective Date and, unless this Agreement is terminated sooner as provided herein, expiring on the date when no royalty or other payment obligations under this Agreement are or will become due.
- 1.60 "Third Party" means an entity other than a Party to this Agreement or its Affiliates.
- **1.61 "Transplantation Indications"** means all indications that involve the suppression of rejection of transplanted organs, bone marrow or other tissue, including, without limitation, solid organ transplantation (including tolerance induction and xenotransplantation), bone marrow transplantation, graft versus host disease and cell transplantation. In any event, if a given indication satisfies the criteria for both an Autoimmune Indication and a Transplantation Indication, such indication shall be deemed a Transplant Indication and not an Autoimmune Indication, provided that an Autoimmune Indication shall not be deemed a Transplant Indication merely because it may cause the need for a transplant (e.g., Type I diabetes, even if it causes the need for an organ transplant). For the avoidance of doubt, Transplantation Indications does not include the treatment or prevention of cancer but does include bone marrow transplantation.
- **1.62 "Valid Claim"** means a claim in any unexpired and issued BioCryst Patent that has not been revoked or held invalid by a final unappealable decision of a court or governmental agency of competent jurisdiction.

1.63 "Western Europe" means the United Kingdom, Italy, France, Germany, and Spain.

In these definitions, the singular shall include the plural and vice versa.

#### **ARTICLE 2 GRANT OF RIGHTS**

# 2.1 License Grants.

- (a) **By BioCryst**. BioCryst hereby grants to the Roche Group a sole and exclusive (even as to BioCryst), royalty-bearing, worldwide right and license under the BioCryst Patents and BioCryst Know-How to make, have made, use, offer for sale, sell and import Licensed Products in the Field. The foregoing license to the BioCryst Patents and BioCryst Know-How is limited to the exercise of the rights granted under the previous sentence and is sublicensable solely as set forth in Section 2.1(d).
- (b) Retained Rights. All rights not specifically granted are reserved to BioCryst. BioCryst further retains (i) all rights under the BioCryst Patents and BioCryst Know-How outside the Field, and (ii) under the BioCryst Patents and BioCryst Know-How to develop, conduct preclinical and clinical activities, make, have made, use, and otherwise exercise all rights in accordance with the terms hereof with respect to Special Indications and Special Indication Products. The license grant under Section 2.1(a) is also subject to (aa) the rights retained by BioCryst's licensors under the Pre-existing Third Party License Agreement, (bb) the rights retained by the United States government as set forth in 35 U.S.C. § 200, et seq. (as more fully set forth in Sections 2.01 and 2.02 of the Pre-Existing Third Party License Agreement), (cc) the right to permit Industrial Research, Ltd. to perform research sponsored in part by the New Zealand Foundation for Research, Science and Technology and related to the "Field" as defined in the Pre-Existing Third Party License Agreement (as more fully set forth in Section 2.03 of the Pre-Existing Third Party License Agreement), (dd) the right to permit Albert Einstein College of Medicine of Yeshiva University, a division of Yeshiva University through the "Investigators" as defined in the Pre-Existing Third Party License Agreement to conduct research in collaboration with the National Cancer Institute and with contractors hired by the National Cancer Institute (as more fully set forth in Section 2.04 of the Pre-Existing Third Party License Agreement), (ee) the rights retained by BioCryst's licensors to make, use and practice those BioCryst Patents that are "Agreement Patents" as defined in the Pre-Existing Third Party License Agreement in their own laboratories solely for non-commercial scientific purposes and for continued non-commercial research (as more fully set forth in Section 4.02 of Pre-Existing Third Party License Agreement), (ff) the rights retained by BioCryst's licensors to make available to not-for-profit scientific institutions and non-commercial researchers small quantities of biological materials covered under those BioCryst Patents that are "Agreement Patents" in the Pre-Existing Third Party License Agreement solely for non-commercial scientific and research purposes, provided this is done pursuant to the material transfer agreement, set forth in Appendix B of the Pre-Existing Third Party License Agreement (as more fully set forth in Section 4.02 of the Pre-Existing Third Party License Agreement), and (gg) the rights retained by BioCryst's licensors to grant licenses to third parties under "Agreement Patents" for all uses outside of the "Field" as such terms are defined in the Pre-Existing Third Party License Agreement (as more fully set forth in Section 4.03 of the Pre-Existing Third Party License Agreement). Other than as set forth above, BioCryst warrants that it is not aware of any retained rights related to making, using or selling the Compound or Licensed Product. If it becomes known to BioCryst that there have been inventions by the licensors under the Pre-Existing Third Party License Agreement relating to the retained rights that are necessary to allow Roche's exercise of its rights under this Agreement, BioCryst shall use commercially reasonable efforts to obtain a license on behalf of Roche to use such improvements in accordance with the terms and conditions of this Agreement.
- (c) **By Roche Group**. Roche Group hereby grants to BioCryst a co-exclusive (with the Roche Group only), royalty-free, fully paid up worldwide right and license, without the right to sublicense (other than to service providers on BioCryst's behalf), under the Roche Patents and Roche Know-How to make, have made, and use Backup Compounds and Special Indication Product in the Field. BioCryst shall not commercially launch or otherwise sell, distribute or supply, or enable any Affiliate of BioCryst, any licensor of the Pre-Existing Third Party License, or any or Third Party, to commercially launch or

otherwise sell, distribute or supply (other than to BioCryst), Licensed Products or Compound in the Field under the BioCryst Patents, Roche Patents, Roche Know-How or BioCryst Know-How.

- (d) Sublicensing. The following license grant is subject to all retained rights set forth in Section 2.1(b).
- (i) Roche shall have the right to grant sublicenses under the license granted to it in Section 2.1(a) of this Agreement to an Affiliate or to engage any contract manufacturer, distributor, subcontractor or outsourced service provider for the benefit of Roche. Notwithstanding the rights granted above, Roche shall not be entitled to sublicense the entirety of its rights or obligations hereunder in any country (except for in Japan to Chugai) without BioCryst's prior written approval, which shall not be unreasonably withheld. In Japan, Roche shall have the right to sublicense the entirety of its rights only to Chugai, and such sublicense shall not require the prior written consent of BioCryst. All obligations set forth in this Agreement which apply to Roche shall be deemed to apply to any permitted Sublicensee, but Roche shall continue to remain liable for all obligations hereunder.
- (ii) Roche shall ensure that each permitted Sublicensee hereunder shall consent to be bound by the terms of this Agreement as a Sublicensee and to the same extent as Roche. At BioCryst's request, Roche shall inform BioCryst, in confidence, of any sublicense granted, and any modification or termination thereof. At BioCryst's request, Roche shall also provide BioCryst with an executed copy of the written agreement between Roche and such Sublicensee.
- 2.2 Backup Compounds. While no rights to any Backup Compounds are licensed hereunder, upon completion of a Phase IIb clinical trial of a Backup Compound (if any), BioCryst shall give prompt written notice thereof to Roche. Roche shall have \*\*\* (\*\*\*) days after receipt of such notice from BioCryst to request in writing that BioCryst provide Roche with a data package for that Backup Compound. Commencing on the date that Roche receives the data package, Roche shall have the right to conduct due diligence related to the Backup Compound for a period of up to \*\*\* (\*\*\*) days (the "Backup Compound Diligence Period"). BioCryst shall cooperate with Roche during the Backup Compound Diligence Period. Roche's due diligence may include, but is not limited to, the following: (i) a full clinical and manufacturing audit of BioCryst with respect to the Backup Compound, at Roche's expense, (ii) the right to request all data, including raw data, obtained to date relating to the Backup Compound, (iii) the right to inspect BioCryst's facilities and, to the extent within the reasonable control of BioCryst, the facilities of its clinicians and manufacturers, each with respect to the Backup Compound (and BioCryst agrees to use good faith and commercially reasonable efforts so that Roche may inspect the facilities of such third parties), and (iv) a complete detailed report of the Development Costs actually incurred with respect to the Backup Compound. The data package, all information learned by Roche during any audit pursuant to this Section 2.2 and any and all other information provided by BioCryst to Roche relating to the Backup Compound shall be treated by Roche as the Confidential Information of BioCryst in accordance with the provisions of ARTICLE 10 of this Agreement. Roche agrees that BioCryst shall have no obligations hereunder to develop any Backup Compounds.
- **2.3 First Right of Negotiation of Backup Compounds.** Roche shall have the right to negotiate with BioCryst to have any Backup Compound licensed to Roche for use in the Field. Such license shall be upon mutually agreeable financial and other terms. BioCryst and Roche shall exclusively negotiate such offer in good faith for \*\*\* (\*\*\*) days from the expiration of the Backup Compound Diligence Period. If the parties reach agreement on the material terms of such a license during the \*\*\* (\*\*\*) day period, then the parties shall promptly execute a license which shall include all additional terms and conditions. If, at the end of the \*\*\* (\*\*\*) day period, the Parties have been unable to reach agreement on the material terms of such a license, then BioCryst shall be free to offer such rights to any Third Party. If BioCryst does sell a product having the same mechanism of action as the Licensed Product in the Field in the United States, then the parties shall meet and confer in good faith as to the appropriate modifications, if any, related to joint actions of the Parties related to Licensed Products (e.g., modifications to the JDC, JSC and co-promotion); provided, however, in no event shall BioCryst be required to waive its right to participate in the activities of any Committees as set forth in this Agreement.

- **2.4 Roche Compounds**. Roche shall promptly notify BioCryst in writing in the event of the identification of a Roche Compound, and such Roche Compound and related Roche Product shall be a Royalty-Bearing Product subject to the terms and conditions of this Agreement. In the event any Development Event Payments (as described in Section 7.2) or Commercial Event Payments (as described in Section 6.3) are triggered by Roche Products achieving the associated development or commercial event, such payments shall be made to BioCryst as if such payments were due for a Licensed Product. Additionally, Royalties (as set forth in Section 7.3) shall be payable to BioCryst on Roche Products.
- **2.5 Fodosine**. \*\*\* for the purposes of clarity, it is understood and agreed that no rights related to Fodosine are granted to Roche in this Agreement.
- 2.6 Pre-Existing Third Party License. BioCryst shall use its good faith and commercially reasonable efforts to maintain the Pre-Existing Third Party License. If BioCryst receives a notice of breach under Section 10.03 from a licensor of the Pre-Existing Third Party License, then BioCryst shall promptly inform Roche of the notice and of the plan to cure the breach. If BioCryst does not plan to, or can not, cure the breach within the time period allowed, then Roche shall have the right to cure the breach on BioCryst's behalf. If the Pre-Existing Third Party License terminates under Section 10.03 of the Pre-Existing Third Party License as a result of Roche's failure to cure such breach, this Agreement shall terminate and such termination shall be treated as any other termination under Section 11.4(b) and the provisions of Sections 11.4(b)-11.4(e), and 11.4(g) shall apply.

# ARTICLE 3 BIOCRYST RIGHT TO PROMOTE.

- **3.1 Co-Promotion**. No later than \*\*\*\* (\*\*\*\*) years prior to the anticipated Regulatory Approval in the U.S. of a Licensed Product for an indication in the area of Neurology or Stem Cell Transplantation or no later than \*\*\*\* (\*\*\*\*) years prior to the anticipated Regulatory Approval in the U.S. of a Licensed Product for an indication in the area of Dermatology, Roche shall notify BioCryst of the anticipated Regulatory Approval date ("**Anticipated Launch"**). After such notice and prior to the date which is \*\*\*\* (\*\*\*\*) months prior to the Anticipated Launch in the U.S. of a Licensed Product for an indication in the area of Neurology or Stem Cell Transplantation or prior to the date which is \*\*\*\* (\*\*\*\*) years prior to the Anticipated Launch in the U.S. of a Licensed Product for a Dermatology indication, BioCryst shall have the right to provide written notice to Roche that it shall Detail Licensed Product in the U.S. as set forth below. BioCryst shall have the right to use BioCryst employees (i.e., not a Third Party) to provide (i) all Details in the U.S. with respect to all Licensed Products for the area of Stem-Cell Transplantation, and (ii) all Details for all Licensed Products in the U.S. in the areas of Neurology and/or Dermatology in those indications for which Roche does not have a full time employed sales force to cover all Details for all Licensed Products in such indications. If Roche is Detailing Licensed Products in the areas of Neurology and/or Dermatology, BioCryst shall have the right to provide up to \*\*\* percent (\*\*\*\*%) of all Details with respect to all sales of Licensed Products for indications in such areas where Roche is providing Details. Notwithstanding the foregoing, for the \*\*\*\* (\*\*\*\*) month period immediately following the actual commercial launch of each Licensed Product for a particular indication, BioCryst shall have the right to discharge its obligations to Detail through a Third Party (i.e., contract sales force), provided that BioCryst will transition a significant portion of such cont
- (a) The Details described in Section 3.1 shall be performed as directed by, and in a manner determined by, the JSC and/or a joint marketing committee constituted by the JSC, and shall be performed in accordance with the terms of this Agreement.
- (b) Roche shall compensate BioCryst on a Detail-by-Detail basis at current market rates for contract sales force FTEs for Details in those indications for which Roche does not have a full time employed sales force to cover all Details for all Licensed Products in such indications.

# **ARTICLE 4 GOVERNANCE**

# 4.1 Steering Committee.

- (a) The Parties shall establish a Joint Steering Committee ("JSC") to oversee and review the research and development activities of the Parties with respect to Licensed Product. The JSC in turn may establish additional committees to achieve this result ("JSC Subcommittees"). Upon notice by BioCryst to co-promote pursuant to ARTICLE 3, the JSC shall establish a Co-Promotion Committee to oversee and address issues related to the parties' activities under ARTICLE 3. All committees established under this Agreement, including the JDC and all JSC Subcommittees, shall be subordinate to the JSC.
- (b) The JSC shall consist of an equal number of representatives of each Party, which shall be at least three (3), who are experts in their field and who shall not serve on the JDC or any other group or committee, including a Subcommittee established pursuant to this Agreement. The size of the JSC may be changed by agreement of the Parties but shall always have an equal number of representatives from each Party. Each Party may select representatives to replace the initial JSC members selected by such Party as necessary. The JSC shall meet at least four (4) times per calendar year, and more often as mutually agreed by the Parties as appropriate for the continued Development of Licensed Products.
- (c) The JSC shall be responsible for overseeing, managing and providing strategic direction to the Parties in Development of Licensed Products and otherwise carrying out their obligations under this Agreement, including: (i) discussing all matters of strategic relevance or other importance to the Parties under this Agreement, (ii) quarterly reviewing and approving all Development Plans (including setting key efficacy endpoints of clinical studies, clinical and regulatory plans) and changes in Development Plans recommended by the JDC; (iii) reviewing and monitoring the activities and verbally communicating the progress of the JDC and Subcommittees, if any; (iv) considering disputes, disagreements and deadlocks that are not resolved by the other committees established under this Agreement pursuant to Section 4.1(a) or Section 4.2(a); (v) overseeing the integration and coordination of the Development of the Licensed Products in accordance with the terms and conditions of this Agreement; (vi) undertaking and/or approving such other matters as are specifically provided for the JSC under this Agreement, (vii) reviewing and approving a global clinical trial program prior to the conduct of any clinical trials for Licensed Products (including Special Indication Products) and the plans for any individual clinical trial of Licensed Product in advance of the anticipated commencement thereof, (viii) updating BioCryst on Roche's sublicensing activities, and (ix) updating Roche on the activities of BioCryst or the licensors of the Pre-Existing Third Party License, the U.S. government, the National Cancer Institute or the New Zealand Foundation for Research, Science and Technology in connection with the Compound or Backup Compounds in the Field to the extent BioCryst is aware of such activities. At Roche's request, BioCryst shall use its commercially reasonable efforts to obtain from its licensors under the Pre-Existing Third Party License and provide to Roche requested information related to the activities of the licensors of the Pre-Existing Third Party License, the U.S. government, the National Cancer Institute or the New Zealand Foundation for Research, Science and Technology in connection with the Compound or Backup Compounds in the Field.
- (d) The Parties shall report to the JSC on all significant clinical and regulatory issues related to Licensed Product, and the JSC shall make recommendations and provide strategic guidance with respect to such issues.
  - (e) Neither Party shall commence any clinical trial of Licensed Product until the JSC has approved plans therefor.
- (f) Each Party shall keep the JSC informed of the progress and results of activities for which it is responsible under this Agreement through its members on the JSC and as otherwise provided herein. BioCryst shall keep the JSC informed regarding its plans for developing any Special Indication Product, including sufficient information to determine potential safety issues and target population. Once per calendar year, Roche shall advise the JSC of its Commercialization plans and activities. Once per calendar year, Roche shall provide BioCryst with a written Commercialization plan, to the extent one exists.

# 4.2 Development Committee.

- (a) The Parties shall establish a Joint Development Committee ("JDC"; the JDC, JSC, JDC Subcommittees and JSC Subcommittees, each a "Committee") to coordinate the conduct and progress of the Development of Licensed Products. The JDC may establish committees to achieve its results ("JDC Subcommittees"). The JDC and JDC Subcommittees shall be subordinate to the JSC.
- (b) The JDC shall consist of an equal number of representatives of each Party, which shall be at least three (3), who are experts in their field and who are not members of the JSC or any Subcommittee or other team established pursuant to this Agreement. The JDC is responsible for, among other things: (i) devising the strategy and plans for the Development of Licensed Products including regulatory strategies; (ii) annually reviewing and updating the Development Plans, as needed, but at a minimum once per year and recommending changes for consideration by the JSC, including, without limitation, changes in the strategy for Developing the Licensed Products, seeking approval of particular indications, or expanding the markets being targeted; (iii) reviewing and approving clinical study endpoints, clinical methodology and monitoring requirements for the clinical studies described in the Development Plans; (iv) reviewing, coordinating and ensuring compliance with the Development Plans; and (v) undertaking and/or approving such other matters as are specifically provided for the JDC under this Agreement.
- (c) The JDC shall meet at least four (4) times per calendar year, and more often as mutually agreed by the Parties as appropriate for the continued Development of Licensed Products.
- **4.3 Committee Membership**. In the event a Committee member from either Party is unable to attend or participate in a meeting of its Committee, the Party who designated such representative may designate a substitute representative for the meeting in its sole discretion.
- **4.4 Committee Chairs**. For each Committee, a Party shall appoint one (1) of its members to such Committee to chair the meetings for such Committee (a "**Chair**"). The JSC Chair shall serve for a one (1) year period. Roche shall have the right to designate the first Chair of the JSC, whose term shall run until December 31, 2006, and the right to designate the Chair of the JSC shall thereafter alternate between the Parties on a calendar year basis. Notwithstanding the above, Roche shall have the right to designate all Chairs for the JDC, JDC Subcommittees, and Co-Promotion Committee. The Chair for each Committee shall (i) coordinate and issue the agenda of such Committee's meetings, (ii) attend each meeting of such Committee, and (iii) issue written minutes of each meeting within thirty (30) days thereafter accurately reflecting the discussions and decisions of such Committee. Minutes from each Committee's meeting shall not be finalized until the other Party has reviewed and confirmed the accuracy of such minutes in writing. The agendas for the JSC and JDC shall be prepared jointly with input from both Parties, provided that if either Party requests an addition to an agenda, it will be added. In the event the Chair is unable to attend or participate in its Committee's meeting, the Party who designated such Chair may designate a substitute Chair for the meeting.
- **4.5 Committee Meetings**. Committees may meet in person or by video conference or telephonically as agreed by the Parties; provided that the JSC and the JDC shall meet at least once annually in person. Each Party shall be responsible for its own expenses relating to such meetings. As appropriate, other employee representatives of the Parties may attend Committee meetings as nonvoting observers, subject to the reasonable approval of the other Party. Each Party may also call for special meetings of a Committee to resolve particular matters requested by such Party and within the areas of responsibility of such Committee. Each Committee's Chair shall ensure that its Committee members receive adequate notice of such meetings.
- **4.6 Decision Making**. Decisions of each Committee shall be made by consensus of the members present in person or by other means (e.g., teleconference) at any meeting, with each Party having one vote. In order to make any decision, any Committee established under this Agreement must have present (in person or telephonically) at least one representative of each Party. In the event that a JDC Subcommittee does not reach consensus with respect to a particular matter endeavoring in good faith for \*\*\*\* (\*\*\*\*) days to do so, then the Parties shall refer such issue to the JDC for resolution. In the event that any JSC Subcommittee or the JDC does not reach consensus with respect to a particular matter after

endeavoring in good faith for \*\*\* (\*\*\*) days to do so, then the Parties shall refer the issue to the JSC for resolution. In the event that the JSC does not reach consensus with respect to a particular matter after endeavoring in good faith for \*\*\* (\*\*\*) days to do so, then the matter shall be submitted to the respective executive officers of the Parties designated below or their successors. The designated executive officers of the Parties are as follows:

> For Roche: Head of Global Development/Pharma Division

For BioCryst: Chairman and CEO

If the positions of the designated executive officers listed above are vacant or no longer exist, then the person having the most nearly equivalent position (or such individual's designee) shall be deemed to be the designated executive officer of the relevant Party. In the event that such executives do not reach consensus with respect to such matter after endeavoring in good faith for \*\*\* (\*\*\*) days to do so, then Roche shall have the right to cast a deciding vote on such matter. Notwithstanding anything herein to the contrary, no Committee shall have any authority to amend, modify or waive compliance with this Agreement.

- 4.7 Interactions Between Committees. The Parties recognize that while they will establish various Committees for the purposes hereof, each Party maintains internal structures (including its own committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. The Parties shall establish procedures to facilitate communications between the various Committees hereunder and the relevant internal committee, team or board within the Party in order to maximize the efficiency of the Parties' activities pursuant to this Agreement. In addition, each Committee shall coordinate with each other as appropriate.
- 4.8 Performance of Representatives. BioCryst and Roche shall cause each of their representatives on a Committee established under this Agreement to vote, and shall otherwise perform their respective activities under this Agreement, in a good faith manner.

# **ARTICLE 5 DILIGENCE AND SPECIAL INDICATIONS**

<b>5.1 Diligence.</b> During the Term of the Agreement, Roche, directly or through its Affiliates, shall use Commercially Reasonable Efforts in the
Major Market Countries in order to Develop, manufacture and Commercialize Licensed Product in the Field. ***. Roche shall fulfill its obligations
hereunder in compliance with all Laws.
(a) ***.

(2)	***
(a)	

- (b) \*\*\*.
- (c) \*\*\*.
- (d) \*\*\*.
- (e) \*\*\*.
- (f) \*\*\*.
- (g) \*\*\*.
- (h) \*\*\*.

5.2 Special Indications. BioCryst shall have the right, at its sole cost and expense, to develop the Compound for use in any Special Indication.

- **5.3 Development Plan.** BioCryst shall, to the extent it exists, deliver to Roche its Development plan for any Special Indication with respect to which it desires to conduct development. BioCryst shall update this plan by delivering a written supplement to Roche from time to time during the term of this Agreement. BioCryst shall also present the development plans to the JSC.
- **5.4 Reports.** BioCryst will provide the JSC within \*\*\* (\*\*\*) days of each June 30 and December 31 during the Term of this Agreement, a written report summarizing for the preceding semi-annual period all BioCryst development activities, including publications, related to any relevant Special Indication Product.

# 5.5 End of Phase IIb.

- (a) BioCryst shall notify in writing Roche in the event that BioCryst determines that any clinical trial results in a Special Indication would justify commencing a pivotal trial directed to obtaining Regulatory Approval in the U.S. for such indication ("End of Phase IIb Notice"). The Notice shall be accompanied by (i) data and information that BioCryst reasonably believes is sufficient to justify commencing such trial, including without limitation the clinical trial results, (ii) the proposed end points with respect to which BioCryst proposes such pivotal trial, and (iii) accrued BioCryst Development Costs through the most recent Calendar Quarter for which BioCryst financial information is available prior to the date of the Notice. Roche shall have the right to request, and BioCryst shall endeavor to timely supply any existing additional data and information from BioCryst that Roche believes to be reasonably required or useful to make its decision to file or not to file hereunder.
- (b) Within \*\*\* (\*\*\*) days after receipt by Roche of the End of Phase IIb Notice and the accompanying information requested by Roche or set forth in Section 5.5(a)(i) (iii), Roche shall notify BioCryst in writing of whether Roche (i) elects to commence such pivotal trial, or (ii) will not commence such a trial (in which case BioCryst shall be entitled to commence the trial and continue to develop the Special Indication Product). If Roche notifies BioCryst pursuant to (i) of the foregoing sentence, then Roche shall, simultaneous with Roche's notice, (i) reimburse BioCryst \*\*\* percent (\*\*\*\*%) of BioCryst's Development Costs, excluding material supplied by Roche, for such Special Indication Product, (ii) bear the costs of making the pivotal trial, and thereafter exercise Commercially Reasonable Efforts in accordance with the terms and conditions of this Agreement to Develop and Commercialize such Special Indication Product (which, for all purposes hereunder, shall be deemed to be a Licensed Product).

# 5.6 Registration.

- (a) BioCryst shall notify in writing Roche in the event that BioCryst determines that any clinical trial results in a Special Indication would justify filing in the U.S. for Regulatory Approval for such indication ("Filing Notice"). The Filing Notice shall be accompanied by (i) data and information that BioCryst reasonably believes is sufficient to justify such filing, including without limitation the clinical trial results, (ii) the proposed labeling with respect to which BioCryst proposes such filing, and (iii) accrued BioCryst Development Costs through the most recent Calendar Quarter for which BioCryst financial information is available prior to the date of the Filing Notice. Roche shall have the right to request, and BioCryst shall endeavor to timely supply, any existing additional data and information from BioCryst that Roche believes to be reasonably required or useful to make its decision to file or not to file hereunder.
- (b) Within \*\*\* (\*\*\*) days after receipt by Roche of the Filing Notice and accompanying information requested by Roche or set forth in Section 5.6(a)(i) (iii), Roche shall notify BioCryst in writing of whether Roche (i) elects to make such a filing, or (ii) will not make such a filing. If Roche notifies BioCryst pursuant to (i) of the foregoing sentence, then Roche shall, simultaneous with Roche's notice, (i) reimburse BioCryst \*\*\* percent (\*\*\*\*%) of BioCryst's Development Costs, excluding material supplied by Roche, of such Special Indication Product and (ii) bear the costs of making any filing. In addition, royalties otherwise due hereunder from Roche to BioCryst with respect to such Special Indication Product shall be increased by \*\*\* (\*\*\*\*%) percent with respect to sales of such Special Indication Product. BioCryst shall not be entitled to make a filing for registration of a Special Indication Product. With any Regulatory Authority and shall not be entitled to commercialize any Special Indication Product.

**5.7 Sequencing of Licensed Products.** The Parties acknowledge that, even within the Major Market Countries, Roche and its Affiliates do not seek to obtain regulatory approval for every potential indication or every compound that has potential for an indication. The parties agree that the JSC shall be responsible for determining the sequencing of Licensed Products on an indication by indication basis.

# ARTICLE 6 CLINICAL TRIALS, REGULATORY MATTERS AND MANUFACTURING

- **6.1 Clinical Trials and Regulatory Matters**. Roche shall be responsible for all prospective costs by or on behalf of the Roche Group that are associated with the Development and Commercialization of Licensed Product in the Field, including clinical trials and regulatory submissions.
- (a) The IND for Licensed Product shall be transferred to Roche as soon as practicable after the Effective Date. Roche shall be responsible for all regulatory affairs in all countries related to Licensed Product, provided that with respect to any activities conducted by BioCryst in the United States that Roche will, to the extent permitted by Law, provide all drug master files or other regulatory dossiers containing information necessary or useful to BioCryst in connection with such activities. In addition, Roche shall promptly provide BioCryst with copies of all clinical data (upon request by BioCryst) and with all material correspondence with Regulatory Authorities and all annual reports and summaries provided to any Regulatory Authority relating to Licensed Products or Compound, to the extent permitted by Law.
- (b) Roche shall be responsible for reporting to the appropriate regulatory authorities all adverse events related to the use of Licensed Product worldwide, except that prior to the transfer of the IND to Roche as provided herein, BioCryst shall be responsible.
- (c) BioCryst shall have the right to file in BioCryst's name INDs for any Special Indication. Roche shall, at no cost to BioCryst, provide permission to allow BioCryst to cross-reference Roche filings to allow BioCryst to carry out without delay any related clinical trial. BioCryst shall advise and consult with Roche with respect to any significant issues or questions raised by any regulatory authorities with respect to any such IND or related clinical trial. BioCryst shall provide copies to Roche of any such IND and any other records of interactions with regulatory authorities (e.g., correspondence, minutes or notes of telephone conferences or meetings, etc.) with respect to any such IND or related clinical trials in a Major Market Country.
- (d) To the extent Roche is required under applicable Law, rule or regulation, Roche shall make all filings necessary to permit the use of the clinical materials supplied by Roche pursuant to Section 6.3(a). BioCryst and Roche shall each supply the other copies of all regulatory filings and/or the appropriate data related to the use of the clinical materials for such development promptly after the time of such filings.
- (e) To the extent permitted by applicable Law, Roche agrees to seek approval from the Regulatory Authorities in the Major Market Countries to prominently include on all packaging, labeling, inserts, Web sites, Promotional Material and other written materials used with Licensed Products for Sale and all samples thereof (collectively, "Product Materials") that BioCryst is licensor of the Licensed Product. BioCryst shall provide the text and style to Roche of the BioCryst trademark (the "BioCryst Trademark") prior to submission to the applicable Regulatory Authority in a Major Market Country. To the extent such approval is received (and in any event in situations where approval is not necessary) Roche agrees to include the BioCryst Trademark on all of the foregoing materials. BioCryst shall also use its reasonable efforts to assist Roche in any submission to the applicable Regulatory Authority in a Major Market Country pursuant to this Section 6.1(e).
- (f) During the Term hereof, BioCryst grants to Roche and its Affiliates a nonexclusive, nontransferable, limited right to use the BioCryst trademark designated by BioCryst on such Product Materials to identify BioCryst as the licensor of the Licensed Product. Roche acknowledges that (i) BioCryst is the sole and exclusive owner of the BioCryst Trademark and all combinations, forms and derivatives thereof which may hereafter be approved by BioCryst for use by Roche or its Affiliates

hereunder, (ii) Roche's right to use the BioCryst Trademark shall be governed exclusively by this Agreement, and (iii) all good will from use of the BioCryst Trademark by Roche or its Affiliates shall inure solely to the benefit of BioCryst. Roche further acknowledges the great value of the goodwill associated with the BioCryst Trademark and acknowledges that the BioCryst Trademark and all the rights therein, and goodwill attached thereto, belong exclusively to BioCryst. Roche shall cooperate fully and in good faith with BioCryst for the purpose of securing, preserving and protecting BioCryst's rights in and to the BioCryst Trademark and any secondary trademarks that may be used by Roche or its Affiliates with the approval of BioCryst. Roche shall not use the BioCryst Trademark except on the Product Materials in accordance with Section 6.1(e), and shall use the BioCryst Trademark strictly in compliance with all applicable Laws. Roche shall duly display all other notices with respect to the BioCryst Trademark on the Product Materials, as are or may be required by the trademark Laws and regulations applicable in each applicable jurisdiction. BioCryst shall have the right to approve all use of the BioCryst Trademark on the Product Materials.

**6.2 Adverse Event Reporting.** Each Party shall notify the other of all information coming into its possession (including information of the BioCryst licensors to the Pre-Existing Third Party License Agreement) concerning any and all side effects, injury, toxicity, pregnancy or sensitivity reaction associated with commercial or clinical uses, studies, investigations or tests with Compound, Backup Compounds, or Licensed Product, throughout the world, whether or not determined to be attributable to Compound, Backup Compounds or Licensed Product ("Adverse Event Reports"). The Parties shall enter into a pharmacovigilance agreement prior to commencing development of a Special Indication Product.

# 6.3 Manufacturing and Technical Assistance.

- (a) Provided that Roche uses good faith efforts in order to assist BioCryst in fulfilling its obligations hereunder, BioCryst shall: (1) during the first twenty-four (24) months after the Effective Date supply (in accordance with the guidelines set forth on Exhibit 6.3(a)(1)) at its own cost all Compound required to be used for Development of Licensed Product in the Field; provided, however, that notwithstanding anything to the contrary contained in Exhibit 6.3(a)(1), BioCryst shall not be obligated to provide Roche more than \*\*\* of Compound, and (2) within sixty (60) days of the Effective Date, commence a Know-How transfer (in accordance with the guidelines set forth on Exhibit 6.3(a)(2)), to Roche that will enable Roche to manufacture Licensed Product. The clinical supply of Compound shall meet current good manufacturing practices of the FDA (as set forth in 21 C.F.R. Parts 210 and 211) and the ICH guidelines of the European Union and all other applicable rules, regulations, guides and guidances. Promptly after the Closing Date, BioCryst shall deliver to Roche: (i) \*\*\* of all intermediates pure enough to calibrate analytical instruments, (ii) analytical methods, (iii) batch records of the whole chemical synthesis, to the extent they exist, (iv) safety investigation reports for all chemical steps, and (v) a list of key suppliers including agreements (if any) and all respective lead times. After transition of manufacturing to Roche as contemplated in this paragraph, Roche shall be responsible to supply, at its own cost, all clinical supply of Compound required for Development of Licensed Product in the Field, as approved by the JSC. In consideration for BioCryst's agreement to supply Roche with Compound as set forth herein, Roche agrees to prepay BioCryst's costs and expenses incurred in manufacturing such Compound in the amount of five million dollars (\$5,000,000) (the "Contract Manufacturing and Manufacturing Transfer Fee"), which shall be due within \*\*\* (\*\*\*) days of (i) the Closing Date of this Agreement and (ii) receipt by Roche of an invoice (in BioCryst's standard invoice format) for such sum.
  - (b) The Contract Manufacturing and Manufacturing Transfer Fee shall be nonrefundable and noncreditable.
- (c) Roche shall be solely and exclusively responsible at its own expense for the technical development, manufacture and supply of Licensed Product during Development and for sale in the Field.
- (d) BioCryst shall be allowed to manufacture Compound for its use in connection with the development of Special Indication Products or, after \*\*\*, request supply of Compound and/or Licensed Product from Roche for use by BioCryst in connection with the development of Special Indication

Products. Provided there is no impact on Roche's Development and Commercialization of Licensed Product or other products, Roche shall supply BioCryst with Compound and/or Licensed Product for use by BioCryst in connection with the development of Special Indication Products at Roche's \*\*\*\*.

(e) If Roche requests that BioCryst provide Roche with technical assistance in transferring technology required for the manufacture of Compound at a Roche Group manufacturing facility, BioCryst shall provide one visit of up to five days in duration of one full time employee's time to provide such services. Thereafter, Roche shall pay BioCryst on a time and materials basis at commercially competitive hourly consulting rates for technical personnel time. In connection with all of the foregoing, Roche shall also reimburse BioCryst for BioCryst's reasonable out-of-pocket expenses, including travel and lodging expenses.

# **ARTICLE 7 CONSIDERATION**

**7.1 Lump Sum Payments.** In consideration for the licenses granted herein, Roche shall pay BioCryst a non-refundable, non-creditable payment in the amount of twenty five million dollars (\$25,000,000) within \*\*\* (\*\*\*) days after (i) the Closing Date of this Agreement and (ii) receipt by Roche of an invoice (in BioCryst's standard invoice format) for such sum.

**7.2 Development Event Payments.** Roche shall promptly notify BioCryst after an event in this Section 7.2 has occurred. If any Royalty-Bearing Product reaches a following event for an Autoimmune Indication, then Roche shall pay BioCryst the corresponding payment within \*\*\* (\*\*\*) days of achievement of such event and receipt by Roche of an invoice from BioCryst (in BioCryst's standard invoice format):

Start Phase IIb:	\$ ***
Start Phase III or Pivotal:	\$ ***
First NDA filing or Foreign Equivalent:	
USA	\$ ***
Western Europe	\$ ***
Japan	\$ ***
NDA Approval or Foreign Equivalent:	
USA	\$ ***
Western Europe	\$ ***
Japan	\$ ***

If any Royalty-Bearing Product reaches a following event for up to two (2) additional Autoimmune Indications, then Roche shall pay BioCryst the corresponding payment within \*\*\* (\*\*\*) days of achievement of such event and receipt by Roche of an invoice from BioCryst (in BioCryst's standard invoice format):

	1 <sup>st</sup> OTHER INDICATION	2 <sup>ND</sup> OTHER INDICATION
Start Phase IIa:	\$ ***	\$ ***
Start Phase IIb:	\$ ***	\$ ***
Start Phase III or Pivotal:	\$ ***	\$ ***
First NDA filing or Foreign Equivalent:		
USA	\$ ***	\$ ***

	1st OTHER	2 <sup>ND</sup> OTHER
	INDICATION	INDICATION
Western Europe	\$ ***	\$ ***
Japan	\$ ***	\$ ***
NDA Approval or Foreign Equivalent:		
USA	\$ ***	\$ ***
Western Europe	\$ ***	\$ ***
Japan	\$ ***	\$ ***

The above payments for Autoimmune Indications are payable for each achievement by any Royalty-Bearing Product of the above-mentioned event; provided, however, no more than one payment can ever be payable for a given Autoimmune Indication, regardless of the number of times of achievement of the event for the given Indication.

By way of example and not limitation, if a first Royalty-Bearing Product in an Autoimmune Indication (the "First Royalty-Bearing Product") reaches the Start of Phase IIb, then the event payment would be \*\*\* dollars (\$\*\*\*). If after the First Royalty-Bearing Product reaches the Start of Phase IIb, any Royalty-Bearing Product in an Autoimmune Indication different than the Autoimmune Indication of the First Royalty-Bearing Product reaches the Start of Phase IIa (the "Second Royalty-Bearing Product"), then the event payment would be \*\*\* dollars (\$\*\*\*). If the Second Royalty-Bearing Product reaches the Start of Phase III, then the event payment would be \*\*\* dollars (\$\*\*\*) because the Second Royalty-Bearing Product is the *first* Autoimmune Indication to reach the Start of Phase III. If after the Second Royalty-Bearing Product reaches the Start of Phase III, then the event payment would be \*\*\* dollars (\$\*\*\*), because the First Royalty-Bearing Product is the *second* Autoimmune Indication to reach the Start of Phase III.

If any Royalty-Bearing Product reaches a following event for a Transplantation Indication, then Roche shall pay BioCryst the corresponding payment within \*\*\* (\*\*\*) days of achievement of such event and receipt by Roche of an invoice from BioCryst (in BioCryst's standard invoice format):

START PHASE IIa	\$ ***
Start Phase IIb	\$ ***
Start Phase III Pivotal:	\$ ***
First NDA filing or Foreign Equivalent:	
USA	\$ ***
Western Europe	\$ ***
ROW	\$ ***
NDA Approval or Foreign Equivalent:	
USA	\$ ***
Western Europe	\$ ***
POW.	¢ ***

The above payments for Transplantation Indications are payable only one time for the given event (e.g. the first time the event is achieved only).

Notwithstanding anything to the contrary above, in examples or otherwise, for any indication for any Royalty-Bearing Product for which a Phase IIa event payment is payable, if a Phase IIa event payment would otherwise be due and Roche decides not to conduct a Phase IIa trial, then the Start of Phase IIa event payment that would otherwise be due shall be paid at the same time as the Phase IIb event payment. If a Phase IIb event payment would otherwise be due and Roche decides not to conduct a

Phase IIb trial, then the Start of Phase IIb event payment that would otherwise be due shall be paid at the same time as the Phase III event payment.

**7.3 Commercial Event Payments.** If aggregate Net Sales for all Royalty-Bearing Products exceed \*\*\* dollars (\$\*\*\*) in any given calendar year, then Roche shall pay BioCryst a one-time payment of \*\*\* dollars (\$\*\*\*) within \*\*\* (\*\*\*) days after achievement of such event. If aggregate Net Sales for all Royalty-Bearing Products exceed \*\*\* dollars (\$\*\*\*) in any given calendar year, then Roche shall pay BioCryst a one-time payment of \*\*\* dollars (\$\*\*\*) within \*\*\* (\*\*\*) days of achievement of such event. If aggregate Net Sales for all Royalty-Bearing Products exceed \*\*\* dollars (\$\*\*\*) in any given calendar year, then Roche shall pay BioCryst a one-time payment of \*\*\* dollars (\$\*\*\*) within \*\*\* (\*\*\*) days after achievement of such event. For the purposes of clarity, each of the above payments is payable only the first time the associated commercial event is triggered.

**7.4 Royalties.** Roche shall pay BioCryst, on a country-by-country basis, and on a Royalty-Bearing Product by Royalty-Bearing Product basis a royalty payment on incremental Net Sales according to the following rates for the following ranges of Net Sales:

CUMULATIVE NET SALES (\$ MILLION)	INCREMENTAL ROYALTY RATE (%)
***	***
***	***
***	***

Notwithstanding the preceding, if no Royalty-Bearing Product has received NDA Approval in a Major Market Country for an Autoimmune Indication, then Roche shall pay BioCryst, on a country-by-country basis, a royalty payment on Net Sales of Royalty-Bearing Products according to the following rates:

NET SALES (\$ MILLION)	INCREMENTAL ROYALTY RATE (%)  ***
***	***
***	***

By way of example, if, in the year 2013, total Net Sales equals \$\*\*\* and Licensed Product has received NDA Approval in a major Market Country for at least one Autoimmune Indication, then the royalty payable to BioCryst hereunder shall equal \$\*\*\*, calculated in the following manner:

AMOUNT OF NET SALES	ROYALTY RATE	ROYALTY	Y PAYMENT
First \$***	***0%	\$	***
Next \$***	***%	\$	***
Total Royalty		\$	***

**7.5 Patent Coverage Adjustment**. For a given country, if there is no Valid Claim in any BioCryst Patent in such country that, but for this Agreement would be infringed by the manufacture, use or sale of Licensed Product in such country, then the royalty obligations from Roche to BioCryst for such country shall be reduced by \*\*\* percent (\*\*\*%) until the end of \*\*\* (\*\*\*) years after First Commercial Sale of Licensed Product in such country, and thereafter by \*\*\* percent (\*\*\*%), for so long as the Roche Group sells Licensed Product in such country. If the royalty obligations in this Section 7.5 are prohibited by applicable Law in any country, then the royalty obligations shall continue on a country-by-country basis until such time as the obligation is prohibited by applicable Law. If after \*\*\* (\*\*\*) years after First Commercial Sale of Licensed Product in a given country in any given year: (i) there is no Valid Claim in any BioCryst Patent in such country that, but for this Agreement would be infringed by the manufacture, use or sale of Licensed Product in such country, and (ii) the global Net Sales of Licensed Product are less than \*\*\* dollars (\$\*\*\*), then the royalty obligations from Roche to BioCryst for such country shall be reduced by \*\*\* percent (\*\*\*%).

- **7.6 Combination Licensed Products.** For a Licensed Product containing (i) one or more pharmaceutically active ingredients which are a Compound and (ii) one or more pharmaceutically active ingredients which are not a Compound, then the Parties shall, on a country-by-country basis, agree to an appropriate adjustment to Net Sales to reflect a good faith determination of the relative value of each pharmaceutically active ingredient, based on the estimated fair market value of each such therapeutically active ingredient, as follows:
- (a) In the case of a combination product for which a Licensed Product and each of the other therapeutically active ingredients contained in the combination product are sold separately in such country by the Roche Group, the Adjusted Gross Sales shall be determined by multiplying actual Adjusted Gross Sales of the combination product by a fraction, the numerator of which shall be the Gross Price of the Licensed Product as sold separately, and the denominator of which shall be the sum of the Gross Price of the Licensed Product as sold separately and the gross amount invoiced for all other active ingredients contained in the combination product, if sold separately.
- (b) In the case of a combination product for which the Licensed Product is sold separately in such country but the non-Licensed Product therapeutically active ingredients contained in the combination product are not sold separately by the Roche Group in such country, Adjusted Gross Sales of the Licensed Product forming a part of the combination product shall be calculated by multiplying actual Adjusted Gross Sales of such combination product by the fraction of A/C where A is the Gross Price for the Licensed Product used in the combination if sold separately by the Roche Group and C is the gross amount invoiced for the combination product.
- (c) If in a country neither the Licensed Product nor the therapeutically active ingredients contained in the combination product are sold separately in said country by the Roche Group, Adjusted Gross Sales of the Licensed Product forming part of the combination product shall be reasonably determined by allocating value between the Licensed Product and the other therapeutically active ingredients based on their relative value as determined by the Parties in good faith. In the case where the parties are unable to agree on the relative value, the Parties shall agree upon an internationally recognized independent certified public accountant who shall make such determination and whose determination shall be final and binding on the Parties.
- **7.7 Payments to Third Parties.** BioCryst shall maintain the Pre-Existing Third Party License at its own cost. If BioCryst's licensor claims a payment is due under the Pre-Existing Third Party License and BioCryst does not agree to make such payment, then BioCryst shall promptly advise Roche in writing of such fact. Other than with respect to the Pre-Existing Third Party License, the Roche Group shall obtain all licenses from any Third Party necessary to make, have made, use, offer for sale, sell or import Royalty-Bearing Products, at its own cost.
- **7.8 Generic Sales Adjustment.** If there is no Valid Claim, then Roche may reduce the royalties otherwise due for Licensed Product in a given country by \*\*\* percent (\*\*\*%) if, in the country, sales of units of Generic Licensed Product in aggregate total at least \*\*\* percent (\*\*\*%) of the aggregate sales of units of (i) Licensed Product sold by the Roche Group and (ii) Generic Licensed Products.
- **7.9 Royalties Due Once.** The obligation to pay royalties to BioCryst under this Agreement is imposed only once with respect to the same unit of Licensed Product.

# ARTICLE 8 PAYMENTS; RECORDS; AUDIT

**8.1 Payment of Royalties.** Following the First Commercial Sale in a country, within \*\*\* (\*\*\*) days after the end of each Calendar Quarter during the Term of this Agreement, Roche shall (i) provide BioCryst with a report detailing, on a Royalty-Bearing Product and country-by-country basis, the Adjusted Gross Sales and Net Sales for the Calendar Quarter and (ii) pay royalties to BioCryst under this Agreement for the Calendar Quarter. Within \*\*\* (\*\*\*) days after the end of each calendar year, Roche shall provide BioCryst with \*\*\*. Roche shall provide reports to BioCryst at the address listed below:

BioCryst Pharmaceuticals, Inc. 2190 Parkway Lake Drive Birmingham, Alabama 35244 Attention: Chief Financial Officer

(a) Roche shall pay royalties to BioCryst under this Agreement by wire transfer to the bank account listed below:

\*\*\*

- **8.2 Currency.** All Royalties shall be paid by Roche in U.S. Dollars. Roche shall convert the amount of all Sales in currencies other than U.S. Dollars into U.S. Dollars using Roche's then current standard practices actually used on a consistent basis.
- **8.3 Payments Nonrefundable.** Except as provided for in this Agreement, all payments made hereunder shall be nonrefundable and noncreditable.
- **8.4 Roche Records and Audit.** Roche and its Affiliates shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all royalties and other payments payable under this Agreement.
- (a) Such books of accounts shall be kept at the maintaining Party's principal place of business. At the expense of BioCryst, BioCryst has the right to engage \*\*\* to perform, on behalf of BioCryst an audit of such books and records of Roche and its Affiliates to report on Net Sales of Licensed Product for the period or periods requested by BioCryst and the correctness of any report or payments made under this Agreement.
- (b) Upon not less than \*\*\* (\*\*\*) days' prior written notice from BioCryst, such audit shall be conducted in the countries specifically requested by BioCryst, during regular business hours in such a manner as to not unnecessarily interfere with Roche's normal business activities, and shall be limited to results in the two (2) calendar years prior to audit notification. Such audit shall not be performed more frequently than once per calendar year.
- (c) All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying royalty statements or compliance with this Agreement, shall be treated as Roche Confidential Information subject to the obligations of this Agreement, and (provided that there is at that time no request or an audit or an ongoing audit), need neither be retained more than one (1) year after completion of an audit hereof, if an audit has been requested; nor more than two (2) years from the end of the calendar year to which each shall pertain; nor more than two (2) years after the date of termination of this Agreement, unless a longer period is required by Law.
- (d) Audit results and findings shall be shared by Roche and BioCryst. If the audit reveals an overpayment, BioCryst shall reimburse Roche for the amount of the overpayment within \*\*\* (\*\*\*) days. If the audit reveals an underpayment, Roche shall make up such underpayment within \*\*\* (\*\*\*) days, \*\*\*. If the audit reveals an underpayment in the amount of \*\*\* percent (\*\*\*%) or more, then Roche shall reimburse BioCryst for the costs of the audit. The failure of BioCryst to request verification of any royalty calculation within the period during which corresponding records must be maintained will be deemed to be acceptance of the royalty reporting.
- **8.5 BioCryst Records and Audit.** BioCryst and its Affiliates shall keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all sums invoiced under this Agreement.
- (a) Such books of accounts shall be kept at the maintaining Party's principal place of business. At the expense of Roche, Roche has the right to engage \*\*\* to perform, on behalf of Roche an

audit of such books and records of BioCryst to verify the correctness of any Development Costs invoiced under this Agreement.

- (b) Upon not less than \*\*\* (\*\*\*) days' prior written notice from Roche, such audit shall be conducted in the countries specifically requested by Roche, during regular business hours in such a manner as to not unnecessarily interfere with BioCryst's normal business activities, and shall be limited to results in the two (2) calendar years prior to audit notification. Such audit shall not be performed more frequently than once per calendar year.
- (c) All information, data documents and abstracts herein referred to shall be used only for the purpose of verifying invoices under this Agreement, shall be treated as BioCryst Confidential Information subject to the obligations of this Agreement, and (provided that there is at that time no request for an audit or an ongoing audit), need neither be retained more than one (1) year after completion of an audit hereof, if an audit has been requested; nor more than two (2) years from the end of the calendar year to which each shall pertain; nor more than two (2) years after the date of termination of this Agreement, unless a longer period is required as a matter of Law.
- (d) Audit results and findings shall be shared by Roche and BioCryst. If the audit reveals an overpayment of Development Costs by Roche, BioCryst shall reimburse Roche for the amount of the overpayment within \*\*\* (\*\*\*) days, \*\*\*. If the audit reveals an overpayment of Development Costs in the amount of \*\*\* percent (\*\*\*%) or more, then BioCryst shall reimburse Roche for the costs of the audit. If the audit reveals an underpayment, then Roche shall promptly pay all amounts due.
- **8.6 Withholding Taxes.** BioCryst shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of event payments, royalties and any other payments accruing or made to BioCryst under this Agreement. If provision is made in Law of any country for withholding of taxes of any type, levies or other charges with respect to any royalty or other amounts payable under this Agreement to BioCryst; then (i) Roche shall promptly notify BioCryst of such Law in advance of the payment requiring the withholding; and (ii) Roche shall promptly pay such tax, levy or charge for and on behalf of BioCryst to the proper governmental authority, and shall promptly furnish BioCryst with receipt of payment. Roche shall be entitled to deduct any such tax, levy or charge actually paid from royalty or other payment due BioCryst or be promptly reimbursed by BioCryst if no further payments are due BioCryst. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted (including by maintaining or changing, as reasonably necessary and in accordance with applicable Law, the payor of amounts under this Agreement) or obtaining any available refund of amounts so withheld or deducted.

# **ARTICLE 9 INTELLECTUAL PROPERTY**

# 9.1 Prosecution of BioCryst Patent Rights.

(a) **BioCryst Patents.** BioCryst shall prepare, file, prosecute and maintain (hereinafter "**Patent Activities**") the BioCryst Patents, at its expense. BioCryst shall consult with Roche as to the Patent Activities, and furnish to Roche copies of all substantive documents relevant to the Patent Activities. BioCryst shall furnish such documents and consult with Roche in sufficient time (at least one week) before any action by BioCryst is due, to allow Roche to provide comments thereon, which comments BioCryst will consider in good faith. BioCryst will not reduce the scope of any claim related to the Compound in a given patent application without the prior written approval of Roche, which approval shall not be unreasonably withheld or delayed. At BioCryst's expense and reasonable request, Roche shall cooperate in all reasonable ways in connection with the Patent Activities. Should BioCryst decide that it does not desire to continue the Patent Activities in relation to a BioCryst Patent in any given country, or in relation to any pending claim, it shall promptly advise Roche thereof. At the written request of Roche, BioCryst shall continue at Roche's expense and direction to prosecute and/or maintain such

BioCryst Patent or pending claim in such country. At Roche's expense and reasonable request, BioCryst shall cooperate in all reasonable ways in connection with the Patent Activities of such BioCryst Patent or pending claim.

- (b) Roche Patents. Roche shall be responsible for the Patent Activities relating to the Roche Patents. Roche shall consult with BioCryst as to the Patent Activities, and furnish to BioCryst copies of all substantive documents relevant to the Patent Activities. Roche shall furnish such documents and consult with BioCryst in sufficient time (at least one week) before any action by Roche is due to allow BioCryst to provide comments thereon, which comments Roche must consider. At Roche's expense and reasonable request, BioCryst shall cooperate, in all reasonable ways in connection with the Patent Activities. Should Roche decide that it does not desire to continue the Patent Activities related to a Roche Patent(s) in a country, it shall promptly advise BioCryst thereof. At the written request of BioCryst, Roche shall then, at no cost to BioCryst, assign to BioCryst such Roche Patent in such country or countries, and BioCryst may thereafter handle the Patent Activities at BioCryst's own cost, to the extent that BioCryst desires to do so. At BioCryst's expense and reasonable request, Roche shall cooperate, in all reasonable ways in connection with the Patent Activities of such Roche Patents.
- **9.2 Infringement.** Each Party shall promptly provide written notice to the other Party during the Term of this Agreement of any (i) known infringement or suspected infringement by a Third Party of any BioCryst Patent or Roche Patent in the Field, (ii) known or suspected unauthorized use or misappropriation by a Third Party of any BioCryst Know-How or Roche Know-How in the Field, or (iii) receipt by the Party of a paragraph iv certification for a Licensed Products pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, or its equivalent in a country other than the United States of America and shall discuss with the other Party all evidence in its possession supporting such infringement or unauthorized use or misappropriation.
- (a) Within a period of \*\*\* (\*\*\*) days after Roche provides or receives such written notice ("**Decision Period**"), Roche, in its sole discretion, shall decide whether or not to initiate a suit or take other appropriate action in the Field and shall notify BioCryst in writing of its decision ("**Suit Notice**").
- (b) Upon BioCryst's receipt of Suit Notice, BioCryst and Roche shall meet and confer within \*\*\* (\*\*\*) days regarding the suit or action proposed by Roche. At this meeting, BioCryst shall present any objections or concerns regarding Roche's proposed suit or action, especially as the proposed suit or action relates to BioCryst Patents that have applicability outside the Field, and Roche shall consider BioCryst's objections or concerns in good faith. Notwithstanding the foregoing, Roche need not obtain BioCryst's consent to proceed with a suit or other action in the Field
- (c) In the event that Roche (i) does not in writing advise BioCryst within the Decision Period that Roche will commence suit or take action in the Field, or (ii) fails to commence suit or take action in the Field within a reasonable time after providing Suit Notice, then BioCryst shall thereafter have the right to commence suit or take action and shall provide written notice to Roche prior to commencement of any such suit or action taken by BioCryst.
- (d) Upon written request, the Party bringing suit or taking action ("Initiating Party") shall keep the other Party informed of the status of any such suit or action and shall provide the other Party with copies of all substantive documents and communications filed in such suit or action that are not protected by the attorney-client privilege or work product protection. The Initiating Party shall have the sole and exclusive right to select counsel for any such suit or action.
- (e) The Initiating Party shall, except as provided below, pay all expenses of the suit or action, including, without limitation, the Initiating Party's attorneys' fees and court costs. Any damages, settlement fees or other consideration received as a result of a suit or action initiated by Roche shall be treated as Net Sales pursuant to this Agreement after the Initiating Party deducts from the damages, settlement fees or other consideration received its actual counsel fees and out-of-pocket expenses. Any damages, settlement fees or other consideration received as a result of a suit or action initiated by BioCryst shall be given \*\*\* percent (\*\*\*%) to \*\*\* after BioCryst deducts from the damages, settlement fees

or other consideration received, its actual counsel fees and out-of-pocket expenses and the actual counsel fees and out-of-pocket expenses of Roche.

- (f) If the Initiating Party believes it reasonably necessary, upon written request the other Party shall join as a Party to the suit or action but shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named Party to the suit or action. At the Initiating Party's written request, the other Party shall offer reasonable assistance to the Initiating Party in connection therewith at no charge to the Initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred by the other Party in rendering such assistance. The other Party shall have the right to participate and be represented in any such suit or action by its own counsel at its own expense.
- (g) When Roche is the Initiating Party, Roche shall not settle, consent to judgment or otherwise voluntarily dispose of the suit or action without discussing such action with BioCryst and considering any objection by BioCryst in good faith. Notwithstanding the foregoing, Roche need not obtain BioCryst's consent to settle, consent to judgment or otherwise voluntarily dispose of the suit or action in the Field with the exception of any settlement, consent judgment, or other voluntary disposal of the suit or action that would have the effect of rendering any of the patent claims invalid, unenforceable, or disclaimed, in which instance Roche must first obtain BioCryst's consent, and said consent shall not be unreasonably withheld or delayed.
- **9.3 Hatch-Waxman.** Notwithstanding anything herein to the contrary, should a Party receive a certification for a Product pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, or its equivalent in a country other than the United States of America, then such Party shall immediately provide the other Party with a copy of such certification. Roche shall have thirty (30) days from date on which it receives or provides a copy of such certification to provide written notice to BioCryst ("**H-W Suit Notice**") whether Roche will bring suit, at its expense, within a forty-five (45) day period from the date of such certification. Should such thirty (30) day period expire without Roche bringing suit or providing such H-W Suit Notice, then BioCryst shall be free to immediately bring suit in its name.

# **ARTICLE 10 CONFIDENTIAL INFORMATION**

- 10.1 Non-Use and Non-Disclosure. During the Term of this Agreement and for \*\*\* (\*\*\*) years thereafter (or, with respect to trade secrets, indefinitely), a Receiving Party shall (i) treat Confidential Information provided by Disclosing Party as it would treat its own information of a similar nature, (ii) take all reasonable precautions not to disclose such Confidential Information to Third Parties, except to Affiliates, without the Disclosing Party's prior written consent, and (iii) not use such Confidential Information other than for fulfilling its obligations under this Agreement. In the event this Agreement is terminated, all Confidential Information assigned by Roche to BioCryst shall be deemed to be BioCryst Confidential Information. The Confidential Information disclosed pursuant to the Non-Disclosure Agreement between Roche-Nutley and BioCryst dated April 5, 2005 shall be considered Confidential Information hereunder.
- 10.2 Authorized Disclosure. Nothing in this Agreement shall prevent either Party from conducting the Patent Activities relating to a patent application or its resulting patents related to a Licensed Product. Nothing in this Agreement shall prevent the Roche Group from disclosing Confidential Information to (i) governmental agencies of any country to the extent required or desirable to secure government approval for the Development, manufacture or sale of Licensed Product, (ii) Third Parties acting on behalf of the Roche Group, to the extent reasonably necessary for the Development, manufacture or sale of Licensed Product (and provided that Roche has a written confidentiality agreement with such Third Party which is as protective of such Confidential Information as the terms of this Agreement), or (iii) Third Parties to the extent reasonably necessary to market Licensed Product (and provided that Roche has a written confidentiality agreement with such Third Party which is as protective of such Confidential Information as the terms of this Agreement). To the extent provided for in this Agreement, BioCryst may disclose Confidential Information to its licensors pursuant to the Pre-Existing Third Party License, provided that

such information shall be treated as Licensee Confidential Information under the Pre-Existing Third Party License.

# **ARTICLE 11 TERMINATION**

11.1 Commencement and Term. The Term of this Agreement shall commence upon the Effective Date and, unless this Agreement is terminated sooner as provided in this Article, expire on the date when no royalty or other payment obligations under this Agreement are or will become due, at which time all the rights and licenses granted to Roche by BioCryst under this Agreement shall automatically become irrevocable and fully-paid.

# 11.2 Termination for Breach.

- (a) A Party ("Non-Breaching Party") shall have the right to terminate this Agreement in accordance with this Section 11.2(a), as follows: (i) \*\*\*; and/or (ii) \*\*\*; and/or (iii) \*\*\*; and/or (iv) \*\*\*; and/or (iv) \*\*\*, in the event the other Party ("Breaching Party") is in breach of any of its material obligations under this Agreement. The Non-Breaching Party shall provide written notice to the Breaching Party, which notice shall identify the breach and the countries in which the Non-Breaching Party intends to have this Agreement terminate. The Breaching Party shall have a period of \*\*\* (\*\*\*) days after such written notice is provided to cure such breach. If such breach is not cured within the \*\*\* (\*\*\*) day period, this Agreement shall effectively terminate in such countries.
- (b) Either Party shall have the right to terminate this Agreement in its entirety by giving written notice to the other Party, in the event of an Insolvency Event of the other Party, such termination to become effective upon delivery of a notice of termination to such Party. Termination pursuant to this Section 11.2(b) shall be considered termination for "cause" for the purposes of this Agreement.
- (c) The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

# 11.3 Termination by Roche Without Cause.

- (a) **Prior to the Commercial Launch of the First Licensed Product**. Prior to the commercial launch of the first Licensed Product, Roche shall have the right to terminate this Agreement (i) \*\*\*, and/or (ii) \*\*\*, and/or (iii) \*\*\*. The effective date of termination shall be \*\*\* (\*\*\*) days after the date Roche provides such written notice.
- (b) **After FDA or EMEA Approval For A Licensed Product.** After FDA or EMEA approval for a Licensed Product, Roche shall have the right to terminate this Agreement on \*\*\* (i) \*\*\*, and/or (ii) \*\*\*, and/or (iii) \*\*\*, and/or (iv) \*\*\*. The effective date of termination shall be \*\*\* (\*\*\*) days after the date Roche provides such written notice.

(c) \*\*\*.

# 11.4 Consequences of Termination.

(a) **Partial Termination.** Upon any partial termination of this Agreement by a Party for breach or by Roche without cause, all rights granted to Roche by BioCryst under this Agreement with respect to such terminated countries shall terminate. Roche shall, to the extent Roche has the right to do so, and hereby does, assign, and shall ensure that its Affiliates assign, and transfer to BioCryst, at no expense to BioCryst, all trademarks and applications used or to be used in connection with Licensed Products in such countries, along with all regulatory filings and approvals and all data, including clinical data, materials (including raw materials and manufactured Licensed Product) and information, along with all INDs, and NDAs submitted by Roche for the Licensed Product in such countries, and to the extent possible, all contract and other rights in Roche's possession or control related to Licensed Products in

such countries, along with tangible embodiments of all of the foregoing. Roche may keep one copy of the foregoing information for archival purposes and to comply with this Agreement. Roche shall deliver to BioCryst all of the foregoing information promptly after the effective date of termination. Upon such transfer and assignment, BioCryst shall have the right to use, disclose and dispose of such materials, rights and licenses in its sole discretion. Roche shall assign or, to the extent such an assignment is prohibited by Law or third party rights, grant an exclusive, fully paid up, sublicensable and transferable license for the Licensed Product in the Field) to BioCryst under Roche Patent Rights and Roche Know-How (with each of the foregoing to include Roche's interest in any joint inventions created by the Parties) in such terminated countries. The parties agree that in the event of a partial termination, BioCryst shall be free to (on its own or with one or more Third Parties) develop and commercialize Licensed Products in any country with respect to which rights under this Agreement have been terminated. To the extent any Roche Patent Rights or Roche Know-How do not solely relate to the Licensed Product, then Roche may grant BioCryst an exclusive license under such rights as set forth above, rather than assign such rights to BioCryst.

- (b) Termination of the Agreement in its Entirety. Upon any termination of this Agreement by a Party for the other Party's uncured material breach or by Roche without cause, (i) all licenses granted to BioCryst by Roche under this Agreement shall become irrevocable, perpetual and fully-paid, (ii) all licenses granted to Roche by BioCryst shall terminate; (iii) Roche shall return to BioCryst all BioCryst Confidential Information and tangible examples and copies thereof; and (iv) Roche shall and hereby does assign or, to the extent such an assignment is prohibited by Law or third party rights, grant an exclusive, fully paid up, sublicensable and transferable license for the Licensed Product in the Field), and shall ensure that its Affiliates assign or exclusively license, to BioCryst all right, title and interest in and to all Roche Know-How and Roche Patents (with each of the foregoing to include Roche's interest in any joint inventions created by the Parties). Roche shall, to the extent Roche has the right to do so, assign and transfer to BioCryst, at no expense to BioCryst, all trademarks and applications used or to be used in connection with Licensed Products in such countries, along with all regulatory filings and approvals and all data, including clinical data, materials (including raw materials and manufactured Licensed Product) and information, along with all INDs, and NDAs submitted by Roche for a Licensed Product and all contract and other rights in Roche's possession or control related to Licensed Products, along with tangible embodiments of all of the foregoing. Roche may keep one copy of the foregoing information for archival purposes and to comply with this Agreement. Roche shall use its commercially reasonable efforts to deliver to BioCryst all of the foregoing in all forms as soon as practicable but no later than \*\*\* (\*\*\*) days of the effective date of termination. Upon such transfer and assignment, BioCryst shall have the right to use, disclose and dispose of such materials, rights and licenses in its sole discretion. To the extent any Roche Patent Rights or Roche Know-How do not solely relate to the Licensed Product, then Roche may grant BioCryst an exclusive license under such rights as set forth above, rather than assign such rights to BioCryst.
- (c) **Further Assurances.** Roche and its Affiliates shall execute and deliver any additional documents or instruments that BioCryst reasonably requests to give effect to the foregoing assignments and licenses under (a) and (b) above.
- (d) **Contract Rights.** Promptly after notice of any termination under (a) or (b) above, Roche shall provide BioCryst with copies of all relevant sublicenses, agreements with clinical research organizations and other Third Party agreements relating to Licensed Products hereunder, and allow BioCryst \*\*\*\* (\*\*\*\*) days from the date of such delivery to choose whether to assume any or all of such contracts to the extent allowed by the applicable contract or Law. Roche shall, subject to its ability to do so, assign to BioCryst those Third Party agreements BioCryst chooses to assume.
- (e) **Transition.** In all cases of termination, Roche shall ensure a swift and orderly transition to BioCryst of all Licensed Products and work in progress, including ongoing clinical trials, in connection with Licensed Products, with the continuing costs for such work assumed by BioCryst as of the effective date of termination.

- (f) **Supply.** In such event, Roche shall supply BioCryst with Compound or with Licensed Product (at BioCryst's option) at \*\*\* for a period of \*\*\* years, and during such period BioCryst shall use its good faith and commercially reasonable efforts to obtain an alternate supply of Compound or Licensed Product. If prior to the end of \*\*\* years BioCryst has obtained an alternate supply of Compound or Licensed Product, then Roche shall be relieved of its supply obligations hereunder.
  - (g) Royalties on Roche Products. Royalties payable on Roche Products will survive termination or expiration of this Agreement.
- **11.5 Royalty and Payment Obligations**. Roche shall continue to make all payments accrued under this Agreement in respect of Net Sales in the terminated countries (for a partial termination) and in all countries (for a complete termination).

# **ARTICLE 12 INDEMNIFICATION**

- 12.1 Indemnification by BioCryst. BioCryst shall indemnify, hold harmless and defend Roche and its Affiliates and Roche's and its Affiliates' directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts Roche becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of or relates to: (i) activities by or on behalf of BioCryst related to Backup Compounds or Special Indication Products that were performed prior to any license to Roche relating to any such Backup Compound or Special Indication Product (provided that all indemnification obligations under this clause (i) with respect to any Backup Compound or Special Indication Product shall terminate immediately upon Roche's license to develop and/or commercialize such Backup Compound or Special Indication Product), and/or (ii) breach of BioCryst's representations and warranties in ARTICLE 13, except to the extent such losses, expenses, costs and amounts are due to the negligence or misconduct or failure to act of Roche.
- 12.2 Indemnification by Roche. Roche shall indemnify, hold harmless and defend BioCryst and its Affiliates and BioCryst's and its Affiliates' licensors, directors, officers, employees and agents from and against any and all losses, expenses, cost of defense (including without limitation attorneys' fees, witness fees, damages, judgments, fines and amounts paid in settlement) and any amounts BioCryst becomes legally obligated to pay because of any claim or claims against it to the extent that such claim or claims arise out of or relates to (i) the making, having made, using, offering for sale, selling or importing Royalty-Bearing Products, Special Indication Products or Backup Compounds (including, with respect to each of the foregoing, Development and/or Commercialization), by or on behalf of Roche or its Affiliates (provided that all indemnification obligations under this clause with respect to any Backup Compound or Special Indication Product shall not include any actions by or on behalf of BioCryst prior to Roche's license to develop and/or commercialize such Backup Compound or Special Indication Product), (ii) any breach of Roche's representations and warranties set forth in ARTICLE 13, and/or (iii) any breach of the Pre-Existing Third Party License Agreement (as read with the Consent and Waiver) arising out of any action or inaction of the Roche Group, or by BioCryst as a result of any action or inaction by or on behalf of the Roche Group or as a result of any direction or request by Roche, except to the extent such losses, expenses and costs are due to the negligence or misconduct or failure to act of BioCryst.
- 12.3 Procedure. In the event of a claim by a Third Party against a Party entitled to indemnification under this Agreement ("Indemnified Party"), the Indemnified Party shall promptly notify the other Party ("Indemnifying Party") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party and may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto, unless the Indemnified Party otherwise agrees in writing.

**12.4 Limitation on Damages.** In no event shall either Party be liable to the other Party for special, indirect, incidental or consequential damages arising out of this Agreement other than in connection with such Party's indemnification obligations under this Agreement.

# **ARTICLE 13 REPRESENTATIONS AND WARRANTIES**

#### 13.1 Mutual Representations and Warranties. Each Party hereby represents and warrants:

- (a) **Authority.** Such Party has the full right and authority to enter into this Agreement, and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.
- (b) **Material Facts.** Such Party has made available to the other Party information in its possession or control which it reasonably deems material to the other Party's decision whether to enter into this Agreement, and to such Party's knowledge, information disclosed does not contain any untrue statement of material fact or omit to state a material fact.

# 13.2 BioCryst Representations and Warranties. BioCryst warrants and represents that:

- (a) **Safety Data.** BioCryst has allowed Roche access to all material information containing, and will continue to allow Roche access to information containing (i) the results of all preclinical testing and human clinical testing of Licensed Product in its possession or control and (ii) all material information in its possession or control concerning side effects, injury, toxicity or sensitivity reaction and incidents or severity thereof with respect to Licensed Product.
- (b) **Patents.** BioCryst has no knowledge of the existence of any patent or patent application owned by or licensed to the licensors of the Pre-Existing Third Party License or any other Third Party which would prevent the Roche Group from making, having made, using, offering for sale, selling or importing Licensed Product. BioCryst has in the past and will continue in the future to comply with its duty of candor to the United States Patent & Trademark Office in connection with the Patent Activities of any BioCryst Patent. Exhibit 1.7 is a complete listing of all patents and patent applications that are necessary for the manufacture, use or sale of the Compound or Licensed Product(s) and that are owned or Controlled by BioCryst as of the Effective Date.
  - (c) Grants. BioCryst has the right to grant Roche the rights and licenses described in this Agreement.
- (d) **Authorization.** The execution, delivery and performance of this Agreement by BioCryst and all instruments and documents to be delivered by BioCryst hereunder: (i) are within the corporate power of BioCryst; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of formation or limited liability company agreement of BioCryst; (iv) to the knowledge of BioCryst, will not violate any Law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which BioCryst is a Party or by which BioCryst or any of its property is bound, which violation would have an adverse effect on the financial condition of BioCryst or on the ability of BioCryst to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other Person, which has not been made or obtained previously (other than approvals required under the HSR Act, Regulatory Approvals required for the Sale of Licensed Products and filings with regulatory authorities required in connection with Licensed Products).
- (e) **Due Execution.** This Agreement has been duly executed and delivered by BioCryst and constitutes a legal, valid and binding obligation of BioCryst, enforceable against BioCryst in accordance with its terms, except as such enforceability may be limited by the availability of equitable remedies.

- (f) **No Claims.** There are no claims or investigations (other than with respect to the Parties' HSR Filings), pending or threatened against BioCryst or any of its Affiliates, at Law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially adversely affect BioCryst's ability to perform its obligations hereunder.
- (g) **No Conflict.** Neither BioCryst nor any of its Affiliates is or will be under any obligation to any person, contractual or otherwise, that is conflicting with the terms of this Agreement or that would impede the fulfillment of BioCryst's obligations hereunder.

# 13.3 Roche Representations and Warranties.

- (a) **Authorization.** The execution, delivery and performance of this Agreement by Roche and all instruments and documents to be delivered by Roche hereunder: (i) are within the corporate power of Roche; (ii) have been duly authorized by all necessary or proper corporate action; (iii) are not in contravention of any provision of the certificate of formation or limited liability company agreement of Roche; (iv) to the knowledge of Roche, will not violate any Law or regulation or any order or decree of any court of governmental instrumentality; (v) will not violate the terms of any indenture, mortgage, deed of trust, lease, agreement, or other instrument to which Roche is a Party or by which Roche or any of its property is bound, which violation would have an adverse effect on the financial condition of Roche or on the ability of Roche to perform its obligations hereunder; and (vi) do not require any filing or registration with, or the consent or approval of, any governmental body, agency, authority or any other Person, which has not been made or obtained previously (other than approvals required under the HSR Act, Regulatory Approvals required for the Sale of Licensed Products and filings with regulatory authorities required in connection with Licensed Products).
- (b) **Due Execution.** This Agreement has been duly executed and delivered by Roche and constitutes a legal, valid and binding obligation of Roche, enforceable against Roche in accordance with its terms, except as such enforceability may be limited by the availability of equitable remedies.
- (c) **No Claims.** There are no claims or investigations (other than with respect to the Parties' HSR Filings), pending or threatened against Roche or any of its Affiliates, at Law or in equity, or before or by any governmental authority relating to the matters contemplated under this Agreement or that would materially adversely affect Roche's ability to perform its obligations hereunder.
- (d) **No Conflict.** Neither Roche nor any of its Affiliates is or will be under any obligation to any person, contractual or otherwise, that is conflicting with the terms of this Agreement or that would impede the fulfillment of Roche's obligations hereunder.
- (e) **Insurance**. Roche represents and warrants that during the Term of this Agreement and for a period of ten years thereafter, it has and shall maintain adequate insurance and/or financial resources to cover all liability for any failure of such Licensed Product including, without limitation, failure in design, manufacture, production and/or operation. BioCryst acknowledges that Roche may choose to be self-insured.
- (f) **Investigation.** Roche has received all information that Roche or any of its Affiliates has requested from BioCryst with respect to the transactions contemplated hereby, and has had a reasonable opportunity to ask questions of BioCryst and its representatives; and BioCryst has answered all inquiries made by Roche, its Affiliates and their representatives. Roche has had the opportunity to evaluate the merits and risks of the transactions as contemplated by this Agreement. Furthermore, no representations or warranties have been made by BioCryst to Roche upon which Roche is relying in connection with the transactions contemplated by this Agreement, other than as set forth in this Agreement.
- **13.4 HSR Act and Other Applicable Governmental Filings.** BioCryst and Roche each covenant to timely make any required application pursuant to the HSR Act. Each Party shall cooperate fully and promptly in the HSR notification process as well as any other applicable governmental or regulatory filing.

13.5 No Debarment. None of the Roche Group has been debarred or is the subject of debarment proceedings by any Regulatory Authority. Roche shall not knowingly use in connection with its performance of its obligations or duties or its exercise of its rights under this Agreement (including, without limitation, the Development of any Licensed Products) any employee, consultant or investigator that has been debarred or the subject or debarment proceedings by any Regulatory Authority. BioCryst and its Affiliates have not been debarred and are not the subject of debarment proceedings by any Regulatory Authority. BioCryst and its Affiliates shall not knowingly use in connection with its performance of its obligations or duties or its exercise of its rights under this Agreement (including, without limitation, the Development of any Licensed Products) any employee, consultant or investigator that has been debarred or the subject or debarment proceedings by any Regulatory Authority.

**13.6 No PNP Inhibitors.** As of the Effective Date, the Roche Group does not have clinical programs relating to, and does not have any current plans to develop, any PNP Inhibitor other than Licensed Product.

13.7 No Other Representations. EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT, THE FOREGOING REPRESENTATIONS AND WARRANTIES ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF COMPOUND AND LICENSED PRODUCTS. SPECIFICALLY, BIOCRYST MAKES NO OTHER REPRESENTATIONS OR WARRANTIES IN RELATION TO THE BIOCRYST PATENTS, THE BIOCRYST KNOW-HOW, THE COMPOUND (INCLUDING COMPOUND SUPPLIED HEREUNDER), THE BACKUP COMPOUNDS OR THE LICENSED PRODUCTS. SPECIFICALLY ROCHE MAKES NO OTHER REPRESENTATIONS OR WARRANTIES IN RELATION TO THE ROCHE PATENTS, THE ROCHE KNOW-HOW, THE COMPOUND OR THE BACKUP COMPOUNDS OR THE LICENSED PRODUCTS. BIOCRYST SHALL HAVE NO LIABILITY WHATSOEVER ARISING OUT OF OR RELATING TO COMPOUND SUPPLIED TO ROCHE HEREUNDER.

# **ARTICLE 14 CONDITIONS TO CLOSING**

# 14.1 Conditions Subsequent.

- (a) The effectiveness of this Agreement and the transactions contemplated hereunder shall be subject to and contingent upon the satisfaction under the following condition subsequent to the execution of this Agreement. The condition subsequent shall be the earlier to occur of (i) approval of the transaction by the Federal Trade Commission or any other applicable governmental authority, or (ii) expiration or termination of all applicable waiting periods, and requests for information (and any extensions thereof) under the HSR Act or other applicable Law. Subject to the terms and conditions of this Agreement, each Party shall use all reasonable efforts to take, or cause to be taken, all reasonable actions and to do, or cause to be done, all things necessary and appropriate to satisfy the condition subsequent and to consummate the transactions contemplated by this Agreement. Each Party shall cooperate with the other Party in the preparation, execution and filing of all documents that are required or permitted to be filed on or before the Closing Date for the purpose of consummating this transaction, including, filings pursuant to the HSR Act or other governmental filing. Each Party shall bear its own costs (including counsel or other expert fees) with respect to preparing, executing and filing such documents; provided that Roche shall be obligated to pay all filing fees under the HSR Act.
- (b) Either Party may terminate this Agreement in its entirety, upon ten (10) days prior written notice to the other Party if the condition subsequent under Section 14.1(a) has not been fulfilled within six (6) months after the Signing Date, in which case, upon termination, there shall be no liabilities for obligations on the part of either Party except if there has been a breach of this Section 14.1.

# ARTICLE 15 DISPUTE RESOLUTIONS AND GOVERNING LAW

**15.1 Disputes.** Unless otherwise set forth in this Agreement, in the event of a dispute arising under or relating to this Agreement between the Parties and/or their Affiliates, such dispute shall be referred to

the respective executive officers of the Parties designated below, or their successors, for good faith negotiations attempting to resolve the dispute. The designated executive officers are as follows:

For Roche: CEO of the Pharma Division

For BioCryst: Chairman and CEO

If the positions of the designated executive officers listed above are vacant or no longer exist, then the person having the most nearly equivalent position (or such individual's designee) shall be deemed to be the designated executive officer of the relevant Party.

- **15.2 Arbitration.** Following the Parties' attempt to resolve a given dispute pursuant to the above Section 15.1, either Party as its exclusive recourse subject to Sections 15.2(c) and 15.3(c) may have the given dispute settled by binding Arbitration in the manner described below:
- (a) **Arbitration Request.** If a Party intends to begin arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues to be resolved. From the date of the Arbitration Request and until such time as any matter has been finally settled, the running of the time periods as to which Party must cure a breach of this Agreement shall be suspended as to the subject matter of the dispute.
- (b) **Additional Issues.** Within \*\*\* (\*\*\*) business days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues to be resolved.
- (c) **No Arbitration of Intellectual Property Issues.** Notwithstanding anything to the contrary in this Agreement, unless otherwise agreed by the Parties, disputes relating to intellectual property shall not be subject to arbitration, and shall be submitted to a court of competent jurisdiction.
- **15.3 Arbitration Procedure.** The Arbitration (including with respect to discovery) shall be conducted pursuant to the rules of the American Arbitration Association. If Roche is the Party initiating Arbitration, the Arbitration shall be held in Birmingham, Alabama. If BioCryst is the Party initiating Arbitration, the Arbitration shall be held in Newark, New Jersey. The Arbitration shall be conducted in English by three arbitrators. Each Party shall select one arbitrator within \*\*\*\* (\*\*\*\*) days of the Arbitration Request. Should a Party not select an independent arbitrator within \*\*\*\* (\*\*\*\*) days of the Arbitration Request, the American Arbitration Association shall select an arbitrator on behalf of the Party. The two (2) arbitrators selected by the Parties shall select a third, neutral, arbitrator within \*\*\*\* (\*\*\*\*) days after the Arbitration Request. Should the arbitrators not select a third, neutral, arbitrator within such time period, the American Arbitration Association shall select an arbitrator on their behalf. The third neutral arbitrator shall not be associated with either Party.
- (a) The arbitrators may award any remedy allowed by Law, excluding punitive damages and attorneys' fees. Promptly after rendering a decision, the arbitrators shall issue to both parties a written opinion of the findings of fact and conclusions of Law. The decision of the arbitrators shall be binding upon the parties without the right of appeal, and judgment upon the decision rendered by the arbitrator may be confirmed and enforced in any court of competent jurisdiction.
- (b) The parties shall share equally the reasonable documented cost of such Arbitration procedure. Each Party shall bear its own cost in participating in such proceeding.
  - (c) Nothing herein limits in any way either Party's right to seek injunctive relief.
- **15.4 Governing Law.** This Agreement is made in accordance with and shall be governed and construed under the Laws of Delaware, without regard to its choice of law principles.

# **ARTICLE 16 PUBLICITY**

16.1 Initial Press Release. The Parties will issue the initial press release(s) attached hereto as Exhibit 16.1 on the Effective Date.

**16.2 Subsequent External Communications.** Each Party shall only issue external media and investor communications, including press releases related to the activities contemplated by this Agreement that have either (i) been approved by the other Party or (ii) are required to be issued by such Party as a matter of Law as determined by such Party's legal counsel. In all circumstances, the Party issuing the external media or investor communication shall provide the other Party with a copy of the press release or external communication at least \*\*\* prior to its intended publication or communication for the other Party's review. During such period, the other Party shall (i) approve the draft press release or communication and permit the party issuing the press release to issue the press release, (ii) contact the Party issuing the press release or communication to discuss modification to the draft press release or communication, or (iii) contact the Party issuing the press release or communication and disapprove the press release or communication. If the other Party asks for modification, then the Party issuing the press release or communication shall either make such modification or work with the other Party to arrive at a press release or communication that the other Party approves.

16.3 Disclosures Required by Law. Nothing in this Agreement shall impair either Party's compliance with any requirements of:
(i) governmental agencies to the extent required or desirable to secure government approval for the development, manufacture or sale of Licensed Product in the Territory (ii) the Securities and Exchange Commission or the national securities exchange or other stock market on which such Party's securities are traded, (iii) or any other applicable Law. In connection with any filing by either Party of a copy of this Agreement with the Securities and Exchange Commission (or the national securities exchange or other stock market on which such Party's securities are traded), the filing Party shall endeavor to obtain confidential treatment of economic and trade secret information. Reasonably in advance of any filing under this Section (whether or not this Agreement is included in the filing), the filing Party shall provide to the other Party a copy of the proposed filing and the Parties shall work cooperatively in good faith, taking into consideration the other Party's suggestions, regarding the information for which the filing Party will seek to obtain confidential treatment. However, in the event of any disagreements that cannot be amicably resolved, the Party which is making the filing shall, together with input from their own legal counsel, have the ultimate authority to make the filing in the fashion in which it feels the filing must be made.

**16.4 Publications.** During the Term of this Agreement, the following restrictions shall apply with respect to disclosure by any Party of Confidential Information relating to the Product in any publication or presentation:

(a) Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines. Roche, in accordance with its internal policies and procedures, shall have the right to publish all studies, clinical trials and results thereof on the clinical trial registries which are maintained by or on behalf of Roche. BioCryst shall not publish any studies, clinical trials or results thereof on its clinical trial registry, provided however, that Roche's clinical trial registry can be accessed via a link from BioCryst's clinical trial registry.

(b) A Party ("Publishing Party") shall provide the other Party with a copy of any proposed publication or presentation at least \*\*\* (\*\*\*) days (or at least \*\*\* days in the case of oral presentations) prior to submission for publication so as to provide such other party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other party to the Publishing party in accordance with the requirements of this Agreement. The incorporation of such recommended changes shall not be unreasonably refused; and If such other party notifies ("Notice") the Publishing Party in writing, within \*\*\* (\*\*\*) days after receipt of the copy of the proposed publication or presentation (or at least \*\*\* (\*\*\*) days in the case of oral presentations), that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived and/or reduced to practice by the other party, for which the other party

reasonably desires to obtain patent protection or (ii) contains any Confidential Information disclosed by the other party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than \*\*\* (\*\*\*) days from the date of the Notice.

**16.5 Use of Name**. Neither Party shall use the other Party's or its Affiliates name or trademarks for publicity or advertising purposes, except with the prior written consent of the other Party. Subject to Section 16.3, Roche shall not use any of BioCryst's licensors' names or trademarks for publicity or advertising purposes (or any other information relating to the Pre-Existing Third Party License), except with the prior written consent of BioCryst.

# **ARTICLE 17 MISCELLANEOUS**

- 17.1 Pre-Existing Third Party License. Roche acknowledges and agrees that the terms of this Agreement are subject in all respects to the terms and conditions of the Pre-Existing Third Party License, as amended, \*\*\*, which have been previously provided to Roche. Roche further agrees that (i) the licensors under the Pre-Existing Third Party License retained certain rights as described in Section 2.1(b) above, which are not granted to Roche hereunder; (ii) such licensors shall be deemed to be third party beneficiaries of this Agreement; (iii) all Confidential Information provided to BioCryst hereunder may be shared with such licensors under the terms and conditions of \*\*\*\*; and (iv) Roche shall fully cooperate with BioCryst to assist BioCryst in complying with its obligations (including but not limited to recordkeeping and information sharing) under the Pre-Existing Third Party License \*\*\*.
- **17.2 Extended Benefits.** Roche may extend any benefit and assign any right under this Agreement to its Affiliates and Roche guarantees the performance of all obligations imposed on such Affiliates by such extension or assignment. Each of Roche Nutley and Roche Basel shall be jointly and severally liable for the obligations of Roche hereunder.
- **17.3 Survival.** Any provisions which by their nature are intended to survive termination of this Agreement shall survive termination of this Agreement for any reason, including, without limitation, Articles 1, 8, 10, 12 and 15 and Sections 7.3, 7.4, 7.5, 7.6, 7.8, 7.9, 11.4, 11.5, 17.3, 17.5, 17.10 and 17.12.
- **17.4 Agency.** Neither Party is, nor will be deemed to be, an employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.
- **17.5 Entire Agreement.** This Agreement, including all Exhibits and Schedules, embodies the entire understanding of the Parties with respect to the subject matter hereof and supersedes all previous communications, representations or understandings, and agreements, whether oral or written, between the Parties relating to the subject matter hereof.
- **17.6 Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which, taken together, shall constitute one and the same instrument. Original signatures hereto may be delivered by facsimile which shall be deemed originals.
- 17.7 Amendment. No amendment or modification hereof shall be valid or binding upon the parties unless made in writing and signed by both Parties.
- **17.8 Assignment.** This Agreement shall not be assignable in part or in whole, by operation of Law or otherwise, by any Party without the prior written consent of the other; provided, however, that either Party, without notice and at any time for any reason, may assign this Agreement in whole or in part to (i) any of its Affiliates who agree to be bound by the terms and conditions of this Agreement or (ii) any successor of

such Party by merger or sale of all or substantially all of its pharmaceutical business assets. In the event of assignment to an Affiliate, the Party making the assignment will remain liable and responsible for the performance and observance of all its duties and obligations hereunder.

17.9 Requirement to Divest. If Roche is required by a relevant Regulatory Authority in a Major Market Country to divest rights to a Licensed Product with respect to which Roche has not commenced the Start of Phase III trial prior to the order to divest, then Roche shall use its commercially reasonable efforts to obtain authority to fulfill such requirements by returning rights to BioCryst in and to such Licensed Product in accordance with the procedures specified in Section 11.4(b). If Roche is required by a relevant Regulatory Authority in a Major Market Country to divest rights to a Licensed Product with respect to which Roche has commenced the Start of Phase III trial prior to the order to divest, then Roche shall afford BioCryst a reasonable opportunity to acquire such rights on terms no less advantageous than those granted to other potential acquirers of such rights, including in bidding or other acquisition processes.

**17.10 Notices.** Any notice or other communication to be given under this Agreement, unless otherwise specified, shall be in writing and shall be deemed to have been provided when delivered to the addressee at the address listed below (i) on the date of delivery if delivered in person or (ii) one (1) day after mailing to the other Party by express mail or overnight delivery service, which obtains a signed receipt, or (iii) three (3) days after mailing by registered or certified mail, postage paid:

# In the case of BioCryst:

BioCryst Pharmaceuticals, Inc. 2190 Parkway Lake Drive Birmingham, Alabama 35244

Attention: Chairman and CEO

Telephone: 205-444-4600 Fax: 205-444-4640

With a copy to:

Proskauer Rose LLP 1585 Broadway New York, New York 10036

Attention: Daryn Grossman, Esq.

Telephone: (212) 969-3000 Fax: (212) 969-2900

In the case of Roche:

Hoffmann-La Roche Inc. 340 Kingsland Street Nutley, New Jersey 07110

Attention: Corporate Secretary

With a copy to:

F.Hoffmann-La Roche Ltd. Grenzacherstrasse 124 CH-4002 Basel, Switzerland

Attention: Law Department

Either Party may change its address for communications by a notice in writing to the other Party in accordance with this Section.

**17.11 Force Majeure.** Any prevention, delay or interruption of performance (collectively "**Delay**") by any Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected by the force majeure, including but not limited to acts of God, embargoes, governmental restrictions, strikes or other concerted acts of workers, fire, flood, earthquake, explosion, riots, wars, terrorism, civil disorder, rebellion or sabotage. The affected Party shall immediately notify the other Party upon the commencement and end of the Delay and any time for performance hereunder shall be extended by the actual time of Delay. If the Delay resulting from the force majeure exceeds six (6) months, the other Party, upon written notice to the affected Party, may elect to (i) treat such Delay as a material breach, or (ii) extend the term of this Agreement for an amount of time equal to the Delay.

**17.12 Affiliates**. Roche shall cause its Affiliates to comply with Roche's obligations hereunder.

17.13 Bankruptcy. All licenses (and to the extent applicable rights) granted under or pursuant to this Agreement by BioCryst to Roche are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, US Code (the "Bankruptcy Code") licenses of rights to "intellectual property" as defined under Section 101(60) of the Bankruptcy Code. Unless Roche elects to terminate this Agreement, the Parties agree that Roche, as a licensee or sublicensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, subject to the continued performance of its obligations under this Agreement.

**17.14 Severability.** If any term or condition of this Agreement is held by a court of competent jurisdiction to be unenforceable for any reason, it shall, if possible, be interpreted to achieve the intent of the Parties to this Agreement rather than voided. If not capable of such interpretation, the Parties shall in good faith seek to agree on an alternative provision reflecting the intent of the Parties which is enforceable. In any event, all other terms, conditions and provision of this Agreement shall be deemed valid and enforceable to the full extent.

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**IN WITNESS WHEREOF**, the Parties have executed this Agreement as of the day and year first above written.

# BIOCRYST PHARMACEUTICALS, INC.

# HOFFMANN-LA ROCHE INC.

By: /s/ Charles E. Bugg

Name: Charles E. Bugg Title: Chairman and CEO By: /s/ Frederick C. Kentz III

Name: Frederick C. Kentz III Title: Vice President

# F. HOFFMANN-LA ROCHE LTD

By: /s/ Peter Hug

Name: Dr. Peter Hug

Title: Executive Vice President

Pharma Partnering

By: /s/ Melanie Frey Wick

Name: Dr. Melanie Frey Wick Title: Authorized Signatory