

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

IMMUNEX CORP /DE/

CIK: **719529** | IRS No.: **510346580** | State of Incorporation: **WA** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-12406** | Film No.: **02637115**
SIC: **2836** Biological products, (no diagnostic substances)

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*51 UNIVERSITY STREET
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

CURRENT REPORT

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

April 12, 2002

Date of Report (Date of earliest event
reported)

IMMUNEX CORPORATION

(Exact Name of Registrant as Specified in Charter)

Washington

0-12406

51-0346580

(State or Other Jurisdiction
of Incorporation)

(Commission File No.)

(IRS Employer
Identification No.)

51 University Street, Seattle, Washington 98101

(Address of Principal Executive Offices)

(Zip Code)

(206) 587-0430

(Registrant's Telephone Number, Including Area Code)

None

Item 5. Other Events.

On April 12, 2002, Immunex Corporation, a Washington corporation ("Immunex"), entered into an ENBREL Supply Agreement with Genentech, Inc., a Delaware corporation ("Genentech"). Under the Supply Agreement, Genentech will manufacture commercial quantities of ENBREL (R) (etanercept) at its manufacturing facility in South San Francisco, California. Subject to approval by the Food and Drug Administration, the facility is expected to supply capacity for ENBREL beginning in 2004.

Item 7. Financial Statements, Pro Forma Financial Information and Exhibits.

(c) Exhibits.

10.1* ENBREL Supply Agreement, dated April 12, 2002, by and between Immunex Corporation and Genentech, Inc.

99.1 Immunex press release dated April 15, 2002.

* Confidential treatment requested.

SIGNATURE

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

IMMUNEX CORPORATION

Dated: May 6, 2002

By /s/ Barry G. Pea

Name: Barry G. Pea

Its: Executive Vice President, General
Counsel and Secretary

EXHIBIT INDEX

| Exhibit Number | Description |
|----------------|---|
| ----- | ----- |
| 10.1* | ENBREL Supply Agreement, dated April 12, 2002, by and between |

99.1

Immunex Corporation and Genentech, Inc.
Immunex press release dated April 15, 2002.

* Confidential treatment requested.

ENBREL SUPPLY AGREEMENT

THIS ENBREL SUPPLY AGREEMENT ("Agreement") is made effective as of April 12, 2002, by and between Immunex Corporation, a Washington corporation, having its principal place of business at 51 University Street, Seattle, Washington 98101 ("Immunex"), and Genentech, Inc., a Delaware corporation, having its principal place of business at One DNA Way, South San Francisco, California 94080 ("Genentech").

BACKGROUND

Immunex markets and sells a certain proprietary biological pharmaceutical product known as ENBREL(R) (etanercept). Immunex desires to obtain additional supply of commercial quantities of ENBREL bulk drug substance. Genentech has the experience and expertise necessary to perform the manufacturing and related services needed to supply ENBREL bulk drug substance, and Genentech owns a facility that, with some modifications, could be suitable for production of commercial quantities of ENBREL bulk drug substance.

Immunex desires to retain Genentech as a nonexclusive manufacturer of commercial quantities of ENBREL bulk drug substance and purchase commercial quantities of such product from Genentech, and Genentech desires to perform such services and sell commercial quantities of such product to Immunex, all on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, IN CONSIDERATION OF the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1. DEFINITIONS

The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement.

1.1 "Acquisition Cost" means the actual invoiced price paid by Genentech to any Third Party for acquiring any materials used in the manufacture of the

Product under this Agreement, including, but not limited to, shipping and handling costs and customs duties incurred and paid by Genentech in connection with the acquisition of such materials, and also including [*] percent ([*]%) of the above amounts to cover such

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Party's storage and overhead costs. This definition, including the [*] percent ([*]%) markup, shall only apply in the circumstances set forth in Section 6.2(a)(5) and Section 19.3(d)(1) hereof.

1.2 "Affiliate" means, with respect to any Party, any other corporation or

business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, resolution or otherwise.

1.3 "Batch" or "Lot" means the quantity of Bulk Drug produced from a single

Run, and refers to a Commercial Batch or Lot, a Development Batch or Lot, and/or a Qualification Batch or Lot, as the context requires. A Run may result in more than one subbatch or subplot due to splitting into tanks downstream in the Manufacturing Process.

1.4 "Batch Records" shall have the meaning set forth in the Quality Agreement.

1.5 "BIP" means Boehringer Ingelheim Pharma KG.

1.6 "BIP Confidential Information" means Immunex Confidential Information that

has been identified in writing as confidential information of BIP, and is referred to in Section 17.6 hereof.

1.7 "Bulk Drug" means the bulk form of the Product which has been manufactured

by Genentech pursuant to this Agreement, which has been purified to a concentrated form from one or more Batches and can be stored in a liquid or

frozen form under appropriate conditions, and, except with respect to Non-Conforming Bulk Drug, which has been manufactured in compliance with cGMP and conforms to the Bulk Drug Specifications.

- 1.8 "Bulk Drug Commitment" refers to the first [*] months of each binding

rolling Product Manufacturing Forecast (including all amendments thereto), and means a commitment by Genentech to comply with and perform the number of Runs set forth therein. The Bulk Drug Commitment is a rolling [*] month commitment, and is described with more particularity in Section 4.2 hereof.

- 1.9. "Bulk Drug Specifications" means specifications developed by Immunex for

Bulk Drug as set forth in the Product sBLA, including, without limitation, testing methods and acceptance criteria for each Batch generated, a summary of which is attached to the Quality Agreement, as such specifications may be amended from time to time in accordance with Section 6.2 hereof,

including, without limitation, such amendments as

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may be required to obtain approval from the FDA and other applicable regulatory authorities in the United States.

- 1.10 "cGMP" means the regulatory requirements for current good manufacturing

practices promulgated by the FDA under the FD&C Act, 21 C.F.R.(S)(S)210, 211 and 600 et seq. and under the PHS Act, 21 C.F.R.(S)(S)600-610, as the same may be amended from time to time.
- 1.11 "Cell Line" means a proprietary Immunex Chinese Hamster Ovary cell line

that expresses the Product.
- 1.12 "Certificate of Analysis" means, for each Batch, a document prepared by

Immunex: (a) listing tests performed by Immunex, specifications, test date(s), and test results, and certifying the accuracy of the foregoing; (b) referring to the related Certificate of Compliance prepared by Genentech, listing the manufacturing date, unique Batch number, and quantity of Bulk Drug in such Batch, as certified by Genentech in such Certificate of Compliance; and (c) referring to the related Certificate of Testing prepared by Genentech, listing tests performed by Genentech,

specifications, test date(s), and test results, as certified by Genentech. The Parties shall from time to time agree upon a format or formats for the Certificate of Analysis to be used under this Agreement.

1.13 "Certificate of Compliance" means, for each Batch, a document prepared by -----

Genentech: (a) listing the manufacturing date, unique Batch number, and quantity of Bulk Drug in such Batch, and (b) certifying that such Batch was manufactured in accordance with the Bulk Drug Specifications and cGMP. The Parties shall from time to time agree upon a format or formats for the Certificate of Compliance to be used under this Agreement.

1.14 "Certificate of Testing" means, for each Batch, a document prepared by -----

Genentech: (a) listing tests performed by Genentech, specifications, and test results, and (b) certifying the accuracy of the foregoing. The Parties shall from time to time agree upon a format or formats for the Certificate of Testing to be used under this Agreement.

1.15 "Change of Control" means the merger, acquisition or consolidation of -----

Immunex with or into Amgen Inc. or a subsidiary of Amgen Inc.

1.16 "Commercial Batch" or "Commercial Lot" means a Batch or Lot produced from a -----

Commercial Run.

1.17 "Commercial Run" means a Run that is initiated following the commencement -----

of Commercial Production and is used to manufacture commercial Bulk Drug.

1.18 "Commercially Reasonable Efforts" means [*]. -----

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1.19 "Commercially Reasonable Best Efforts" means: for Immunex, [*]; and for -----

Genentech, [*].

1.20 "Confidential Information" means Immunex Confidential Information and/or -----

Genentech Confidential Information, as the context requires.

1.21 "Development Batch" means a Batch or Lot produced from a Development Run.

-
- 1.22 "Development Run" means a Run used for process demonstration and

confirmation of some or all of the Manufacturing Process steps, and is
described in Section 3.7(a) hereof.

- 1.23 "Effective Date" means April 12, 2002, which is the date set forth in the

first paragraph of this Agreement and shall be the effective date of this
Agreement.
- 1.24 "EMEA" means the European Medicines Evaluation Agency, or any successor

agency.
- 1.25 "Enbrel License Agreement" means that certain License Agreement for

Etanercept between Immunex and Genentech dated [*].
- 1.26 "Facility Modifications and Services Costs" means the actual invoiced price

paid by Genentech to any Third Party for acquiring services, including,
without limitation, design and engineering services, and necessary
equipment, for modifications to the Genentech Facility needed to implement
the Manufacturing Process at the Genentech Facility, all to the extent
incurred in accordance with the Tech Transfer Agreement, and including,
without limitation, such amounts incurred in accordance with the Letter of
Intent (and also including, without limitation, such amounts incurred in
accordance with the Letter of Intent after expiration of the Letter of
Intent and prior to or on the Effective Date of this Agreement, as if the
Letter of Intent had been extended through and including the Effective Date
of this Agreement).
- 1.27 "Facility Validation" shall have the meaning ascribed to it in the Tech

Transfer Agreement.
- 1.28 "FD&C Act" means the United States Federal Food, Drug and Cosmetic Act, as

the same may be amended from time to time.
- 1.29 "FDA" means the United States Food and Drug Administration, or any

successor agency thereto.
- 1.30 "Field" shall mean the manufacture of Product utilizing the manufacturing

process in actual use as of the Effective Date, as well as any
modifications to such manufacturing process that are implemented in

accordance with this Agreement into the manufacturing process actually used by Genentech in manufacturing Product pursuant to this Agreement, as well as any other modifications to such manufacturing process

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that are implemented by Immunex, its Affiliates, Product licensees or contract manufacturers for Product either during or, with respect to [*].

1.31 "Finished Product" means Bulk Drug which has been formulated, compounded, -----
filled into containers, and labeled, and placed in final commercial packaging.

1.32 "For Cause Audit" shall have the meaning set forth in the Quality -----
Agreement.

1.33 "Genentech Confidential Information" means all technical and other -----
information, whether patented or unpatented, relating to the Genentech Facility and/or Genentech processes, methods, operations, technologies, forecasts and business information that are disclosed or supplied to, or used on behalf of Immunex by Genentech pursuant to this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or of which Immunex may become aware of through the presence of their employees or agents at Genentech offices or at the Genentech Facility, including, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans and information and facility layout and schematics.

1.34 "Genentech Facility" means Genentech's commercial manufacturing facility -----
located at One DNA Way in South San Francisco, California. In addition, in the event Genentech, in its sole discretion, utilizes storage capacity in its Vacaville, California facility to store Bulk Drug, then the term "Genentech Facility" includes, when and as the context requires, -----
Genentech's facility located in Vacaville, California, but only to the extent that, and with respect to those portions of, the Vacaville facility that is used by Genentech to perform Genentech's obligations hereunder.

1.35 [*]

1.36 "Genentech Patents" shall have the same definition as set forth in the

Enbrel License Agreement.

1.37 "Genentech [*] Patents" shall mean Patents containing claims covering [*],

in each case which were [*].

1.38 "Immunex Confidential Information" means the Cell Line, Master Cell Bank,

Working Cell Bank, Manufacturing Documentation, Manufacturing Process, and Product, and all technical and other information, whether patented or unpatented, relating thereto and/or to Immunex processes, methods, operations, technologies, forecasts and business information that are disclosed or supplied to Genentech by or on behalf of Immunex pursuant to this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or of which Genentech may become aware of through the presence of its employees or agents at Immunex offices or facilities or at other facilities that manufacture the Product, including, without limitation, trade secrets, know-how, processes, concepts, experimental methods and results and business and scientific plans and information and facility layout and schematics. All portions of documents

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and records describing or to the extent relating to the Manufacturing Process at the Genentech Facility, including, without limitation, process trend and variability data related to the Product, shall be deemed to be Immunex Confidential Information.

1.39 "Letter of Intent" means that certain letter of intent and authorization to

proceed between the Parties dated February 4, 2002, as amended on March 22, 2002, regarding the intent of the Parties to negotiate in good faith and execute this Agreement, and which letter is superceded in accordance with its terms by this Agreement.

1.40 "Manufacturing Documentation" means all documents and records describing or

otherwise related to the Manufacturing Process or any part of the Manufacturing Process provided to Genentech by or on behalf of Immunex under this Agreement, the Tech Transfer Agreement or the Quality Agreement, including, without limitation, documents and records consisting of or containing piping and instrumentation diagrams, software logic and descriptions, batch records, standard operating procedures, including, without limitation, standard operating procedures for in-process quality

control testing, facility layout schematics, equipment and instrumentation specifications and process trend and variability data.

- 1.41 "Manufacturing Process" means the [*] production process for the

manufacture of Bulk Drug pursuant to this Agreement, as summarily described
in the Quality Agreement and as described in the Tech Transfer Agreement,
as such process may be changed from time to time in accordance with this
Agreement. [*]
- 1.42 "Master Cell Bank" means Immunex's reference deposit or collection of vials

of the Cell Line, from which the Working Cell Bank is derived.
- 1.43 "Milestone I" means [*], and is referred to in Section 5.2(a) hereof.

- 1.44 "Milestone II" means [*] referred to in Section 5.2(b) hereof.

- 1.45 "Milestone III" means [*] or, if earlier, [*], and is referred to in

Section 5.2(c) hereof.

- 1.46 "Milestone IV" means [*], and is referred to in Section 5.2(d) hereof.

- 1.47 "Net Sales" shall have the same definition as set forth in the Enbrel

License Agreement.
- 1.48 "Non-Conforming Bulk Drug" means Bulk Drug that fails to conform to any of

the warranties set forth in Section 6.1(a) hereof.

- 1.49 "Non-Portable Equipment" means the Equipment (as defined in Section 14.2

hereof), excluding any Portable Equipment. Components of the Non-Portable
Equipment, such as valves, pumps and agitators, shall also be deemed
Non-Portable Equipment. Non-Portable Equipment includes the related
documentation regarding the design,

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validation, operation, calibration and maintenance of such equipment.

1.50 "PHS Act" means the Public Health Service Act, Biological Products, as

amended, as the same may be amended from time to time.

1.51 "Party" or "Parties" means Genentech and/or Immunex, as the context

requires.

1.52 "Patents" shall mean, with respect to an invention, any patent or patent

application, and any patent issuing therefrom, together with any
extensions, reissues, reexaminations, substitutions, renewals, divisions,
continuations and continuations-in-part thereof, and any patent or patent
application claiming priority to any application in common with any such
patent containing a disclosure substantially similar to any such patent,
all to the extent the foregoing contain claims covering such invention.

1.53 "Portable Equipment" means the portable equipment described with

particularity in the Tech Transfer Agreement and referred to in Section 5.1

hereof, including, without limitation, the related documentation regarding
the design, validation, operation, calibration, and maintenance of such
equipment. The Portable Equipment is a part of the Equipment, as defined in
Section 14.2 hereof. Components of the Portable Equipment, such as valves,

pumps and agitators, shall also be deemed Portable Equipment.

1.54 [*]

1.55 "Product" means the proprietary biological pharmaceutical product known as

ENBREL (R) (etanercept), which is a [*].

1.56 "Purchase Price" means the purchase price to be paid by Immunex to

Genentech for Bulk Drug as determined in accordance with the terms of this
Agreement.

1.57 "Qualification Batch" or "Qualification Lot" means a Batch or Lot produced

from a Qualification Run.

1.58 "Qualification Run" means a Run used to document the operability and

reproducibility of the Manufacturing Process at the Genentech Facility, and
is described in Section 3.7(b) hereof.

1.59 "Quality Agreement" means the quality agreement between the Parties of even

date herewith which refers to this Agreement.

1.60 "Roche" means Roche Holdings, Inc., a Delaware corporation, and its

"Affiliates" (as hereinafter defined) other than Genentech and Genentech's
subsidiaries. With respect to Roche, "Affiliates" means any other

corporation or business entity that directly, or indirectly through one or
more intermediaries, controls, is controlled by or is under common control
with Roche Holdings, Inc.; and, for purposes of this definition, the

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term "control" means direct or indirect ownership of fifty percent (50%) or
more of the securities or other ownership interests representing the equity
voting stock or general partnership or membership interest of such entity
or the power to direct or cause the direction of the management or policies
of such entity, whether through the ownership of voting securities, by
contract, resolution or otherwise.

1.61 "Run" means a single fermentation start or run of the Manufacturing Process

at the [*] liter fermentation scale at the Genentech Facility, and refers
to a Commercial Run, Development Run and/or Qualification Run, as the
context requires. A fermentation start for the Product shall be deemed to
be a Run if such fermentation start proceeds to the [*] at the [*] liter
scale or later in the Manufacturing Process.

1.62 "sBLA" means a biologics license application for the Product, any

equivalent successor filing thereto with the FDA, and any supplements or
amendments to any of the foregoing.

1.63 "Specialized Raw Materials" means the specialized raw materials described

with particularity in the Tech Transfer Agreement and referred to in
Section 3.6 hereof.

1.64 [*]

1.65 "Tech Transfer Agreement" means the technology transfer agreement and

process implementation plan between the Parties of even date herewith which refers to this Agreement, and which describes the agreement of the Parties regarding the transfer of technology and implementation of the Manufacturing Process at the Genentech Facility, and the modifications to the Genentech Facility needed to implement the Manufacturing Process at the Genentech Facility, including a timeline, budget and statement of work jointly developed by the Parties, as the same may be amended from time to time by mutual written agreement of the Parties.

1.66 "Territory" means the entire world.

1.67 "Third Party" means any party other than Immunex, Genentech and their

respective Affiliates.

1.68 "United States" or "U.S." means the United States of America, its

territories and possessions, and the Commonwealth of Puerto Rico.

1.69 [*]

1.70 "Working Cell Bank" means a vialled collection of serially subcultivated

cells generated by Immunex that is derived from the Master Cell Bank. The Working Cell Bank is used to establish seed cultures of the Cell Line to initiate the Manufacturing Process.

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1.71 Each of the following definitions are found in the body of this Agreement, or elsewhere, as indicated below:

<TABLE>

<CAPTION>

| Defined Term ----- | Section ----- |
|-----------------------|------------------|
| <S> | <C> |
| "Acceptance Date" | 4.3 (e) |
| [*] | 13.2 (b) (2) (A) |
| "Allocable Overhead" | 3.9 |
| "Annual Maximum" | 4.1 |
| "Annual Minimum" | 4.1 |
| "Approved Suppliers" | 3.6 (a) |
| "Assigned Inventions" | 14.1 (d) |

| | |
|----------------------------------|-------------------|
| "Batch Record" | Quality Agreement |
| "BIP ENBREL Supply Agreement" | 17.6 |
| "Commercial Production" | 6.3 |
| "Delivery Schedule" | 4.3 (a) |
| "Delivery Date" | 4.3 (b) |
| "Designated Carrier" | 4.4 |
| "Designated Purchaser" | 3.6 (a) |
| "Disclosing Party" | 13.2 (c) |
| "Equipment" | 14.2 |
| "FDA Approval" | 3.4 (d) |
| "Finance Contact" | 3.2 (b) |
| "Force Majeure Event" | 20.1 |
| "Genentech Improvements" | 14.1 (c) |
| "Immunex IP Rights" | 13.1 |
| "Indemnatee" | 16.3 (a) |
| "Indemnitor" | 16.3 (a) |
| "Internal Costs" | 3.9 |
| "JPT" | 3.3 (a) |
| "Liabilities" | 16.1 (a) |
| "Non-Requesting Party" | 22.2 (b) |
| "Notified Party" | 17.4 (a) |
| "Notifying Party" | 17.4 (a) |
| "Operations Team" | 6.3 |
| "Product Manufacturing Forecast" | 4.2 (a) |
| "Project Team Leader" | 3.2 |
| "Recipient" | 13.2 (c) |
| "Records" | 5.4 |
| "Term" | 19.1 |
| "Warning Letter" | Quality Agreement |

</TABLE>

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ARTICLE 2. COMMITMENT TO MANUFACTURE; PURCHASE

2.1 Commitment to Manufacture; Purchase. Subject to the terms and conditions

set forth in this Agreement, during the Term, Immunex shall retain Genentech as a non-exclusive manufacturer of Bulk Drug, Genentech shall manufacture Bulk Drug exclusively for the benefit of Immunex and sell Bulk Drug exclusively to Immunex, and Immunex shall purchase such Bulk Drug from Genentech.

ARTICLE 3. TECHNOLOGY TRANSFER AND PROCESS IMPLEMENTATION

3.1 Technology Transfer and Manufacturing Process Implementation.

(a) Process Description and Tech Transfer Agreement. The Parties

acknowledge that in order to enable them to fulfill their respective obligations under this Agreement, they have entered into the Tech Transfer Agreement and, pursuant thereto, jointly developed a plan for the transfer of technology and implementation of the Manufacturing Process at the Genentech Facility. Pursuant to this Agreement and the Tech Transfer Agreement, Immunex shall promptly disclose to Genentech the Manufacturing Process for the Bulk Drug and the Bulk Drug Specifications and other specifications related thereto, in order to enable Genentech to fulfill its obligations under this Agreement. The Tech Transfer Agreement sets forth the specific responsibilities of the Parties in connection with technology transfer and implementation of the Manufacturing Process at the Genentech Facility, and the modifications to the Genentech facility needed to implement the Manufacturing Process at the Genentech Facility, including a timeline, budget and statement of work jointly developed by the Parties, as the same may be amended from time to time by mutual written agreement of the Parties. The Tech Transfer Agreement includes milestones for the transfer of technology, exchange of information, and implementation of the project, reasonable timelines for achieving such milestones, and criteria for assessing the progress and success of the project as it progresses.

(b) Commercially Reasonable Best Efforts; Cooperation; Tech Transfer

Agreement. The Parties shall use Commercially Reasonable Best Efforts

to complete their respective responsibilities in a timely manner under and in accordance with the Tech Transfer Agreement and Section 3.1 of

this Agreement. In addition, each Party agrees to use Commercially Reasonable Best Efforts to cooperate with and assist the other Party in its efforts to perform its obligations under the Tech Transfer Agreement and Section 3.1 of this Agreement; and, notwithstanding

anything in this Agreement to the contrary, a Party shall not be deemed to have failed to use Commercially Reasonable Best Efforts to the extent the failure or delay in such Party's performance of its obligations is caused by a Force Majeure Event (as defined in Section

20.1 below), or the failure or delay on the part of the other Party in

performance of such other Party's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement.

(c) On-Site Participation. Pursuant to and as set forth in greater detail

in the Tech Transfer Agreement and Quality Agreement, in order to expedite the

implementation of the Tech Transfer Agreement, Immunex may have its personnel on-site at the Genentech Facility, in such numbers as may be agreed to by the Parties but in no event less than a reasonable number of personnel. All such personnel will coordinate closely with Genentech in order to minimize impact on other Genentech operations. Unless otherwise agreed by Genentech: (i) such Immunex personnel shall have access only to those portions of the Genentech Facility reasonably related to the technology transfer and implementation of the Manufacturing Process, and (ii) while at the Genentech Facility, such Immunex personnel shall, at Genentech's option, be accompanied by a Genentech employee, in which case Genentech will make good faith efforts to have such Genentech employee available. Employees or agents of one Party who will be at the other Party's site may be required by the other Party to sign confidentiality agreements protecting the other Party's information, using a form of confidentiality agreement mutually agreed to by the Parties in writing in advance in order to give effect to the confidentiality provisions set forth in this Agreement. In addition, all Parties' personnel shall have executed a confidentiality agreement with their employer, which shall include an obligation of maintaining the confidentiality that would cover the other Party's confidential information.

(d) Delivery of Working Cell Bank. By not later than the applicable

delivery deadline set forth in the Tech Transfer Agreement, Immunex shall deliver to Genentech the Working Cell Bank, which shall conform to Immunex's applicable release criteria, as set forth in Immunex's Working Cell Bank specifications.

3.2 Appointment of Project Team Leaders and Finance Contacts.

(a) Appointment of Project Team Leader. Immunex and Genentech shall each

appoint a Project Team Leader (each, a "Project Team Leader") to act as the

primary contact for such Party in connection with matters related to the implementation of the Manufacturing Process and in connection with activities to be performed under the Tech Transfer Agreement. The initial Project Team Leaders are:

[*]

A Party may replace its Project Team Leader at any time and from time to time for any reason by providing written notice of the change to the other Party.

- (b) Appointment of Finance Contacts. In addition, Immunex and Genentech -----
 shall each appoint a Finance Contact (each, a "Finance Contact") to -----
 act as the primary contact for such Party in connection with matters related to financial activities and issues arising hereunder.

The initial Finance Contacts are:

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[*]

A Party may replace its Finance Contact at any time and from time to time for any reason by providing written notice of the change to the other Party.

3.3 Joint Project Team.

- (a) Role and Authority Generally. The Parties will form a Joint Project -----
 Team ("JPT") to facilitate the activities under the Tech Transfer ---
 Agreement and to resolve issues that may arise in connection with such activities or in connection with the other matters described in Section 3.3(b) below. The JPT will be composed of an appropriate equal -----
 number of representatives from each Party, to be determined by mutual agreement, and will include the Project Team Leaders. The membership in the JPT, and the role and authority generally of the JPT, may change after commencement of Commercial Production of Bulk Drug under this Agreement (see Section 6.3 below).

- (b) Scope of Authority Prior to Commercial Production; Changes to Tech -----
 Transfer Agreement; Changes to the Manufacturing Process.

- (1) Prior to the commencement of Commercial Production of Bulk Drug under this Agreement (see Section 6.3 below), and subject to

Section 3.3(c) hereof, the JPT shall have the authority to modify

or supplement the Tech Transfer Agreement (to the extent permitted in the Tech Transfer Agreement, which provides therein that the JPT shall have the authority to amend the attachments and exhibits attached to the Tech Transfer Agreement but shall not have authority to amend the body of the Tech Transfer Agreement) or the Manufacturing Process as necessary or useful to ensure implementation of the Manufacturing Process in the Genentech Facility in a timely manner. If the JPT is considering a modification or supplement to the Tech Transfer Agreement or the Manufacturing Process that would require Genentech to perform additional or repeat work under the Tech Transfer Agreement, or which would delay Genentech's performance, or ability to perform, under the Tech Transfer Agreement or this Agreement, or would result in additional capital expenditures that would not be subject to reimbursement under this Agreement or the Tech Transfer Agreement, then a Project Team Leader may request that Genentech provide to the JPT (with Immunex's assistance, if reasonably requested by Genentech) an estimate of the increased cost of or delay to Genentech's performance caused by such amendment or supplement. The JPT's formal written approval of such modification or supplement shall constitute Immunex's agreement to pay Genentech's costs and expenses for such increased work or additional capital expenditures as set forth in such estimate and agreed to in a writing signed by the Project Team Leaders (or other authorized representatives of the Parties), and/or to extend the time for performance as set forth in such estimate and agreed to in a writing signed by the Project Team Leaders (or other authorized representatives of the Parties).

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- (2) Similarly, the JPT shall be empowered, as and when appropriate, acting in good faith, to adjust the reimbursement trigger dates set forth in Section 3.4(d) hereof, to adjust the milestone dates

set forth in Section 5.2 hereof, to adjust the date set forth in

Section 19.2(c) (ii) hereof, and to reduce, extend or otherwise

adjust the budget, timeline and scope of work in the Tech Transfer Agreement; provided, however, that adjustments should be made only on account of events that have a material adverse effect on the critical path to completing the related goal. The Parties acknowledge that there are various amounts of float time included in the schedules, dates and deadlines set forth in the Tech Transfer Agreement, the reimbursement trigger dates set forth in Section 3.4(d) hereof, the milestone dates set forth in

Section 5.2 hereof, and the date set forth in Section 19.2(c) (ii)

hereof. Float time should be considered by the JPT in determining whether to make any such adjustments, and the Parties understand that a certain amount of float time may be appropriate for the remainder of the schedule. Notwithstanding the foregoing, the JPT's authority shall be subject to Section 3.3(c) below.

(3) The members of the JPT shall operate in good faith and shall act reasonably in exercising their authority and in approving or rejecting proposals.

(4) After Commercial Production of Bulk Drug has commenced (see Section 6.3 hereof), the JPT shall operate in accordance with

Section 6 hereof, and all other changes to the Manufacturing

Process shall be made as set forth in Section 6.2 hereof and the

Quality Agreement or as the Parties may otherwise agree in writing.

(c) Decision-making. All decisions of the JPT shall be made by the

unanimous agreement of all of its members or their designated representatives, and shall be reflected in written meeting minutes of the JPT, which shall be signed by the Project Team Leaders (or other authorized representatives of the Parties). In addition, any decision by the JPT to adjust the reimbursement trigger dates set forth in Section 3.4(d) hereof, to adjust the milestone dates set forth in

Section 5.2 hereof, to adjust the date set forth in Section

19.2(c) (ii) hereof, shall only be effective upon the written approval

of, at Immunex, the Senior Vice President of Supply Operations, and, at Genentech, the Senior Vice President of Product Operations, or other individuals having the same or substantially similar positions, which approval and execution shall not be unreasonably withheld. The

JPT may amend the Tech Transfer Agreement in accordance with the terms thereof. In the event that the JPT is unable, despite the good faith efforts of all members, to resolve within [*] business days a disputed issue that is within the purview of the JPT, the disputed issue shall be referred immediately by the JPT to the Project Team Leaders. In the event the Project Team Leaders are unable to resolve the disputed issue within an additional [*] business days, the disputed issue will be referred to, at Immunex, the Senior Vice President of Supply Operations and, at Genentech, the Senior Vice President of Product Operations or their successor in

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an equivalent position. If the dispute cannot be resolved by Immunex's and Genentech's senior management as designated above within an additional [*] business days, it shall be referred to, at Immunex, the Chief Operating Officer, and, at Genentech, the Executive Vice President of Development and Product Operations, or their respective successors in interest. If the dispute is still unresolved within an additional [*] business days, the matter will be handled in accordance with Section 22.2 hereof. Notwithstanding the foregoing, issues

relating to quality shall be resolved in accordance with the Quality Agreement, and disputes relating to whether Bulk Drug is Non-Conforming Bulk Drug shall be governed by Article 8 herein.

3.4 Regulatory Matters.

- (a) Regulatory Approach. As set forth in greater detail below, Immunex

shall use Commercially Reasonable Best Efforts to timely file, and Commercially Reasonable Efforts to maintain, the sBLA for the manufacture of Bulk Drug at the Genentech Facility, and Genentech shall use Commercially Reasonable Best Efforts to timely file, and Commercially Reasonable Efforts to maintain, supplements to its existing FDA licenses for the manufacture of Bulk Drug at the Genentech Facility.

- (b) Immunex Obligations. Except with respect to obligations of Genentech

under Section 3.4(c) below, Immunex shall use Commercially Reasonable

Best Efforts to timely prepare and obtain, and Commercially Reasonable

Efforts to maintain, all regulatory approvals that are required to market and sell in the United States the Product resulting from the Manufacturing Process as carried out at the Genentech Facility, including, without limitation, the preparation, filing and maintenance of the sBLA for the manufacture of Bulk Drug at the Genentech Facility, and Immunex shall reasonably assist Genentech in meeting its obligations under this Section 3.4.

(c) Genentech Obligations. Except with respect to obligations of Immunex

under Section 3.4(b) above, Genentech shall use Commercially Reasonable

Best Efforts to timely prepare and obtain, and Commercially Reasonable Efforts to maintain, all regulatory approvals that are required to manufacture Bulk Drug at the Genentech Facility in South San Francisco, California, including, without limitation, the preparation, filing and maintenance of supplements to Genentech's existing FDA licenses (and drug master file), and Genentech shall reasonably assist Immunex in meeting its obligations under this Section 3.4, including, without

limitation, reasonably assisting with the preparation and review of the drafts of the chemistry, manufacturing and controls sections of the sBLA to be filed by Immunex with FDA. Genentech shall also reasonably assist Immunex in responding to requests and inquiries from the FDA prior to, during and after regulatory review periods and by attending meetings with such regulatory authorities to the extent it is essential for Genentech to participate given its unique

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knowledge or its status as manufacturer of Bulk Drug under this Agreement. Genentech personnel shall also facilitate pre-approval inspection of the Genentech Facility conducted by such regulatory authorities. The assistance to be provided by Genentech under this Section 3.4(c) shall be provided at no additional cost to Immunex,

except as otherwise provided in Sections 3.9 and 4.5 hereof.

(d) Target Date for FDA Approval. Each Party agrees to use Commercially

Reasonable Best Efforts to obtain by [*], FDA approval for the manufacture of Bulk Drug at the Genentech Facility ("FDA Approval").

[*]. In accordance with Section 3.3(b), [*] may be extended for delays

that are caused by a Force Majeure Event (as defined in Section 20.1

below) affecting Genentech which, for purposes of this Section 3.4(d),

may include, without limitation, [*] all to the extent beyond the control and without the fault or negligence of the Party affected thereby, to the extent that such delays have a material adverse effect on the critical path for obtaining FDA Approval. Each Party agrees to give the other Party prompt written notice of any such potential Force Majeure Event, the nature thereof, and the extent to which FDA Approval is likely to be delayed. Each Party further agrees to use Commercially Reasonable Best Efforts to cure the Force Majeure Event as quickly as practicable. The JPT shall determine, in accordance with Section 3.3 hereof, whether the above dates in this Section 3.4(d)

that trigger Genentech's reimbursement obligations shall be extended, and, if so, the appropriate length of time for the extension, and to approve or adopt standards, requirements or actions intended to correct the Force Majeure Event as quickly as practicable, and each Party shall act in good faith and exercise reasonable judgment in connection therewith. Notwithstanding anything in this Agreement seemingly to the contrary, Immunex agrees that Immunex's sole compensation under this Agreement as a result of failure to obtain FDA Approval shall be limited to [*]. The Parties further agree that Immunex shall use its Commercially Reasonable Efforts to [*], and, if Immunex does not do so and the failure to do so has a material adverse effect on the critical path to [*], then the JPT shall be empowered to adjust the FDA Approval termination date set forth in Section

19.2(c) (ii) hereof. The JPT shall determine, in accordance with

Section 3.3 hereof, whether such date shall be extended, and, if so,

the appropriate length of time for the extension, and each Party shall act in good faith and exercise reasonable judgment in connection therewith.

3.5 Facility Modifications and Improvements. Genentech shall use Commercially

Reasonable Efforts to: (a) make facility modifications as required to conduct the Manufacturing Process at the Genentech Facility; and (b) procure, engineer, install, scale-up, test and validate the equipment and systems necessary to conduct the Manufacturing Process at the Genentech Facility; in each case as described in, and in accordance with, the Tech Transfer Agreement.

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3.6 Raw Materials and Suppliers.

(a) Raw Materials. Immunex has developed specifications for the raw

materials, including, without limitation, Specialized Raw Materials, used in the Manufacturing Process. The raw materials specifications and a list of certain "Approved Suppliers" for raw materials will be

included in the Tech Transfer Agreement. Immunex has entered into supply contracts with the Approved Suppliers of raw materials. During the Term, Immunex shall provide Genentech with access to the favorable pricing and services provided under Immunex's contracts with those Approved Suppliers and Genentech shall become a "Designated Purchaser" under those contracts and Immunex shall provide Genentech with a true and correct copy of each such contract; and, if Immunex enters into new supply contracts for raw materials used in the manufacture of the Bulk Drug, then, during the Term, Immunex shall provide Genentech with access to the favorable pricing and services provided thereunder and Genentech shall become a "Designated Purchaser" thereunder, and Immunex shall provide Genentech with a true and correct copy of each such contract. Immunex shall provide oversight and coordination of inventories of Specialized Raw Materials. Immunex further agrees that to the extent Immunex controls or influences the allocation of Specialized Raw Materials provided to Immunex for the manufacture of Product in Rhode Island and to Genentech as a Designated Purchaser under Immunex's supply contracts with the Approved Suppliers for the manufacture of Bulk Drug hereunder, Immunex will use its Commercially Reasonable Efforts to ensure that, in the event a shortage of Specialized Raw Materials exists, or is anticipated, each shall receive a pro rata amount of available Specialized Raw Materials under such supply contracts based on an allocation of [*] percent ([*] %) to Genentech for its forecasted production at the Genentech Facility with respect to the then-current Bulk Drug Commitment, and [*] percent ([*]%) to Immunex for its forecasted production in Rhode Island with respect to the same time period, until such shortage is abated. If any such shortage continues beyond such period, the allocation will continue in accordance with the foregoing sentence, on a rolling basis for subsequent then-current Bulk Drug Commitments, until such shortage is abated.

(b) Raw Materials for Development Runs and Qualification Runs.

Notwithstanding anything seemingly to the contrary herein, Immunex shall timely procure, at [*]'s sole cost and expense, and timely provide to Genentech, sufficient quantities of all Specialized Raw

Materials as required for the Development Runs and Qualification Runs described in Section 3.7 below. The Parties shall in good faith

determine the amount and value of usable Specialized Raw Materials remaining after the Development Runs and Qualification Runs, [*], upon the expiration or termination of this Agreement, Immunex shall pay Genentech the amounts payable under Section 19.3(d) (1) of this

Agreement.

- (c) Raw Materials Management. Genentech shall procure, at [*]'s sole cost

and expense (except for Specialized Raw Materials [*]), maintain and store such amounts of raw materials and components as required for the Development Runs

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and Qualification Runs described in Section 3.7 below and the

Commercial Runs. Except as set forth in Section 6.2(a) (5) or 19.3(d) (1)

hereof, Genentech will provide such raw materials and components and such procurement and management services [*].

- (d) Raw Materials Testing. Genentech shall perform testing and evaluation

of the raw materials (including, without limitation, the Specialized Raw Materials procured by Immunex and provided to Genentech pursuant to Section 3.6(b) above) as required by the applicable raw material

specifications or Bulk Drug Specifications and cGMP, and otherwise in accordance with the Quality Agreement and standard operating procedures to be agreed upon in writing by the Parties.

3.7 Initial Runs and Batches. -----

- (a) Development Runs. Genentech shall perform Development Runs and

manufacture Development Batches at such size and in such number as is set forth in the Tech Transfer Agreement. Genentech will provide the Product resulting from such Development Runs and Development Batches to Immunex, [*], in accordance with the delivery terms set forth in Section 4.4 hereof. Immunex may make whatever further use of such

Product as it shall determine; provided, however, that Immunex agrees that (i) such Product shall not be used in humans, (ii) the warranties provided in Section 6.1(a) of this Agreement shall not apply to such

Product, (iii) the disclaimer of warranties set forth in Section

6.1(c) of this Agreement shall apply to such Product, and (iv) this

Section 3.7(a) shall survive termination or expiration of this

Agreement.

(b) Validation and Qualification Batches. Once scale-up of the

Manufacturing Process is completed at the Genentech Facility, Genentech shall perform all required process validation and shall perform Qualification Runs and manufacture Qualification Batches at commercial scale as set forth in the Tech Transfer Agreement in order to document the operability and reproducibility of the Manufacturing Process and permit the Parties to complete and file the regulatory documents described in Section 3.4 hereof. Genentech shall provide the Product

and Bulk Drug resulting from such Qualification Runs and Qualification Batches to Immunex, [*], in accordance with the delivery terms set forth in Section 4.4 hereof.

3.8 Manufacturing Documentation. In accordance with the terms of the Tech

Transfer Agreement, Immunex shall, by the relevant date that is set forth in the Tech Transfer Agreement as such date may be modified by the JPT, provide to Genentech the items listed within exhibits and schedules to the Tech Transfer Agreement, and shall, thereafter, from time to time and in accordance with the timeline set forth in the Tech Transfer Agreement, provide to Genentech such additional Manufacturing Documentation as Genentech shall reasonably require in order to implement the

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Tech Transfer Agreement and the Manufacturing Process and otherwise perform its obligations under this Agreement. In accordance with the terms of the Tech Transfer Agreement, Genentech shall provide certain information to Immunex, including, without limitation, the process trend and variability data. Both Parties' obligations under this Section 3.8 shall be subject to

obligations to Third Parties as set forth in written agreements in effect prior to the Effective Date of this Agreement. In the event an obligation to a Third Party prohibits a Party from rendering such assistance, that Party shall promptly seek from such Third Party permission to render such assistance.

3.9 [*] At Immunex's request prior to [*], Genentech agrees to discuss in good faith with Immunex and give serious consideration to [*]. The determination as to whether Genentech could accept such a [*] would be made by Genentech, in its sole discretion, after good faith discussion with Immunex, and after a good-faith and serious evaluation of the following factors: [*]. If such a [*] were acceptable to Genentech, in its sole discretion, Immunex would be responsible for any additional costs to be agreed upon by the Parties, including but not limited to [*] (as defined below) associated with [*], and the Parties would agree upon new dates and deadlines set forth in this Agreement to the extent impacted by such [*]. The Bulk Drug Commitment outstanding at the time Immunex issues a request for [*] shall remain binding upon the Parties; provided, however, that Immunex shall, notwithstanding such request for [*], unless and until such [*] occurs, purchase Bulk Drug in accordance with this Agreement up to the applicable Annual Minimum set forth in Exhibit A hereto. [*]. For purposes of this Agreement, the term [*]. For purposes of this Agreement, the term [*].

ARTICLE 4. RUNS; PRODUCTION AND SUPPLY;

DELIVERIES

4.1 Minimum and Maximum Runs. Notwithstanding anything seemingly to the

contrary in this Article 4, but subject to the other terms of this

Agreement, in each calendar year during the Term, Genentech shall perform at least the number of Runs identified as the "Annual Minimum" for such

calendar year on Exhibit A attached hereto and incorporated herein, and

may in its sole discretion perform up to the number of Runs identified as the "Annual Maximum" for such calendar year on said Exhibit A. Subject to

Section 3.9 and Section 4.5 hereof, Genentech shall have sole discretion

to determine the actual number of Runs in any calendar year, within the ranges set forth in Exhibit A hereto, and subject to the Product

Manufacturing Forecast and applicable Bulk Drug Commitment. For purposes of this Article 4, the term "Runs" refers to Commercial Runs, and does

not refer to Qualification Runs or Development Runs.

4.2 Production and Supply

(a) Product Manufacturing Forecast. By not later than the Effective Date

of this Agreement and thereafter on the [*] business day of each
month, beginning [*], for

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the remainder of the Term, the Parties shall issue a rolling "Product

Manufacturing Forecast" which shall establish, on a monthly basis, for

the remainder of the Term, the number of Runs to be performed and the
quantity of Bulk Drug reasonably expected to be manufactured, released
and supplied to Immunex, within the ranges set forth in Exhibit A

hereto. The Product Manufacturing Forecast shall be used for joint
planning purposes and shall be nonbinding unless otherwise specified
herein, and may be amended by the Parties from time to time as the
Parties deem appropriate. Beginning [*] or such other date as agreed
upon by the Parties in writing, each Product Manufacturing Forecast
shall be binding for the first [*] months, and non-binding for the
remainder of the Term, as further described below. Beginning with the
initial binding Product Manufacturing Forecast, the forecasts for Bulk
Drug within the first [*] months of each such rolling Product
Manufacturing Forecast shall constitute a Bulk Drug Commitment and
shall be binding upon the Parties and cannot be changed except upon
mutual written consent of the Parties (or except upon mutual agreement
of the Parties under Section 3.9 or Section 4.5 hereof, which

agreement shall not, without the consent of Genentech, affect any Runs
that are in process [*]), and the [*]-month period shall be that
period which commences on the first day of the month immediately
following the month in which the Product Manufacturing Forecast is
issued. By way of example only, when the rolling Product Manufacturing
Forecast for [*], is issued, the [*]-month period covered by such
forecast shall commence on [*], and shall end on [*]. The Bulk Drug
Commitment shall include approximate harvest dates for each Commercial
Run.

(b) Weekly Meetings. The Parties shall participate in a weekly meeting, in

person or via telephone, to review and discuss production, supply and

logistics operations for the next [*]-month period, including: (i) dates or approximate dates on which Runs will occur; (ii) dates or approximate dates for Genentech's and Immunex's release of Bulk Drug; (iii) size or approximate size of Batches; (iv) dates or approximate dates for delivery of Batches; (v) destination for shipment of Batches; and (vi) status of Batches undergoing investigation, and related matters, and to issue and, as appropriate, update the Product Manufacturing Forecast.

4.3 Management of Product Manufacturing Forecast.

(a) Delivery. Immunex and Genentech will work together in good faith to -----
determine delivery dates and a shipping schedule for deliveries of Bulk Drug under this Agreement, and shall establish a written "Delivery Schedule" as a part of the Product Manufacturing Forecast -----
and the related Bulk Drug Commitment.

(b) Delivery Dates. For each Run, the delivery date respectively set forth -----
in the Delivery Schedule will be the "Delivery Date" for such Run, -----
unless the Parties agree on an alternative delivery date; provided, however, that for purposes of Section 8.1(a)(ii) hereof, the "Delivery -----
Date" for any particular Bulk Drug shall be the actual date on which such Bulk Drug is delivered to Immunex's Designated

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Carrier at Genentech's Facility in accordance with Section 4.4 hereof. -----

(c) Purchase Quantities. Except as otherwise set forth in this Agreement -----
(including, without limitation, upon mutual agreement of the Parties under Section 3.9 or Section 4.5 hereof, which agreement shall not, -----
without the consent of Genentech, affect any Runs that are in process [*]), Immunex shall purchase all Bulk Drug that complies with the warranties set forth in Section 6.1(a), up to the applicable Annual -----
Maximum set forth in Exhibit A hereto.

(d) Shortages; Shortfalls; Delivery Delays. If at any time during the

Term, Genentech is unable to fulfill the Bulk Drug Commitments on the related Delivery Date(s), and which inability results from other than a Force Majeure Event, then Genentech shall (1) immediately notify Immunex in writing as to the reason for the shortfall, shortage and/or delay, and provide an indication of the likely duration of the shortfall, shortage and/or delay, and (2) unless and except to the extent such inability to fulfill the Bulk Drug Commitment is caused by an Immunex material breach, use Commercially Reasonable Efforts to provide Immunex with additional Commercial Runs to meet outstanding Bulk Drug Commitments under this Agreement, to the extent that Genentech has excess capacity and/or can reasonably revise its production schedule without material adverse impact to itself or its obligations to Third Parties and/or Affiliates. In addition, Genentech shall also promptly notify Immunex in writing when any such shortfall, shortage and/or delay is over. Unless otherwise directed in writing by Immunex, after Immunex's receipt of notice from Genentech that a shortfall, shortage and/or delay as described above is over, Genentech shall use Commercially Reasonable Efforts to make up shortfalls in delivery as promptly as practicable, to the extent that Genentech has excess capacity and/or can reasonably revise its production schedule without material adverse impact to itself or its obligations to Third Parties and/or Affiliates, and shall promptly supply Bulk Drug to Immunex and/or their respective designee, as appropriate, to meet such Bulk Drug Commitments. Notwithstanding the foregoing, any shortfalls, shortages and/or delays resulting from a Force Majeure Event shall be governed by Article 18 below.

(e) Acceptance of Bulk Drug. Genentech shall deliver to Immunex samples of

all Batches manufactured under this Agreement, as and when Batches are manufactured, and otherwise in accordance with the Quality Agreement and applicable standard operating procedures approved by both Parties, to enable Immunex to perform release testing on the Bulk Drug as required by Article 11 of this Agreement and the Quality Agreement.

Genentech shall also provide the related Batch Record and other Batch documentation described in the Quality Agreement for each Batch of Bulk Drug as soon as practicable after each such Batch is manufactured. Upon receipt of samples of a particular Batch of Bulk Drug together with the related Batch Record and other Batch documentation, Immunex shall perform release testing and review the Batch Record and other

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Batch documentation for each Batch, in good faith and as soon as reasonably practicable, and, in the absence of an investigation for said Batch pursuant to the Quality Agreement or Section 8.1 hereof,

such testing and review shall be completed within [*] days after Immunex's receipt of samples of such Batch together with the related Batch Record and other Batch documentation. Any investigation shall be initiated and conducted in accordance with Immunex's applicable standard operating procedure. Subject to Immunex's rights to make claims under Article 8 hereof, a Batch shall be deemed to have been

accepted by Immunex on the date (the "Acceptance Date") on which the

first of the following events occurs: (i) the receipt by Genentech of written notice from Immunex that such Batch has been released by Immunex pursuant to applicable release testing standard operating protocols as described in the Quality Agreement, (ii) the failure of Immunex to issue a notice of investigation or rejection within [*] days after Immunex's receipt of samples of such Batch together with the related Batch Record and other Batch documentation, and (iii) the determination under Section 8.1(b) below that Genentech has no

liability for such non-conforming Batch. The Parties agree that, subject to prior written approval by Immunex on a Batch by Batch basis, Genentech may deliver Batches of Bulk Drug prior to the Acceptance Date, provided, however, that the procedures set forth in this Agreement for acceptance of such Batches under this Section 4.3

and payment for such Batches under Section 5.3 hereof shall

nevertheless apply to such Batches, and provided, further, that, for the avoidance of doubt, Genentech shall have no liability to Immunex for costs and expenses incurred by Immunex for filling and finishing Bulk Drug that is delivered prior to the Acceptance Date in accordance with this Section 4.3.

4.4 Delivery Terms. Genentech shall deliver Bulk Drug to Immunex's "Designated

Carrier" at Genentech's Facility, and Immunex shall arrange for shipment of

Bulk Drug from Genentech's Facility to Immunex via Immunex's Designated Carrier at the expense of Immunex. Immunex shall arrange for shipment and take delivery of Bulk Drug within [*] days after the Acceptance Date related thereto. Genentech shall provide storage for such Bulk Drug at no charge during this period. Title to and risk of loss of Bulk Drug shall be

and remain with Genentech until the earlier of (i) the date on which such Bulk Drug is delivered to Immunex's Designated Carrier at Genentech's Facility and (ii) the expiration of such [*]-day period, at which time title to and risk of loss for the Bulk Drug shall transfer to Immunex. Genentech shall not be required to deliver Bulk Drug to Immunex's Designated Carrier until Immunex's Designated Carrier informs Genentech that it has obtained all appropriate approvals and consents of any governmental authority necessary for the transportation or shipment of such Bulk Drug. Genentech shall comply with all applicable laws and regulations regarding the packaging of Bulk Drug for shipment. Product resulting from Development Runs and Qualification Runs (see Sections 3.7(a) and (b)

hereof), and Non-Conforming Bulk Drug (see Section 8.1(d)) shall also be

subject to the delivery terms set forth in this Section 4.4. Immunex shall

procure, at Immunex's sole cost and expense, and provide to Genentech sufficient quantities of freeze tanks for shipment of Bulk Drug from

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Genentech's Facility to Immunex via Immunex's Designated Carrier. Title to and risk of loss of such freeze tanks shall transfer to Genentech upon initial delivery of such freeze tanks to Genentech; such freeze tanks shall be deemed to be "Portable Equipment" and shall be subject to transfer to

Immunex pursuant to Sections 14.2 and 19.3 of this Agreement.

4.5 [*] Any time following the completion of Milestone III, Immunex may request that Genentech [*]. Upon such request, the JPT will meet to discuss timelines, costs, activities and responsibilities necessary to [*], and Immunex shall reimburse Genentech for such costs as agreed upon by the JPT. [*] The supply, purchase and payment provisions of this Agreement would not be affected by a decision to [*] hereunder unless otherwise agreed to in writing by the Parties, and Immunex would continue to purchase the Bulk Drug Commitment in accordance with the terms of this Agreement, at least up to the applicable Annual Minimum set forth in Exhibit A hereto. The Parties

would negotiate in good faith to amend the Agreement as appropriate to address [*].

ARTICLE 5. PAYMENTS

5.1 Reimbursement for Facility Modifications and Services Costs. Immunex shall

reimburse Genentech for Facility Modifications and Services Costs, in
accordance with the Tech Transfer Agreement, including, without limitation,
the acquisition of Portable Equipment (provided, however, that Immunex
shall not be required to reimburse Genentech for the costs of acquiring
Portable Equipment under the Tech Transfer Agreement or this Agreement if
Immunex paid for such Portable Equipment directly or if Immunex has already
reimbursed Genentech for such costs), and Genentech shall bear all of
Genentech's internal costs and expenses (including, without limitation,
Genentech's internal labor and material costs) for the modifications needed
to implement the Manufacturing Process at the Genentech Facility, except as
otherwise provided in Section 3.9 or Section 4.5 hereof. All Portable

Equipment acquired by Genentech under this Agreement (including, without
limitation, the freeze tanks referred to in Section 4.4 above) or the Tech

Transfer Agreement shall be subject to Sections 14.2 and 19.3 of this

Agreement.

5.2 Milestone Payments. For each Milestone that is completed by the deadline

respectively described below, Immunex shall pay the related milestone,
within [*] days of receipt of a correct invoice, which may be delivered
on or after the date earned:

(a) Completion of Milestone I: [*]: Immunex shall pay Genentech [*]

Dollars (\$[*]) upon the completion of Milestone I.

(b) Completion of Milestone II: [*]: Immunex shall pay Genentech [*]

Dollars (\$[*]) upon the completion of Milestone II, provided that [*];
and, in addition, Genentech shall also be entitled to receive
additional payments of [*] Dollars

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\$([*]) [*], which such additional payment amounts shall be payable
upon [*].

(c) Completion of Milestone III: [*]: Immunex shall pay Genentech [*]

Dollars (\$[*]) upon the completion of Milestone III, provided that

this milestone has been completed by not later than [*].

(d) Completion of Milestone IV: [*]: If Milestone IV is completed by not

later than [*], then Immunex shall pay Genentech [*] Dollars (\$[*]).

(e) Adjustment of Milestone Dates. In accordance with Section 3.3(b)

hereof, the dates in Sections 5.2(b), (c) and (d) above may be

extended for delays occasioned by a Force Majeure Event (as defined in
Section 20.1 below), which, for purposes of this Section 5.2(e), may

include, without limitation, [*], all to the extent beyond the control
and without the fault or negligence of the Party affected thereby, and
to the extent that such delays have a material adverse effect on the
critical path for completing the related milestone. Each Party agrees
to give the other Party prompt written notice of any such potential
Force Majeure Event, the nature thereof, and the extent to which
completion of the related milestone is likely to be delayed. Each
Party further agrees to use Commercially Reasonable Best Efforts to
cure the Force Majeure Event as quickly as practicable. The JPT shall
determine, in accordance with Section 3.3 hereof, whether the date(s)

in this Section 5.2(b), (c) or (d) that trigger the related milestone

payment shall be extended, and, if so, the appropriate length of time
for the extension, and to approve or adopt standards, requirements or
actions intended to correct the Force Majeure Event as quickly as
practicable, and each Party shall act in good faith and exercise
reasonable judgment in connection therewith.

5.3 Bulk Drug Pricing; Invoicing.

(a) Bulk Drug Pricing. Except as otherwise expressly set forth in this

Agreement, including, without limitation, in Sections 3.7, 6.2, and

8.1 hereof, Immunex shall pay Genentech [*] Dollars (\$[*]) per gram

for all Bulk Drug manufactured in compliance with this Agreement and
cGMP that conforms with the Bulk Drug Specifications and the
warranties provided in Section 6.1(a) hereof, and such amount shall be

the Purchase Price for such Bulk Drug. The Purchase Price may be
adjusted in accordance with Section 5.3(d) below. Notwithstanding

anything in this Section 5.3(a) seemingly to the contrary, the

Purchase Price for Bulk Drug [*].

(b) Invoicing Immunex for Bulk Drug. Invoices may be issued on or after

the related Acceptance Date, and amounts due thereunder shall be due and payable in U.S. currency within [*] days after receipt of invoice. Such invoices shall reference the Acceptance Date, the quantity delivered and the total Purchase Price. Payments shall be made by wire transfer. Past due amounts shall bear interest at a floating rate equal to [*] percent ([*]%) per annum above the rate of interest set forth from

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time to time in the Wall Street Journal and identified therein as the prime rate of interest. Invoices may be issued prior to the completion of [*].

(c) Changes in Cost of Raw Materials. In case the net average cost of raw

materials or components used for a Batch in the Manufacturing Process for producing Bulk Drug increases or decreases by more than [*] percent ([*]%) with respect to production of Bulk Drug for a Calendar Year, as compared to the net average cost of raw materials or components used for a Batch in the Manufacturing Process for producing Bulk Drug (including both Immunex's and Genentech's combined costs for such raw materials or components) in Calendar Year [*], which change must be reasonably substantiated, the Parties shall, acting reasonably and in good faith, within [*] days agree upon the direct amount of such increase or decrease, for each Batch that is manufactured after the date of the Parties' agreement to the change, and the effective date for such increase or decrease, based on good faith negotiations. In the event of an increase, if Immunex can reasonably demonstrate to Genentech that any equivalent materials or components used for producing Bulk Drug can be purchased at a lower price than Genentech's cost of such materials, and that such materials or components can be supplied on a reasonably consistent and reliable basis, then Genentech shall accept such lower price for purposes of this Section 5.3(c). The

Purchase Price shall not be adjusted as a result of any such increase or decrease; instead, the direct amount of any such increase or decrease as agreed upon shall be payable to the other Party by Immunex or Genentech, as appropriate, pursuant to a separate invoice within [*] days after receipt thereof.

(d) Adjustment to Purchase Price. The Purchase Price shall be adjusted

prior to the first Commercial Run to a price equal to:

[*]

5.4 Commercial Audit. For at least three (3) years after final payment under

this Agreement (or for such longer period of time as may be required by applicable laws and regulations), Genentech shall maintain complete and accurate books, records, documents, and other evidence of costs, expenses and allowances pertaining to this Agreement and/or the Tech Transfer Agreement and the Facility Modifications and Services Costs (for purposes of this Section 5.4, hereinafter collectively called "Records") to the

extent and in such detail as will properly reflect all costs and expenses incurred by Genentech in connection with this Agreement and/or the Tech Transfer Agreement. Immunex, acting through its independent public accountants of recognized national standing selected by Immunex and reasonably acceptable to Genentech, shall have a right to examine and audit Genentech's Records once annually, upon at least [*] days' prior written notice, but only in the event that Immunex makes payments under either Section 6.2(a)(5) hereof (Specification and Process Changes) or Section

19.3(d)(1) hereof, or under the Letter of Intent or the Tech Transfer

Agreement, and only to the extent that such Records are applicable to determining the accuracy of such payments.

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ARTICLE 6. GENENTECH PRODUCT WARRANTIES; SPECIFICATIONS

6.1 Warranties by Genentech.

(a) Product Warranties. Genentech hereby warrants to Immunex that the Bulk

Drug, at the time of Delivery to Immunex's Designated Carrier, shall:

- (1) conform to the Bulk Drug Specifications; provided, however, that solely with respect to Bulk Drug that is delivered prior to the Acceptance Date, Genentech hereby warrants to Immunex, effective as of the Acceptance Date for such Bulk Drug, that, as of the time of Delivery to Immunex's Designated Carrier, such Bulk Drug

shall conform to the Bulk Drug Specifications;

- (2) be manufactured in compliance with the requirements of cGMP;
- (3) be manufactured in compliance with the requirements of all applicable material national, state and local laws, ordinances and governmental rules and regulations of the U.S. [*]; and
- (4) be transferred free and clear of any liens or encumbrances of any kind to the extent arising through or as a result of the acts or omissions of Genentech, its Affiliates or their respective agents.

(b) Genentech Facility. Genentech hereby warrants that it owns or lawfully

controls the Genentech Facility, and that, provided the Manufacturing Process is successfully implemented in accordance with the Tech Transfer Agreement, and provided no Force Majeure Event shall occur, it has sufficient manufacturing capacity to enable Genentech to manufacture Bulk Drug throughout the Term in quantities sufficient to fulfill, in each calendar year, the minimum Runs for such year as set forth in Exhibit A hereto, in accordance with this Agreement.

Genentech hereby covenants that it will use Commercially Reasonable Efforts to ensure that the Genentech Facility shall be maintained in accordance with cGMP and in such condition as will allow Genentech to manufacture the Bulk Drug in compliance with cGMP and in conformance with the Bulk Drug Specifications.

(c) Disclaimer by Genentech. OTHER THAN AS SET FORTH IN THIS SECTION 6.1

AND SECTION 15.2 HEREOF, ALL OTHER WARRANTIES, BOTH EXPRESS AND

IMPLIED, ARE HEREBY EXPRESSLY DISCLAIMED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE.

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6.2 Specification and Manufacturing Process Changes. Except as otherwise

expressly set forth to the contrary in the Quality Agreement, the Parties agree as follows:

(a) Specification and Process Changes. In the event that (i) Immunex is

required to change the Bulk Drug Specifications or the Manufacturing Process pursuant to applicable law, rule or regulation or in response to the order or request of a governmental authority or in response to the order or request of a governmental authority or regulatory body, or (ii) Immunex requests the change pursuant to its strategy for global synchronization and worldwide consistency of Product, or (iii) Immunex wishes to change the Bulk Drug Specifications or the Manufacturing Process after commencement of Commercial Production hereunder, the following provisions will apply:

- (1) Immunex shall promptly advise Genentech in writing of any such change(s), and provide information reasonably necessary for Genentech to evaluate the effect of such change(s), and Genentech shall promptly advise Immunex as to scheduling and/or Purchase Price adjustments, if any, which may result from such change(s). The notification and approval procedure shall be in accordance with standard operating procedures (i.e., change control procedures) agreed upon by the Parties from time to time. The Parties shall hold a JPT meeting in a timely manner with appropriate advisors invited to discuss such changes as appropriate.
- (2) Prior to implementation of such change(s) to the Bulk Drug Specifications or Manufacturing Process, the Parties agree to negotiate in good faith in an attempt to reach agreement on (i) the new Purchase Price for any Bulk Drug manufactured under this Agreement by Genentech which embodies such change, giving due consideration to the effect of such change on Genentech's direct manufacturing costs for Bulk Drug, and (ii) any other amendments to this Agreement which may be necessitated by such changes.
- (3) Prior to implementation of such change(s), Genentech will provide Immunex with an estimate of the reasonable and necessary expenses that would be incurred by Genentech as a result of the implementation of any such change(s) to the Bulk Drug Specifications or Manufacturing Process, including, but not limited to, its validation and analytical development costs, capital expenditure costs, and [*], as defined in Section 3.9

above. If such change(s) are implemented, Immunex will reimburse Genentech for the reasonable and necessary expenses as agreed upon in advance and incurred by Genentech as a result of any such change(s) to the Bulk Drug Specifications or Manufacturing Process, including, but not limited to, reimbursing Genentech for its validation and analytical development costs, capital expenditure costs, and Internal Costs.

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- (4) Genentech shall use Commercially Reasonable Best Efforts to accommodate changes described in Section 6.2(a)(i) hereof as soon

as practicable after notice thereof, but in any event within [*] days' lead time, unless otherwise agreed upon by the Parties or required by an applicable regulatory authority. Immunex shall not unreasonably require Genentech to implement changes to the Manufacturing Process or Bulk Drug Specifications within such [*]-day period if such changes would typically require Genentech a longer period of time to implement, or that would have a material adverse effect on Genentech's then current operations. Genentech shall use Commercially Reasonable Efforts to accommodate changes described in Section 6.2(a)(ii) and (iii)

hereof in light of, among other considerations, Genentech's facilities and resource constraints, current operations and commercial goals; and notwithstanding the foregoing, Genentech shall not be required to implement any changes to the Manufacturing Process or Bulk Drug Specifications if such changes would have a material adverse effect on Genentech's then current operations. Genentech shall cooperate with Immunex in good faith to implement all agreed upon changes to the Bulk Drug Specifications or Manufacturing Process in accordance with the agreed upon schedule. During the pendency of Genentech implementing any such changes to the Manufacturing Process or Bulk Drug Specifications, Genentech shall produce and Immunex shall purchase Bulk Drug in accordance with the terms of the Agreement.

- (5) If any such changes to the Bulk Drug Specifications or Manufacturing Process renders obsolete or unusable any raw materials (including, without limitation, Specialized Raw Materials), components or supplies used to manufacture the Bulk Drug, and to the extent such materials may not be either returned to the appropriate vendor for a credit or utilized by Genentech for its other manufacturing operations, Immunex shall purchase from Genentech, at Genentech's Acquisition Cost, that amount of inventory of such raw materials, components or supplies, as the case may be, so rendered obsolete or unusable, not to exceed the amount of such raw materials, components or supplies which would have been required for Genentech to manufacture and supply the total quantity of Bulk Drug specified in Bulk Drug Commitments outstanding under this Agreement.
- (6) The notification and formal approval procedure for those changes to the Bulk Drug Specifications or Manufacturing Process approved

by the Parties under this Section shall be in accordance with the Quality Agreement and standard operating procedures (i.e., change ----- control procedures) agreed upon in writing by Immunex and Genentech from time to time.

(b) Procedure for Specification or Manufacturing Process Changes by ----- Genentech. Genentech shall not change the Bulk Drug Specifications or ----- the Manufacturing Process except as set forth in Section 6.2(a) ----- hereof, or in the Quality Agreement

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and standard operating procedures to be agreed upon by Immunex and Genentech from time to time.

(c) Vendor or Supplier Changes. Genentech shall not change any vendor or ----- supplier of raw materials or analytical reagents used in the manufacture or testing of Bulk Drug except as set forth in the Quality Agreement and standard operating procedures to be agreed upon by Immunex and Genentech from time to time or with the prior written consent of Immunex.

(d) Ongoing Process Improvement Obligations. Immunex agrees to provide ----- assistance to Genentech [*] in "trouble-shooting" and optimizing the Manufacturing Process, at such times and to such extent as Genentech may reasonably request, given Immunex's unique expertise and understanding of the Product and the Manufacturing Process.

6.3 JPT as Commercial Operations Team. Following [*], "Commercial Production" ----- of Bulk Drug will commence under this Agreement, with the first Commercial Run performed after the completion of [*]. After commencement of Commercial Production under this Agreement, the membership in the JPT may change to reflect the changing nature of the project. During Commercial Production, the JPT shall meet (i) in person or by telephone in accordance with Section ----- 4.2(b) hereof to review the Bulk Drug Commitment and Product Manufacturing ----- Forecast, and (ii) at least twice a year to review the overall results of

the manufacturing operations, and (iii) at such additional times as appropriate and as may be requested by either Party. Issues relating to quality of Product shall be resolved in accordance with the Quality Agreement.

ARTICLE 7. PACKAGING

7.1 In General. Genentech shall package and label the Bulk Drug according to the Bulk Drug Specifications and according to packaging procedures mutually agreed upon by Immunex and Genentech in writing.

ARTICLE 8. CLAIMS

8.1 Claims.

(a) Notice of Claims. In the event that any Bulk Drug is Non-Conforming

Bulk Drug, Immunex may reject the same by giving written notice thereof to Genentech (1) within the later of (i) [*] after the applicable Acceptance Date for such Bulk Drug, and (ii) [*] days after the applicable Delivery Date for such Bulk Drug, based on an inspection of such Bulk Drug and related freeze tanks and packing and shipping materials and components, for matters that were not readily ascertainable by the release testing of the related samples and review of the related Batch Record and other Batch documentation described in Section 4.3(e) hereof, or, (2) in the case of a latent defect, within

[*] days after discovery of such latent defect,

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but in no event later than [*] after delivery to Immunex's Designated Carrier at the Genentech Facility), which notice shall specify the manner in which such Bulk Drug fails to conform to any warranty and shall be accompanied by any test results or reports evidencing such non-conformity. Alternatively, rather than initially issuing a notice of rejection, Immunex may give written notice to Genentech within the applicable time period set forth in this Section 8.1(a) of an Immunex

decision to investigate whether a potentially Non-Conforming shipment should be rejected, which investigation shall, unless otherwise agreed by Immunex and Genentech, be completed within the applicable time

period set forth in this Section 8.1(a), and in accordance with the

procedures set forth in the Quality Agreement.

(b) No Genentech Liability. If it is determined by agreement of the

Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that either (1) there is no nonconformity, in which case Immunex shall pay to Genentech the Purchase Price for such Bulk Drug, or (2) there is nonconformity but the nonconformity was not caused by Genentech's failure to perform its obligations under the Agreement, in which case Genentech shall have no liability to Immunex with respect thereto, and Immunex shall pay to Genentech the Purchase Price for such Bulk Drug and the Bulk Drug shall be treated in all other respects under this Agreement as though it conformed with all of the warranties set forth in Section 6.1(a) of this Agreement.

(c) Genentech Liability; Replacement of Product. If it is determined by

agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party whose fees shall be paid by the non-prevailing Party) that the nonconformity was caused by Genentech, Genentech shall as soon as practicable use Commercially Reasonable Efforts to replace such Non-Conforming Bulk Drug with conforming Bulk Drug, to the extent that Genentech has excess capacity and/or can reasonably revise its production schedule without adverse impact to itself or its obligations to Third Parties and/or Affiliates, at no additional cost to Immunex except for payment of the Purchase Price for the replacement conforming Bulk Drug, which shall be payable as follows: if Immunex previously paid the Purchase Price for the Non-Conforming Bulk Drug, then Genentech shall promptly and in any event within [*] days credit such amount to Immunex on the next invoice (or, at Immunex's option, Immunex may set off such amount against amounts owed to Genentech under this Agreement), and Immunex shall pay the Purchase Price for the replacement conforming Bulk Drug; and, if Immunex did not previously pay the Purchase Price for the Non-Conforming Bulk Drug, then Immunex shall pay the Purchase Price for the replacement conforming Bulk Drug. In addition, if, despite its use of Commercially Reasonable Efforts, to the extent that Genentech has excess capacity and/or can reasonably revise its production schedule without adverse impact to itself or its obligations to Third Parties and/or Affiliates, Genentech

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cannot replace Non-Conforming Bulk Drug with conforming Bulk Drug by a date that is acceptable to Immunex, then Genentech shall upon demand by Immunex reimburse Immunex for any amount of the applicable Purchase Price that Immunex paid to Genentech for such Non-Conforming Bulk Drug. Notwithstanding anything herein seemingly to the contrary, with respect to latent defects only, if it is determined by agreement of the Parties (or in the absence of such agreement, by a mutually acceptable qualified independent Third Party, whose fees shall be paid by the non-prevailing Party) that the nonconformity was caused by both Genentech and Immunex, Genentech's obligation to reimburse Immunex for any amount of the applicable Purchase Price that Immunex paid to Genentech for such Non-Conforming Bulk Drug shall be measured in terms of proportionate liability and shall be diminished in proportion to the amount of causation attributable to Immunex.

(d) Cooperation in Investigations; Disposition of Non-Conforming Bulk

Drug. If Immunex desires to make a claim against Genentech with

respect to and reject a Batch of Non-Conforming Bulk Drug pursuant to Section 8.1(c), Immunex agrees that it shall not dispose of or allow

such Bulk Drug to be disposed of without written authorization and instructions from Genentech either to dispose of or return to Genentech such Non-Conforming Bulk Drug. Upon written request by Immunex, Genentech agrees promptly to give Immunex such authorization and instructions within a reasonable period of time. Each Party shall act in good faith and shall cooperate with the other Party and with any mutually acceptable qualified independent Third Party in connection with an investigation as to the existence of or source of any nonconformity of Bulk Drug supplied under this Agreement. At the request of Immunex, Genentech will provide all Non-Conforming Bulk Drug to Immunex, at no cost to Immunex (except for shipping and delivery expenses payable under Section 4.4 hereof), in accordance

with the delivery terms set forth in Section 4.4 hereof, and Immunex

may make whatever further use of such Product as it shall determine; provided, however, that Immunex agrees that (i) such Product shall not be used in humans, (ii) the warranties provided in Section 6.1(a) of

this Agreement shall not apply to such Product, and (iii) the disclaimer of warranties set forth in Section 6.1(c) of this Agreement

shall apply to such Product.

ARTICLE 9. MANUFACTURING AUDITS; CERTIFICATE OF

COMPLIANCE; REGULATORY MATTERS

9.1 Manufacturing Audits. Immunex shall have the right to perform, directly or -----
through its representatives, one annual standard cGMP compliance audit, and additional For Cause Audits, all in accordance with the audit provisions set forth in the Quality Agreement. During the standard audits, personnel of Immunex or its representatives shall have access only to those areas that are directly related to the performance of Genentech's obligations under this Agreement, including the manufacture, testing, storage and shipping of Bulk Drug. No more than a reasonable number of representatives shall be permitted on Genentech's premises for any such audit and, at Genentech's option, each representative shall be accompanied by a Genentech employee at all times while on Genentech's premises.

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9.2 Certificates; Manufacturing Issues; Records.

- (a) Certificates; Manufacturing Issues. As soon as possible after -----
manufacture and, unless otherwise agreed by Immunex, in any event by not later than the date of each shipment of Bulk Drug, Genentech shall furnish to Immunex the Batch Records and Manufacturer's Release Documentation described in the Quality Agreement, including, without limitation, a Certificate of Testing, a Certificate of Compliance and a summary (in a format to be agreed upon by Immunex and Genentech) of any deviations or investigations that occurred during the manufacturing or testing of the Bulk Drug that is part of such shipment. The provisions set forth in the Quality Agreement regarding deviations shall control whether a deviation results in Non-Conforming Bulk Drug.
- (b) Records. Genentech shall maintain all of its manufacturing and -----
analytical records, all records of shipments of Bulk Drug and all validation data relating to Bulk Drug for the time periods required by applicable laws and regulations of the FDA. Genentech agrees that, in response to any complaint, or in the defense by Immunex of any litigation, hearing, regulatory proceeding or investigation relating to Bulk Drug, Genentech shall use reasonable efforts to make available to Immunex during normal business hours and upon reasonable prior written notice, such Genentech employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections. Immunex shall reimburse Genentech for all reasonable costs and expenses incurred by Genentech in connection with the performance of Genentech's obligations under the immediately preceding sentence.

9.3 Complaints. Immunex shall have responsibility for reporting any

complaints relating to the Product to the FDA and any other regulatory authorities, including, but not limited to, complaints relating to the manufacture of the Product and adverse drug experience reports. Immunex shall maintain complaint files in accordance with cGMP. Genentech shall provide Immunex with a copy of any complaints received by Genentech with respect to the Product in accordance with the Quality Agreement and standard operating procedures to be agreed upon by Immunex and Genentech from time to time. Immunex shall have responsibility for responding to all complaints, and for promptly providing Genentech with a copy of any responses to complaints relating to the manufacture of the Product. Genentech shall use Commercially Reasonable Efforts to respond to requests from Immunex for information in Genentech's possession that is necessary for Immunex to respond to complaints arising out of the manufacture of the Bulk Drug.

9.4 Regulatory Correspondence.

(a) Notification to Other Parties of Regulatory Correspondence. Each

Party shall immediately and within at least [*] business days
notify the other Party in writing

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of, and shall provide the other Party with copies of, any correspondence and other documentation received or prepared by such Party in connection with any of the following events: (1) receipt of a regulatory letter, Warning Letter, or similar item, from the FDA or any other regulatory authority directed to the manufacture, packaging, and storage of Bulk Drug, or in connection with any general cGMP inspections applicable to any Genentech Facility to the extent associated with Genentech's activities under this Agreement; (2) any recall, market withdrawal or correction of any Batch of Bulk Drug or resulting Finished Product; and (3) any regulatory comments related to the manufacture of Bulk Drug or resulting Finished Product requiring a response or action by a Party.

(b) Regulatory Correspondence Requiring a Genentech Response. In the event

Genentech receives any regulatory letter or comments from any federal, state or local regulatory authority directed to its manufacture of

Bulk Drug requiring a response or action by Genentech, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a Warning Letter, Immunex promptly will provide Genentech with any data or information required by Genentech in preparing any response related to Genentech's manufacture of Bulk Drug and will cooperate fully with Genentech in preparing such response. Genentech shall provide Immunex with a copy of each such response (redacted to remove information not related to the manufacture of Bulk Drug or Genentech's other obligations under this Agreement) for Immunex's review and comment prior to Genentech's submission of its detailed written response. Genentech shall give all due consideration to any Immunex comments to each such proposed Genentech response provided Immunex timely responds. Likewise, in the event Immunex receives any regulatory letter or comments from any federal, state or local regulatory authority directed to the manufacture of Bulk Drug at the Genentech Facility requiring a response or action by Immunex, including, but not limited to, receipt of a Form 483 (Inspectional Observations) or a Warning Letter, Genentech will, to the extent within its control or possession, promptly provide Immunex with relevant data or information sufficient for Immunex to prepare any response related to the manufacture of Bulk Drug and will cooperate fully with Immunex in preparing such response. Immunex shall provide Genentech with a copy of each such response (redacted to remove information not related to the manufacture of Bulk Drug at Genentech's Facility or Immunex's obligations under this Agreement) for Genentech's review and comment prior to Immunex's submission of its detailed written response. Immunex shall give all due consideration to any Genentech comments to each such proposed Immunex response provided Genentech timely responds.

9.5 Inspections; Non-Compliance; Failure to Manufacture.

(a) Inspections. In the event the Genentech Facility is inspected, or -----

Genentech is notified that the Genentech Facility will be inspected, by representatives of any federal, state or local regulatory agency directed to Genentech's manufacture of Bulk Drug, Genentech shall notify Immunex promptly after receipt of notice of such inspection, and shall supply Immunex with copies of any correspondence or portions of correspondence which relate to Bulk Drug. Immunex may send, and

upon the request of Genentech shall send, representatives to the Genentech Facility to participate in any portion of such inspection directed to Bulk Drug.

(b) Non-Compliance; Failure to Manufacture. In the event that the FDA shall

determine, as a result of an inspection described in Section 9.5(a)

above, that Genentech is not in compliance with applicable laws or regulations or otherwise not in compliance with cGMP with respect to the manufacture of Bulk Drug, Genentech shall at its expense use Commercially Reasonable Best Efforts to cure any such non-compliance with cGMP, and use Commercially Reasonable Efforts to cure any other such non-compliance as soon as practicable. In the event that any regulatory agency other than the FDA shall determine that Genentech is not in material compliance with applicable laws and regulations relating to the manufacture of Bulk Drug, the Parties shall discuss any potential Genentech curative efforts in good faith. In the event Genentech receives a Warning Letter from the FDA and as a result Genentech is unable to manufacture Bulk Drug for a particular period, then, except in the event of Genentech's gross negligence or willful misconduct, the provisions of Sections 20.3, 20.4 and 20.5 hereof shall

apply, it being understood that Genentech's inability to manufacture Bulk Drug for the reasons set forth in this Section 9.5 shall be deemed

to be a Force Majeure Event unless Genentech's inability to manufacture was caused by Genentech's gross negligence or willful misconduct.

ARTICLE 10. RECALLS -----

10.1 Recalls. Immunex shall notify Genentech promptly (and in any event within

[*] business days of receipt of written notice) if any batch of Bulk Drug or resulting Finished Product is the subject of a recall, market withdrawal or correction. Immunex shall (i) bear the cost of and be responsible for conducting all recalls, market withdrawals or corrections of Bulk Drug or Finished Product, (ii) remain obligated to pay Genentech the Purchase Price for the Bulk Drug recalled or used to make such recalled Finished Product and (iii) reimburse Genentech for its out-of-pocket expenses related to the recall, if any. Notwithstanding the foregoing, [*] recall, market withdrawal or correction was caused by Genentech's breach of any of its warranties set forth in Section 6.1 hereof, [*] Genentech shall credit

Immunex for all or a portion of the Purchase Price for the Bulk Drug recalled or used to make such recalled Finished Product and shall reimburse Immunex for [*] Immunex's out-of-pocket expenses related to the recall, if any, [*]. Immunex or its agent shall in all events be responsible for conducting any recalls, market withdrawals or corrections with respect to the Product in the Territory.

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ARTICLE 11. QUALITY ASSURANCE; QUALITY CONTROL; VALIDATION; STABILITY

11.1 Responsibility for Quality Assurance and Quality Control. Responsibility

for quality assurance and quality control of Bulk Drug shall be allocated between Immunex and Genentech as set forth in the Quality Agreement and in standard operating procedures agreed upon in writing by Immunex and Genentech from time to time. In general, (a) Genentech shall be responsible for performing certain in-process testing and selected acceptance testing on the Bulk Drug as set forth in the Tech Transfer Agreement and the Quality Agreement, and (b) Immunex shall be responsible for all final acceptance testing and authorizing final release of all Bulk Drug. In the event the Parties disagree on whether a Batch shall be released, the dispute shall be resolved in compliance with the provisions set forth in Section 8.1 hereof.

11.2 Validation of Genentech Facility; Utilities and Equipment. Genentech shall

maintain cGMP validation status of the Genentech Facility, as well as the utilities and equipment used in the manufacture of Bulk Drug at the Genentech Facility, and shall make relevant validation reports applicable thereto (redacted to remove information not related to the manufacture of Bulk Drug) available to Immunex for review at Genentech's Facility, at Immunex's reasonable request.

11.3 Validation of Bulk Manufacturing Process. In accordance with the

requirements of and timelines set forth in the Tech Transfer Agreement, Immunex shall provide Genentech with Manufacturing Documentation related to the validation of the Manufacturing Process, as further described therein, including, without limitation, drafts of the product comparability protocol and the process validation protocol related to the Manufacturing Process. Immunex is responsible for Process Validation. A Process Qualification plan to be developed by Genentech and approved by Immunex will identify additional process validation related to the technology transfer to Genentech, if required, at commercial scale. Genentech shall provide Immunex with copies of documentation related to the validation of the Manufacturing Process, as implemented by Genentech, and validation reports applicable thereto, to Immunex, at Immunex's reasonable request, on a frequency and in a format to be agreed upon by Genentech and Immunex.

11.4 Change Control. Any changes to the Genentech Facility, utilities, equipment

or processes used by Genentech in its performance under this Agreement, including those relating to the manufacturing, storage, testing, shipping

and cleaning procedures that are used by Genentech in the manufacture of Bulk Drug under this Agreement, shall occur pursuant to change control procedures agreed upon by Genentech and Immunex and as set forth in the Quality Agreement.

11.5 Stability. Immunex shall conduct all necessary stability testing to comply -----

with cGMP and other applicable regulatory guidelines. Such stability testing shall include testing to validate the lead times for shipment, the shelf life of Bulk Drug and the Bulk Drug Specifications applicable to shipment, storage and handling of Bulk Drug. Genentech shall prepare all stability samples, and shall subplot stability samples and package and ship stability samples to Immunex, all in accordance with timelines, protocols and procedures agreed upon by Genentech and Immunex and set forth in the Quality Agreement.

11.6 Person in the Plant. As further described in the Quality Agreement, Immunex -----

shall have the right to designate one employee of Immunex to be present in the Genentech Facility in South San Francisco during normal business hours during the Term of this Agreement to observe the Runs and observe Genentech's performance of its obligations under this Agreement. Such person shall have sufficient technical expertise and delegated corporate authority to, at a minimum, approve change control authorizations and deviations. While at the Facility, such representative of Immunex shall be restricted to such areas as are directly relevant to the manufacture of the Bulk Product, or as otherwise authorized by Genentech, and shall comply with all applicable Genentech policies and procedures and may, at Genentech's option, be escorted by Genentech personnel. Such representative shall have no right to direct or supervise Genentech personnel.

ARTICLE 12. GENENTECH'S OBLIGATIONS AS MANUFACTURER -----

12.1 Control of Working Cell Bank. Genentech shall maintain all portions of the -----

Working Cell Bank that it receives in safe and secure storage under its control in the Genentech Facility at One DNA Way in South San Francisco, California, and shall not permit the transfer of the Working Cell Bank to any Genentech Affiliate or any Third Party that is not specifically authorized in advance and in writing by Immunex. Genentech shall comply with all applicable FDA regulatory requirements relating to general safety in handling the Working Cell Bank and any raw materials and components used in manufacturing Product and Bulk Drug.

12.2 Manufacturing Capabilities. Genentech shall at all relevant times -----

throughout the Term use Commercially Reasonable Efforts consistent with the terms of this Agreement to (a) own or lawfully control all the necessary plant, equipment and facilities, and (b) have sufficient numbers of appropriately qualified personnel, in each case to enable Genentech to manufacture Bulk Drug in accordance with the Bulk Drug Specifications and in quantities sufficient to fulfill its obligations to supply Bulk Drug under this Agreement.

12.3 Compliance with Law. Genentech shall perform all work and services under -----

this Agreement in conformance with cGMP and in conformance with the substantive requirements of all applicable material national, state and local laws, ordinances and governmental rules or regulations of the United States, the noncompliance with which would materially adversely affect the marketability of the Bulk Drug, and shall have all applicable licenses and permits required to perform the work and services hereunder, the absence of which would materially adversely affect the marketability of the Bulk Drug.

12.4 Genentech Facility. Genentech will use Commercially Reasonable Efforts to -----

ensure that the Genentech Facility shall be maintained in accordance with cGMP and in such condition as will allow Genentech to manufacture the Bulk Drug in accordance with the Bulk Drug Specifications.

12.5 Storage Facilities. Subject to Section 4.4, Genentech shall provide -----

sufficient and suitable storage facilities that meet the Bulk Drug Specifications for Bulk Drug and raw

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materials.

12.6 Regulatory Documentation. -----

(a) Genentech shall provide Immunex in a timely manner with a copy of any Genentech manufacturing and control records for Bulk Drug which are required for any Immunex regulatory filings with respect to the Product, which records shall be in Genentech's standard formats unless otherwise agreed upon by the Parties.

(b) Genentech shall provide Immunex promptly after the end of each annual reporting period for the Product (as calculated consistent with appropriate regulations and guidelines) with such information as is reasonably requested in writing by Immunex for the preparation of the annual report with respect to the manufacturing and control of the Product for such annual reporting period. Thereafter, Immunex shall provide to Genentech at least [*] days prior to Immunex's filing with

the respective regulatory authorities a copy of such Immunex annual report, and Immunex shall take into consideration any Genentech comments to such annual report with respect to the manufacture of Product.

12.7 Manufacturing Data. Genentech shall collect data on the yield from each -----
Batch, as well as the date of manufacture of each such Batch and make reports of the same available to Immunex in the form of a monthly manufacturing status report in Genentech's standard format or in such other format as may be agreed by the Parties. Genentech shall retain such manufacturing data in accordance with the requirements of applicable laws, rules and regulations.

12.8 Retention and Reserve Samples. Genentech shall isolate, identify and, -----
subject to Section 19.3 hereof, retain retention and reserve samples of all -----
raw materials and in-process production steps used in the production of Bulk Drug as may be required by standard operating procedures to be agreed upon in writing by Genentech and Immunex from time to time.

12.9 Analytical Testing. Except as otherwise contemplated by this Agreement or -----
expressly set forth in the Quality Agreement, Genentech shall not perform any analytical testing on Bulk Drug unless agreed to by Genentech and Immunex.

12.10 Accurate Documentation. Each Party shall use diligent efforts to ensure -----
all records and documentation provided to the other Party in connection with the manufacture of Bulk Drug shall be accurate in all material respects.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. The omitted portions of this exhibit have been filed separately with the SEC.

ARTICLE 13. LICENSE GRANTS

13.1 License to Genentech. During the Term (subject to early termination in -----
accordance with Article 19 hereof), Immunex hereby grants to Genentech a -----
royalty-free, non-exclusive license under any and all intellectual property

rights owned or controlled by Immunex (including, without limitation, such rights as are licensed to Immunex by a Third Party and which may be sublicensed to Genentech in accordance with the terms set forth herein) and which are necessary for Genentech to perform its obligations under this Agreement, including, without limitation, all rights necessary to the use of the Cell Line, the Manufacturing Process, and/or the Immunex Confidential Information (such rights are collectively the "Immunex IP

Rights") for the sole and limited purpose of Genentech's performance of its

obligations under this Agreement, including, without limitation, to manufacture and supply Bulk Drug to Immunex.

13.2 [*].

(a) [*] Expressly conditioned on Immunex' representation and warranty under Section 15.1(e) hereof, Genentech, for itself and its

subsidiaries, hereby [*]. The terms of this Section 13.2(a) shall [*],

and shall survive expiration or termination of this Agreement, and shall be binding upon and inure to the benefit of the successors and assigns of the Parties. In the event that Genentech [*]; provided, however, that Genentech's good faith and inadvertent failure to do so shall not be considered a material breach of this Agreement.

(b) [*].

(1) License to [*]. Except for Genentech Improvements assigned to

Immunex pursuant to Section 14.1(c) hereof, Genentech hereby grants

Immunex [*] to make, have made, use, market, distribute, import, offer for sale and sell Product within the Territory within the Field. The license granted under this Section 13.2(b) (1) is also subject to the

last sentence of [*].

(2) [*]

(A) [*].

(B) [*]

(3) [*]

(c) [*] Subject to the exceptions below in this Section 13.2(c) (1), the [*]

provisions of this Section 13.2(c) shall apply to the Confidential

Information of a Party ("Disclosing Party") disclosed to or received by the

other Party ("Recipient") in the course of performance of this Agreement, the Tech Transfer Agreement or the Quality Agreement, or in the course of negotiating said agreements, or effecting

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the technology transfer of the Product manufacturing process in effect as of the Effective Date or the Manufacturing Process, or information relating to the Product or to the manufacture thereof disclosed to a Party by the other Party or received by a Party from the other Party pursuant to the Confidentiality Agreements between the Parties dated August 16, 2000, December 13, 2001 and March 29, 2002 (collectively, the "CDAs"). The obligations of this Section 13.2(c) shall cease to

apply to Confidential Information of a Party, as well as to knowledge and information obtained by Recipient from access to said Confidential Information, upon said Confidential Information becoming subject to the exclusions listed in Section 17.3 hereof. Neither Party shall

disclose its) confidential information to other Party that is not reasonably necessary or appropriate for the performance of its obligations under this Agreement, the Tech Transfer Agreement or the Quality Agreement, and this Section 13.2(c) shall not apply to the

Disclosing Party's Confidential Information that is not reasonably necessary or appropriate to be disclosed by the Disclosing Party for purposes of the Recipient's performance of its obligations under this Agreement, the Tech Transfer Agreement or the Quality Agreement, including, without limitation, any information on manufacturing processes for other products. Notwithstanding the foregoing, the Disclosing Party's Confidential Information of which the Recipient becomes aware due to the presence of its employees, agents or contractors at the Disclosing Party's facilities, either through inadvertent good faith disclosures or through misappropriation, shall be subject to the provisions of this Section 13.2(c). Each Party shall

use good faith efforts to provide the Disclosing Party's Confidential Information to the Recipient through the Disclosing Party's employees having responsibility for the performance of the Disclosing Party's obligations under this Agreement, the Tech Transfer Agreement or the Quality Agreement, but inadvertent failures to do so shall not limit the applicability of this Section 13.2(c).

(1) [*]

(2) [*]

(d) Survival. The obligations of the Parties set forth in this Section

13.2 shall survive the expiration or termination of this Agreement.

ARTICLE 14. OWNERSHIP OF INTELLECTUAL PROPERTY, MATERIALS AND EQUIPMENT

14.1 Ownership of Intellectual Property, Confidential Information,

Biological Materials and Manufacturing Documentation.

(a) Intellectual Property. In accordance with the rules of inventorship of

the United States of America, each Party shall solely own any and all
inventions or discoveries that are conceived or reduced to practice in
the course of or resulting

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confidential treatment filed with the Securities and Exchange Commission. The
omitted portions of this exhibit have been filed separately with the SEC.

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from this Agreement, the Tech Transfer Agreement and/or the Quality
Agreement by the Party or its employees or agents, and the Parties
shall jointly own inventions or discoveries that are conceived or
reduced to practice in the course of or resulting from this Agreement,
the Tech Transfer Agreement and/or the Quality Agreement with an
inventive contribution by employees or agents of both Parties.
Licenses to the foregoing are described in Article 13 above. The

Parties hereby agree that neither Party shall be considered an
"employee or agent" of the other Party.

(b) Confidential Information. As between the Parties, Immunex shall own

all Immunex Confidential Information, and Genentech shall own all
Genentech Confidential Information; provided, however, that the
foregoing shall not limit Immunex' ownership of, or ability to use,
the Cell Line, Master Cell Bank, Working Cell Bank, and/or the
Product, including, without limitation, aspects of Genentech
Confidential Information that result in or contribute to modifications
to said Cell Line, Master Cell Bank, Working Cell Bank, and/or the
Product in the course of or resulting from this Agreement, the Tech

Transfer Agreement and/or the Quality Agreement, either by Immunex in an authorized manner under said agreements or by Genentech.

- (c) Biological Materials. As between the Parties, Immunex shall own all -----
rights in and title to the biological materials described as the Cell Line, Master Cell Bank, Working Cell Bank, and/or the Product, and any and all improved or enhanced versions of the foregoing that are created by either Party in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, including, without limitation, any derivatives or variants of the foregoing created by either Party in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement. Genentech hereby assigns to Immunex any Genentech Improvements that relate solely to the Cell Line, Master Cell Bank, Working Cell Bank, and/or the Product. For purposes of this provision, "Genentech Improvements" shall mean any and all patentable inventions made in the course of or resulting from this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, solely by Genentech or its employees or agents, or jointly by the employees and/or agents of each Party, and all intellectual property rights therein. [*].

- (d) Manufacturing Documentation. As between the Parties, Immunex shall own -----
the Manufacturing Documentation.

- (e) Survival. The terms of this Section 14.1 shall survive the expiration -----
or termination of this Agreement, and shall be binding upon and inure to the benefit of the successors and assigns of the Parties. The Parties will continue to reasonably cooperate with each other to perfect the rights granted in this Section 14.1.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. The omitted portions of this exhibit have been filed separately with the SEC.

14.2 Ownership of Equipment. Genentech shall own all right, title and interest -----
in and to any and all equipment, materials, facilities improvements and other assets purchased by Genentech and which are required to be reimbursed by Immunex under the Tech Transfer Agreement, including, without limitation, the Portable Equipment and the Non-Portable Equipment (collectively, the "Equipment"), free and clear of any right or claim of -----
Immunex and anyone claiming through Immunex. All Equipment shall be

maintained in good repair. Notwithstanding the foregoing, however, at the expiration or termination of this Agreement, Immunex may, at its option, take title to and possession of some or all of the Portable Equipment (at no charge but with Immunex paying reasonable costs and expenses to remove such equipment from Genentech's facilities and ship and deliver it to Immunex's facilities), and Genentech may, at no cost, retain all other portions of the Equipment. The freeze tanks described in Section 4.7 hereof

shall be deemed to be "Portable Equipment" and shall be subject to transfer to Immunex pursuant to the terms of this Section 14.2. In addition, all of

the Equipment shall also be subject to the provisions of Section 19.3

below. If Genentech fails to timely arrange for the removal of the Portable Equipment from the Genentech Facility, Immunex shall send written notice requesting such removal. If such removal has not occurred within [*] days of such notice, then Immunex shall be entitled to hire a qualified Third Party at Genentech's reasonable expense to enter the Genentech Facility with written notice at least [*] business days in advance and remove the Portable Equipment, which shall be removed in a reasonable manner without damage to the Genentech Facility. For clarification purposes, removal of the Portable Equipment shall not in and of itself be considered damage to the Genentech Facility.

ARTICLE 15. REPRESENTATIONS AND WARRANTIES

15.1 Immunex. Immunex hereby represents and warrants to Genentech that:

- (a) To the best of Immunex's knowledge, after reasonable inquiry, Immunex is free to supply to Genentech the Working Cell Bank, Immunex Confidential Information (including, without limitation, the Manufacturing Documentation), and all information to be supplied by Immunex to Genentech under the Tech Transfer Agreement; and Immunex's supply to Genentech of the Working Cell Bank and Immunex Confidential Information (including, without limitation, the Manufacturing Documentation), and all information supplied by Immunex to Genentech under the Tech Transfer Agreement, and Genentech's use thereof in accordance with the terms of and in performance of its obligations under this Agreement, does not, to the best of Immunex's knowledge, after reasonable inquiry, infringe any valid claim of any Third Party patent; and, to the best of Immunex's knowledge, after reasonable inquiry, except for the pending suit brought by ZymoGenetics, Inc., there is no suit pending against Immunex or Wyeth in the U.S. that alleges patent infringement by the manufacture or sale of the Product; and to the best of Immunex's knowledge, after reasonable inquiry, Immunex has not received written notice alleging infringement of a Third Party

* Portions of this exhibit have been omitted pursuant to a request for

patent by the manufacture or sale of the Product;

- (b) Immunex has made Genentech aware of any known hazards involved in handling the Cell Line, Working Cell Bank, the Specialized Raw Materials and the Bulk Drug, and will continue to make Genentech aware of such matters in the future;
- (c) Immunex has the corporate power and authority and consents and the legal right to enter into this Agreement and to perform its obligations under this Agreement, including, but not limited to, consents of [*], Immunex's Board of Directors, and Amgen Inc.;
- (d) Immunex has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its respective obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of Immunex, and constitutes a legal, valid, binding obligation, enforceable against Immunex and its successors and assigns in accordance with its terms;
- (e) [*]; and
- (f) To the best of Immunex' knowledge after reasonable inquiry, Immunex has the legal right to [*] set forth in [*] above and the [*] set forth in [*] above.

15.2 Genentech. Genentech hereby represents and warrants to Immunex that:

- (a) To the best of Genentech's knowledge, after reasonable inquiry, Genentech is free to supply the Genentech Confidential Information to Immunex;
- (b) Genentech has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations under this Agreement;
- (c) Genentech has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement. This Agreement has been duly executed and delivered on behalf of Genentech, and constitutes a legal, valid, binding obligation, enforceable against Genentech in accordance with its terms;

(d) Genentech owns or lawfully controls the Genentech Facility, and, to the best of its knowledge after reasonable inquiry, has a sufficient number of employees with such expertise and experience as is necessary or appropriate to produce Bulk Drug in accordance with the terms hereof and in quantities sufficient to fulfill the Annual Minimums set forth in Exhibit A hereof; and

(e) To the best of Genentech's knowledge after reasonable inquiry, Genentech has the legal right to [*] above and to [*]; as of the Effective Date, Genentech has not [*].

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ARTICLE 16. INDEMNIFICATION

16.1 Indemnification by Immunex.

(a) Indemnification by Immunex. Subject to and except to the extent of any

indemnification from Genentech pursuant to Section 16.2 below, Immunex

shall indemnify, defend and hold Genentech, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses), (collectively, the "Liabilities") to

the extent such Liabilities arise out of or result from (1) any claim, lawsuit or other action or threat by a Third Party arising out of the manufacture, use, handling, distribution, marketing or sale of the Product, in any form, (2) any material breach of the representations, warranties and covenants made by Immunex under this Agreement, (3) Immunex's grossly negligent acts or omissions or willful misconduct, and/or (4) any recall of the Product, except and to the extent arising out of or resulting from any material breach of the representations, warranties and covenants made by Genentech under this Agreement, or Genentech's grossly negligent acts or omissions or willful misconduct.

(b) Additional Indemnification by Immunex. Immunex shall indemnify, defend

and hold Genentech, its Affiliates, and their respective directors, officers, employees and agents harmless from and against all

Liabilities to the extent such Liabilities arise out of or result from any claim by a Third Party that Genentech's manufacture of Bulk Drug for Immunex hereunder, to the extent such manufacture of Bulk Drug hereunder is in compliance with the Manufacturing Documentation, Manufacturing Process and Bulk Drug Specifications, infringes the intellectual property rights of such Third Party. [*]

16.2 Indemnification by Genentech. Subject to and except to the extent of any

indemnification from Immunex pursuant to Section 16.1(a) and (b) above,

Genentech shall indemnify, defend and hold Immunex, and its Affiliates, directors, officers, employees and agents harmless from and against all Liabilities to the extent such Liabilities arise out of or result from (a) any material breach of the representations and warranties made by Genentech under this Agreement or any material breach of any of the covenants made by Genentech [*], or (b) Genentech's grossly negligent acts or omissions or willful misconduct. For the purposes of this Section 16.2, "willful

misconduct" shall not include [*].

16.3 Indemnification Procedures.

(a) Identification of Indemnitor and Indemnatee. An "Indemnitor" means

Immunex with respect to Section 16.1(a) and (b) hereof, and Genentech

with respect to

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Section 16.2 hereof. An "Indemnatee" means any of Genentech, its

Affiliates, and their respective directors, officers, employees and agents with respect to Section 16.1(a) and (b) hereof, and any of

Immunex, and its respective Affiliates, directors, officers, employees and agents with respect to Section 16.2 hereof.

(b) Indemnification Procedures. An Indemnatee which intends to claim

indemnification under Section 16.1 or 16.2 hereof shall promptly

notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, such settlement does not adversely affect the Indemnitee's rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein in order for the Indemnitor to exercise such rights. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

16.4 Survival of Indemnification Obligations. The provisions of this Article 16

shall survive the termination or expiration of this Agreement.

16.5 Disclaimer of Consequential Damages. Except for claims arising from [*], in

no event shall either Party be liable to the other Party for incidental, indirect, special, punitive or consequential damages arising from or related to breach of this Agreement, including, without limitation, any claims for damages based upon lost profits [*].

ARTICLE 17. CONFIDENTIALITY

17.1 Confidentiality Obligations.

(a) Genentech Confidentiality Obligations. Genentech shall not disclose

Immunex Confidential Information to any third party other than

(1) its employees or employees of its subsidiaries who have a need to know such information in order to perform their duties in carrying out Genentech's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement,

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- (2) contractors who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to provide direction to Genentech or Immunex regarding their respective obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or
- (3) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

For purposes of clarity, Genentech shall not be authorized to disclose any Immunex Confidential Information to Roche without Immunex' prior written consent. Further, Genentech shall not disclose any confidential information of Roche to Immunex.

(b) Immunex Confidentiality Obligations. Immunex shall not disclose any -----

Genentech Confidential Information to any third party (including, without limitation, Amgen, prior to the effective date of the Change of Control, if any) other than

- (1) employees, consultants, agents or contractors of Immunex or Immunex's Affiliates who are bound by similar obligations of confidentiality and nonuse and who have a need to know such information in order to perform their duties in carrying out Immunex's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, or in order to provide direction to Immunex regarding production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, or
- (2) regulatory authorities, for example, the FDA, that require such information in order to review a BLA or sBLA for the Product or other regulatory filing.

For purposes of this Section 17.1(b), American Home Products -----

Corporation, now known as Wyeth, and its Affiliates shall not be deemed to be affiliates of Immunex [*].

(c) Responsibility for Compliance with Confidentiality and Nonuse -----

Obligations. Each Party shall be responsible for any intentional -----

misuse or misappropriation, by such Party, its Affiliates, or the

employees, consultants, agents or contractors of such Party or such Party's Affiliates, of the other Party's Confidential Information.

17.2 Terms of Agreement. Subject to Sections 17.4 and 18.1 hereof, and except

for any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations (including the rules and regulations of any national stock exchange on which such Party's securities are traded),

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neither Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the terms and conditions of this Agreement; provided that this Section 17.2 shall not prohibit the

disclosure of this Agreement by Immunex to Amgen Inc., and shall not prohibit the disclosure of this Agreement by Genentech to Roche.

17.3 Exclusions. The obligations of confidentiality and nonuse applicable

hereunder to Genentech with respect to Immunex Confidential Information and to Immunex with respect to Genentech Confidential Information shall not apply to any information which:

- (a) at the time of disclosure, is known publicly or thereafter becomes known publicly through no fault of the recipient, its Affiliates or agents;
- (b) becomes available to the recipient from a Third Party which is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from the disclosing Party;
- (c) was developed by the recipient independently of information obtained from the disclosing Party as evidenced by written records;
- (d) was already known to the recipient before receipt from the disclosing Party, as shown by its prior written records, provided that such information was not acquired directly or indirectly from the disclosing Party; or
- (e) is released with the prior written consent of the Party that had originally disclosed such information to the other Party hereunder.

In determining whether or not the disclosing Party's Confidential Information has entered the public domain, the obligations of confidentiality shall no longer apply to only that portion of said Confidential Information that has become public, and portions remaining confidential shall retain their status as Confidential Information.

17.4 Notification of Mandatory Disclosure.

(a) Notification and Consultation. In the event that a Party (in such -----
case, the "Notifying Party") believes it is required by applicable -----
statute or regulation (including the rules and regulations of any national stock exchange on which such Party's securities are traded), or by judicial or administrative process to disclose any part of the other Party's (in such case, the "Notified Party") Confidential -----
Information which is disclosed to it under this Agreement, the Notifying Party shall (1) promptly notify the Notified Party of each such requirement and identify the documents so required thereby, so that the Notified Party may seek an appropriate protective order or other remedy and/or waive compliance by the Notifying Party with the provisions of this Agreement, and (2) consult with the Notified Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

(b) Limited Disclosure. If, in the absence of such a protective order or -----
such a waiver by the Notified Party of the provisions of this Agreement, the Notifying Party is nonetheless required by mandatory applicable law to disclose any part of the Notified Party's Confidential Information which is disclosed to it under this Agreement, the Notifying Party may disclose such Confidential Information without liability under this Agreement, except that the Notifying Party shall furnish only that portion of the Confidential Information which is legally required.

17.5 No Licenses; Maintenance of Confidentiality; Nonuse Obligations.

(a) No Licenses. Except as expressly provided in [*], no right or license, -----
either express or implied, under any intellectual property right is granted under this Agreement, the Tech Transfer Agreement, or the Quality Agreement, by virtue of the disclosure of Confidential Information under this Agreement, the Tech Transfer Agreement, or the

- (b) Maintenance of Confidentiality. Each Party shall use reasonable and -----
customary precautions to safeguard the other Party's Confidential Information, including ensuring that all employees, consultants, agents or contractors who are provided access to such Confidential Information are informed of the confidential and proprietary nature of such Confidential Information and have contractual confidentiality and nonuse obligations that are at least as restrictive as those contained in this Agreement.
- (c) Nonuse Obligations. Immunex Confidential Information shall not be -----
utilized by Genentech for any purpose other than performing its obligations under this Agreement, the Tech Transfer Agreement, or the Quality Agreement, without first obtaining Immunex's prior written consent to each such utilization. Genentech Confidential Information shall not be utilized by Immunex except as set forth in this Agreement, the Tech Transfer Agreement, or the Quality Agreement, or except for the limited purpose of production, testing, storage or quality of the Product or regulatory or compliance issues related to the Product, without first obtaining Genentech's prior written consent to each such utilization.
- (d) Equitable Relief. Each Party agrees that the other Party and their -----
respective Affiliates would be irreparably injured by a material breach of the confidentiality and nonuse provisions of this Agreement by the breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, that monetary remedies would be inadequate to protect the other Party against any actual or threatened material breach of the provisions of this Article 17 by the -----
breaching Party or by its employees or the employees of its Affiliates, consultants, agents or contractors, and, without prejudice to any other rights and remedies otherwise available to the other Party, the breaching Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance, in the other Party's favor

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without proof of actual damages. It is further understood and agreed

that no failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

17.6 Survival of Confidentiality Obligations. The provisions of this Article 17

shall survive the termination or expiration of this Agreement for a period of [*] years; provided, however, that with respect to Immunex Confidential Information that is identified by Immunex as "BIP Confidential

Information," the provisions of this Article 17 shall survive for the

longer of the following time periods: [*] years after the termination or expiration of the ENBREL supply agreement among BIP, American Home Products Corporation, and Immunex dated November 5, 1998, as amended (the "BIP

ENBREL Supply Agreement"); and (b) [*] years after the termination or

expiration of this Agreement.

17.7 Termination of Certain Prior Agreements and Letter of Intent. This

Agreement supersedes (a) the Confidentiality Agreements between the Parties dated August 16, 2000 and December 13, 2001, (b) the Letter of Intent, and (c) the Confidential Disclosure Agreement between the Parties dated March 29, 2002. All Confidential Information (as defined in such Confidentiality Agreements, Letter of Intent and Confidential Disclosure Agreement), exchanged between the Parties under such Confidentiality Agreements, Letter of Intent and Confidential Disclosure Agreement shall be deemed Confidential Information under this Agreement (either Immunex Confidential Information or Genentech Confidential Information, as the context requires) and shall be subject to the terms of this Agreement.

17.8 No Disclosure of Unrelated Information. Neither Party shall disclose

confidential information to the other Party that is not reasonably necessary for performance of a Party's obligations under this Agreement, the Tech Transfer Agreement and/or the Quality Agreement, including but not limited to manufacturing processes for other products, marketing plans and clinical development plans. Notwithstanding the foregoing, nothing in this provision shall limit the confidentiality and non-use obligations and rights herein.

ARTICLE 18. PRESS RELEASES; USE OF NAMES

18.1 Press Releases. The Parties agree that the public announcement of the

execution of this Agreement shall be in the form of a draft press release

to be agreed upon by the Parties, and, after the press release is published, each Party shall be entitled to make or publish any public statement consistent with the contents thereof. Except as set forth in the preceding sentence, no press release, publicity or other form of public written disclosure related to this Agreement shall be permitted by either Party unless the other Party has indicated its consent to the form of the release in writing. This Section shall not apply

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to any disclosure as is deemed necessary, in the reasonable judgment of the responsible Party, to comply with national, federal or state laws or regulations (including the rules and regulations of any national stock exchange on which such Party's securities are traded).

18.2 Use of Names. No Party shall make use of the name of any other Party in any -----
advertising or promotional material, or otherwise, in connection with this Agreement or any related agreements, without the prior written consent of such other Party; provided, however, either Party may include the other Party on a general list of business partners or collaborations.

ARTICLE 19. TERM; TERMINATION

19.1 Term; Option to Extend. Unless sooner terminated pursuant to the terms of -----
this Agreement, the term of this Agreement (the "Term") shall commence on ----
the Effective Date and shall continue until December 31, 2005. The Parties may, by mutual written agreement, extend the Term of this Agreement for an additional year, and, in such case, the Term would be extended through December 31, 2006.

19.2 Termination. This Agreement may be terminated prior to the end of the Term -----
as follows:

(a) Material Breach.

(1) Genentech Material Breach. This Agreement may be terminated in -----
its entirety by Immunex upon written notice thereof to Genentech in the event of a material breach by Genentech which is not cured

within [*] days after receipt of written notice from Immunex to Genentech, specifying in reasonable detail the nature of such breach, or such longer period of time if Genentech delivers a certificate that such material breach is not reasonably capable of being cured within [*] days and that Genentech is working diligently to cure such breach, but in no event shall the time for curing such breach exceed an additional [*] days. In the event such breach is not cured within such cure period, this Agreement shall terminate as set forth in Immunex's notice of breach and in accordance with the terms of this Article; provided, however, that this Agreement shall not be terminated prior to the end of such cure period.

(2) Immunex Material Breach. This Agreement may be terminated by

Genentech upon written notice thereof to Immunex in the event of a material breach by Immunex which is not cured within [*] days from written notice to Immunex specifying in reasonable detail the nature of such breach or longer if Immunex delivers a certificate that such material breach is not reasonably capable of being cured within [*] days and that

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Immunex is working diligently to cure such breach, but in no event shall the time for curing such breach exceed an additional [*] days. Notwithstanding the foregoing, if the material breach referred to in this Section 19.2(a)(2) arises out of or consists

of the failure to pay Genentech amounts due under this Agreement in accordance with the terms hereof, there shall be a single period of [*] days after notice of breach within which Immunex shall have the right to cure such default by making payment in full of the amount then due and payable. In the event such breach is not cured within such cure period, this Agreement shall terminate as set forth in Genentech's notice of breach and in accordance with the terms of this Article; provided, however, that this Agreement shall not be terminated prior to the end of such cure period.

(b) Force Majeure; No Fault Termination. This Agreement may be terminated

as follows: If, as a result of a Force Majeure Event, a Party is unable fully to perform its obligations under this Agreement for any consecutive period of [*] days, unless the Parties mutually agree in

writing upon a shorter time period, Immunex (in the case of a Force Majeure Event affecting Genentech) or Genentech (in the case of a Force Majeure Event affecting Immunex) shall have the right to terminate this Agreement, upon providing written notice thereof to the other Party, such termination to be effective [*] days from the effective date of such notice.

(c) Failure to Obtain FDA Approval for Genentech Facility. This Agreement

may be terminated as follows: (i) in the event FDA Approval for the manufacture of Bulk Drug at the Genentech Facility is not received by [*], or if at any time either Party receives information which indicates that FDA approval by [*] would be highly unlikely, the Parties agree to enter into good faith discussions to determine whether this Agreement should be terminated and, upon agreement of the Parties, this Agreement shall be terminated on the date agreed to by the Parties; and (ii) in the event FDA Approval for the manufacture of Bulk Drug at the Genentech Facility is not received by [*], Immunex may, in its sole discretion, terminate this Agreement in its entirety upon at least [*] days' prior written notice to Genentech; provided, however, that Immunex may not issue a termination notice pursuant to this Section 19.2(c)(ii) after FDA Approval for the manufacture of

Bulk Drug at the Genentech Facility has been received. The date set forth in Section 19.2(c)(ii) hereof may be adjusted by the JPT in

accordance with Section 3.4(d). Immunex may exercise its termination

rights under Section 19.2(c)(ii) hereof so long as Immunex has not

acted in bad faith to materially and adversely affect the critical path to FDA Approval.

(d) Withdrawal of Product. This Agreement may be terminated by Immunex, in

its sole discretion, upon at least [*] days' prior written notice to Genentech, in the event the BLA for the Product is irrevocably withdrawn by Immunex.

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19.3 Consequences of Termination.

(a) Payment of Amounts Due; Cumulative Remedies. Expiration or termination

of this Agreement for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination. Except as expressly stated otherwise herein, remedies under this Agreement are cumulative, and nothing in this Agreement shall prevent any Party, in the case of a material breach (after expiration of applicable cure period and notice periods), from terminating this Agreement and seeking to enforce its rights under this Agreement.

(b) [intentionally omitted]

(c) Termination of Bulk Drug Commitment.

(1) Upon termination of this Agreement in its entirety by Immunex pursuant to Section 19.2(a(1) (Genentech Material Breach),

Immunex may, in its discretion, cancel, in whole or in part, any Runs that were scheduled to be initiated on or after the effective date of such termination. Likewise, upon termination of this Agreement in its entirety by Genentech pursuant to Section 19.2(a(2) (Immunex Material Breach), Genentech may, in

its discretion, cancel, in whole or in part, any Runs that were scheduled to be initiated on or after the effective date of such termination. Runs that are in process and [*] as of the effective date of any such termination shall not be cancelled without the mutual agreement of the Parties, and the Agreement shall continue to survive with respect to those in-process Runs.

(2) Upon the issuance of a notice of termination of this Agreement pursuant to Section 19.2(b) (Force Majeure; No Fault Termination)

hereof, all Runs which were scheduled to be initiated after the date on which the notice of termination was issued shall be automatically cancelled. Runs that are in process and [*] on the date on which the notice of termination was issued shall not be cancelled without the mutual agreement of the Parties, and the Agreement shall continue to survive with respect to those in-process Runs.

(3) Upon the termination of this Agreement pursuant to Section 19.2(c) (Failure to Obtain FDA Approval for Genentech

Facility), Genentech shall immediately stop all Bulk Drug manufacturing hereunder, other than completing testing and release of Bulk Drug that has been fully-manufactured as of the date of termination. Bulk Drug that has been fully-manufactured as of the date of termination but for which testing and release

has not been completed shall remain subject to the terms of this Agreement, and the Agreement shall continue to survive with respect to such Bulk Drug.

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- (4) Upon the issuance by Immunex of a notice of termination of this Agreement pursuant to Section 19.2(d) (Withdrawal of Product),

Genentech shall immediately stop all Bulk Drug manufacturing hereunder, other than completing testing and release of Bulk Drug that has been fully manufactured as of the date on which the notice of termination was issued. Bulk Drug that has been fully-manufactured as of the date on which the notice of termination was issued but for which testing and release has not been completed shall remain subject to the terms of this Agreement, and the Agreement shall continue to survive with respect to such Bulk Drug. In lieu of termination, it shall be Immunex's option to request that Genentech [*].

(d) Other Financial Obligations.

- (1) Raw Materials. Upon expiration of this Agreement or termination

of this Agreement pursuant to Section 19.2(a(2) (Immunex

Material Breach), Immunex shall purchase from Genentech, at the request of Genentech, at Genentech's Acquisition Cost, all remaining usable raw materials, intermediates and packaging components acquired and paid for by Genentech for the manufacture and packaging of Bulk Drug under this Agreement, and, upon termination of this Agreement pursuant to Section 19.2(b) (Force

Majeure; No Fault Termination), Section 19.2(c) (Failure to

Obtain FDA Approval for Genentech Facility), or Section 19.2(d)

(Withdrawal of Product) hereof, Immunex shall purchase from Genentech, at the request of Genentech, at Genentech's Acquisition Cost, all remaining usable Specialized Raw Materials, and Immunex may purchase from Genentech, at the request of Genentech, at Genentech's Acquisition Cost, all remaining usable raw materials (other than Specialized Raw Materials), intermediates and packaging components acquired and paid for by

Genentech for the manufacture and packaging of Bulk Drug under this Agreement; provided, however, that Immunex shall not be obligated to purchase an amount of such raw materials, intermediates and packaging components in excess of the amount reasonably necessary to fulfill the outstanding Bulk Drug Commitment for Bulk Drug that are outstanding at the time of such termination plus a reasonable safety stock; and provided, further, that Genentech shall have an obligation upon receipt of a notice of termination to place no further orders for raw materials, intermediates or packaging components except as may be necessary for completion of any portion of Genentech's services hereunder that are not immediately terminated. Upon expiration of this Agreement, Immunex shall purchase from Genentech, at the request of Genentech, at Genentech's Acquisition Cost, all remaining usable raw materials, intermediates and packaging components acquired and paid for by Genentech for the manufacture and packaging of Bulk Drug under this Agreement; provided, however, that Immunex shall not be obligated to purchase an amount of such raw materials, intermediates and packaging components in excess of the amount

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reasonably necessary to fulfill the outstanding Bulk Drug Commitment for Bulk Drug that are outstanding at the time of such expiration plus a reasonable safety stock; and provided, further, that Genentech shall have an obligation to place no orders for raw materials, intermediates or packaging components except as may be necessary for completion of any portion of Genentech's services hereunder prior to expiration.

(2) Termination Fee for Withdrawal of Product. Upon termination of -----

this Agreement pursuant to Section 19.2(d) (Withdrawal of -----

Product), Genentech shall be entitled to payment by Immunex of an amount which shall be equal to and calculated as of the notice of termination is received, as follows: [*]

(e) Return of Materials and of Immunex Confidential Information; Transfer -----

of Portable Equipment. Upon expiration or termination of this -----

Agreement, unless otherwise directed by Immunex, Genentech shall promptly (1) return or, at Immunex's election, destroy all quantities

of the Cell Line, Master Cell Bank, and Working Cell Bank received by Genentech under this Agreement, the Tech Transfer Agreement or the Quality Agreement, with any such destruction to be certified in writing to Immunex by an authorized Genentech officer, (2) return all Immunex Confidential Information to Immunex, except for a single copy and/or sample which may be retained for documentation purposes only and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement, and (3) return to Immunex all retention and reserve samples being held by Genentech pursuant to Section 12.8 hereof, provided that Genentech may retain one set of -----

such samples for documentation purposes only. In addition, if requested by Immunex, Genentech shall transfer the Equipment to Immunex in accordance with Section 14.2 hereof.

(f) Return of Genentech Confidential Information. Upon expiration or -----
termination of this Agreement, and at Genentech's written request, Immunex shall promptly return all Genentech Confidential Information to Genentech, except for a single copy and/or sample to be retained by Immunex and Immunex for documentation purposes only and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.

(g) Accrued Rights. Except as otherwise expressly set forth herein, any -----
termination or expiration of this Agreement shall be without prejudice to any right which shall have accrued to the benefit of either Party and shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein or, if no period is provided therein, then such obligations shall remain in full force and effect indefinitely.

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ARTICLE 20. FORCE MAJEURE

20.1 Effects of Force Majeure. No Party shall be in breach of this Agreement if -----

there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement) occasioned by any reason

beyond the control and without the fault or negligence of the Party affected thereby, including, without limitation, an act of God, fire, act of government or state, war, civil commotion, insurrection, embargo, [*], prevention from or hindrance in obtaining energy or other utilities, a market shortage of raw materials or necessary components, labor disputes of whatever nature, or any other reason beyond the control and without the fault or negligence of the Party affected thereby (a "Force Majeure

Event"). Such excuse shall continue as long as the Force Majeure Event

continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement.

20.2 Notice of Force Majeure. Each Party agrees to give the other Party prompt

written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under this Agreement. Each Party further agrees to use Commercially Reasonable Efforts to correct the Force Majeure Event as quickly as practicable and to give the other Party prompt written notice when it is again fully able to perform such obligations.

20.3 Allocation of Capacity. If, as a result of a Force Majeure Event, Genentech

at any time is unable fully to supply outstanding Bulk Drug Commitments for Bulk Drug, Genentech shall use reasonable efforts to equitably allocate its available resources and production capacity among Genentech, Immunex and Genentech's other Third Party customers, as the case may be, taking into consideration the respective requirements of each during a reasonable time period prior to the allocation, as well as such requirements during the allocation period. Genentech shall not grant a higher priority to itself or any Third Party than to Immunex with respect to manufacture or shipment of products from the Genentech Facility except as required by contractual obligations pre-dating this Agreement and except and to the extent such Force Majeure Event affects only the manufacture or shipment of Bulk Drug and does not affect the manufacture or shipment of other products.

20.4 Termination. This Agreement may be terminated as a result of a Force

Majeure Event in accordance with Section 19.2(b) hereof.

20.5 Reduction in Annual Maximum Amount and Annual Minimum Amount. If a Force

Majeure Event prevents Genentech from manufacturing Bulk Drug under this Agreement in any calendar year, the parties shall in good faith discuss and Genentech shall use Commercially Reasonable Efforts to increase proportionately the Annual Maximum and Annual Minimum in the subsequent calendar year, if Genentech has excess capacity or can reasonably revise its production schedule without adversely impacting itself or its obligations to Third Parties and/or Affiliates.

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ARTICLE 21. ASSIGNMENT

21.1 Assignment. This Agreement shall be binding upon the successors and assigns

of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld; provided, however, either Party may assign its interest under this Agreement, without the prior written consent of the other Party, (a) to an Affiliate, so long as the assigning Party unconditionally guarantees the obligations of such Affiliate or (b) to a successor of the assigning Party's business by reason of merger, sale of all or substantially all of its assets or other form of acquisition. Any purported assignment without a required consent shall be void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.

ARTICLE 22. DISPUTE RESOLUTION

22.1 Exclusions. Section 22.2 below shall not apply to any disputes arising

under Article 17 (Confidentiality) or Section 23.9 [*].

22.2 Dispute Resolution.

(a) Disputes. The Parties recognize that a bona fide dispute as to certain

matters may from time to time arise during the term of this Agreement that relates to a Party's rights and/or obligations under this Agreement. In the event of the occurrence of such a dispute, any Party may, by written notice to the other Parties, have such dispute referred to their respective officers designated below, or their respective designees, for attempted resolution by good faith negotiations within [*] days after such notice is received. Such designated officers are as follows:

For Immunex - Chief Executive Officer

In the event the designated officers, or their respective designees, are not able to resolve such dispute within such [*]-day period, or such other period of time as the Parties may mutually agree in writing, either Party may, by written notice to the other, invoke the following provisions of this Section 22.2 hereinafter.

- (b) Mediation and Arbitration. The Parties agree that, except as otherwise

set forth in Section 22.1 above or Section 22.2(d) below, any dispute,

controversy or claim arising out of or relating to this Agreement, the
Tech Transfer Agreement, or the Quality Agreement, or the breach,
termination, or invalidity thereof, shall be resolved

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through mediation and binding arbitration. If a dispute arises between the Parties, and if such dispute cannot be resolved pursuant to Section 22.2(a) above, the Parties agree to try in good faith to

resolve such dispute by mediation administered by the American Arbitration Association (unless otherwise agreed in writing by the Parties) in accordance with its Commercial Mediation Rules (unless otherwise agreed in writing by the Parties). If efforts at mediation are unsuccessful within [*] days, any unresolved controversy or claim between the Parties shall be resolved by binding arbitration administered by the American Arbitration Association (unless otherwise agreed in writing by the Parties) in accordance with its Commercial Arbitration Rules (unless otherwise agreed in writing by the Parties), except as modified herein. Each Party shall select one arbitrator and the two (2) arbitrators so selected shall choose a third arbitrator to resolve the dispute. A reasoned arbitration decision shall be rendered in writing within [*] months of the conclusion of arbitration and shall be binding and not be appealable to any court in any jurisdiction. The prevailing Party may enter such decision in any court having competent jurisdiction. Unless otherwise mutually agreed upon by the Parties, the mediation and arbitration proceedings shall be conducted at the location of the Party not originally requesting the resolution of the dispute (the "Non-Requesting Party"), and, if

the Non-Requesting Party is Immunex, then the location shall be, at

Immunex's option, Seattle, Washington, or Los Angeles, California, or such other location as may be agreed in writing by the Parties and, if the Non-Requesting Party is Genentech, then the location shall be, at Genentech's option, San Francisco, California, or such other location as may be agreed in writing by the Parties. The Parties agree that they shall share equally the cost of the mediation and arbitration filing and hearing fees, and the cost of the mediator/arbitrator. Each Party must bear its own attorneys' fees and associated costs and expenses.

(c) Jurisdiction. For the purposes of this Article 22, the Parties agree to -----

accept the jurisdiction of the federal courts located in (a) the Northern District of California for the purposes of enforcing awards entered on behalf of Genentech pursuant to this Article 22 and for enforcing the agreements reflected in this Article, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction, and (b) the Western District of Washington, or the Southern District of California, for the purposes of enforcing awards entered on behalf of Immunex pursuant to this Article 22 and for enforcing the agreements reflected in this Article, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction, and the Parties hereby consent to the jurisdiction and venue of such courts.

(d) Determination of Patents and Other Intellectual Property. -----

Notwithstanding the foregoing, any dispute relating to the determination of validity of a Party's patents or other issues relating to a Party's intellectual property shall be submitted exclusively to the federal court located in the jurisdiction of the defendant, or to a state court in such jurisdiction if the applicable rules of civil procedure preclude federal court jurisdiction, and the Parties hereby consent to the jurisdiction and venue of such courts.

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ARTICLE 23. MISCELLANEOUS

23.1 Notices. Other than notices within the jurisdiction of the respective -----

Project Team Leaders, which shall be given to those individuals, any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered

mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with the original promptly sent by any of the foregoing manners), to the addresses or facsimile numbers of the other Parties set forth below, or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to Genentech: Corporate Secretary
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Fax: (650) 952-9881
Phone: (650) 225-1672

with a copy to: Senior Vice President of Product Operations
Genentech, Inc.
1 DNA Way, MS 53
South San Francisco, CA 94080
Fax: (650) 225-5007
Phone: (650) 225-3978

with a copy to: Vice President of Business & Commercial Development
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Phone: (650) 225-3009
Fax: (650) 225-3705

If to Immunex: Immunex Corporation
51 University Street
Seattle, Washington 98101
Attention: Senior Vice President, Supply Operations
Fax: (206) 682-9927
Phone: (206) 389-4016

with a copy to: Immunex Corporation
51 University Street
Seattle, Washington 98101
Attention: General Counsel
Fax: (206) 292-9271
Phone: (206) 587-0430

23.2 Applicable Law. This Agreement shall be construed, interpreted and enforced

in accordance with the internal substantive laws of the State of [*],

without reference to the choice of law doctrine of such state.

23.3 Headings. The table of contents and all headings in this Agreement are for -----
convenience of reference only and shall not affect the interpretation of this Agreement.

23.4 Exhibits. All exhibits referred to herein form an integral part of this -----
Agreement and are incorporated into this Agreement by such reference.

23.5 Severability. Each Party hereby expressly agrees that it has no intention -----
to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries; that if any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any Party hereto, in a final unappealed order, to be in violation of any such provisions in any country or community or association of countries, such words, sentences, paragraphs, clauses or combination shall be inoperative in such country or community or association of countries and the remainder of this Agreement shall remain binding upon the Parties, so long as enforcement of the remainder does not violate the Parties' overall intentions in this transaction.

23.6 Independent Contractors. Each of the Parties is an independent contractor -----
and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall hold itself out to Third Parties as purporting to act on behalf of, or serving as the agent of, the other Party.

23.7 Waiver. No waiver of any term, provision or condition of this Agreement -----
whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement.

23.8 Counterparts. This Agreement and any amendment hereto may be executed in -----
any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

23.9 [*]

* Portions of this exhibit have been omitted pursuant to a request for

23.10 Entirety; Amendments. This Agreement, including any exhibits attached

hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof (i.e.,

purchase and supply of Bulk Drug), and no terms, conditions, understandings or agreements purporting to modify or vary the terms thereof shall be binding unless it is hereafter made in writing and signed by each of the Parties. No modification to this Agreement shall be effected by the acknowledgment or acceptance of any purchase order or shipping instruction forms or similar documents containing terms or conditions at variance with or in addition to those set forth herein. In the event of a conflict between this Agreement and the exhibits hereto, the terms of this Agreement shall control. This Agreement may be amended and supplemented only by a written instrument signed by each of the Parties.

23.11 Preference. Unless otherwise specifically provided for in the Quality

Agreement and/or Tech Transfer Agreement, the terms of this Agreement shall prevail in the event of a conflict between this Agreement and any of the aforementioned agreements.

[the remainder of this page intentionally blank]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

Immunex Corporation

By: /s/ Efraim Cohen-Arazi

Efraim Cohen-Arazi
Senior Vice President, Supply Operations

Genentech, Inc.

By: /s/ David Ebersman

David Ebersman

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Exhibit A

Minimum and Maximum Runs*

| Calendar Year | Minimum Runs | Maximum Runs |
|---------------|--------------|--------------|
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |

*When used in this Exhibit, the term "Runs" is a defined term, and it shall have the meaning given in the Agreement.

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For Immediate Release, April 15, 2002

CONTACT :

Robin Shapiro (media), 206.389.4040
Mark Leahy (investors), 206.389.4363

Immunex Secures Additional Manufacturing Capacity for ENBREL(R) (etanercept) at Genentech, Inc.

Immunex Takes Additional Steps to Expand Supply To Help Keep Up with Growing Demand for Sales of ENBREL

SEATTLE, WA - Immunex Corporation [Nasdaq: IMNX] today announced a manufacturing agreement with Genentech, Inc. to produce ENBREL(R) (etanercept) at Genentech's manufacturing facility in South San Francisco. Subject to the approval of the U.S. Food and Drug Administration, the facility is expected to add supply capacity for ENBREL, beginning in 2004. Currently, ENBREL is manufactured at a plant operated by Immunex's manufacturing partner, and at Immunex's Rhode Island facility, expected to be approved later this year.

"We're working hard to help assure that the growing demand for ENBREL is met," said Peggy Phillips, Immunex's executive vice president and chief operating officer.

ENBREL was launched in 1998 and is now marketed for reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis (RA). ENBREL is also the first and only therapy approved to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis. Additionally, Immunex is studying ENBREL in a Phase 2/3 clinical study for psoriasis, and Phase 3 clinical studies for ankylosing spondylitis and Wegener's granulomatosis.

"This Genentech agreement adds flexibility and depth to our plans to expand the production capacity of ENBREL to the multi-billion dollar level," said Phillips.

The agreement will be for a fixed time frame. Upon approval of the FDA, which the parties hope to obtain in early 2004, the Genentech facility will become a licensed manufacturing site for commercial supply of ENBREL. Under the terms of the agreement, Genentech will produce ENBREL through 2005, and the parties can by mutual agreement extend production through 2006.

The collaboration with Genentech represents another in a series of strategic steps Immunex is taking to increase both short-term and long-term supply of ENBREL. In November 2001, Immunex broke ground on the BioNext Project(TM), second manufacturing plant in West Greenwich, Rhode Island, which will be dedicated to the production of ENBREL and other products. Once completed, it will be one of the largest and most advanced cell culture manufacturing centers in the world.

ABOUT ENBREL

ENBREL is the only TNF receptor on the market. It acts by binding TNF, one of the dominant inflammatory cytokines or regulatory proteins that play an important role in both normal immune function and the cascade of reactions that cause the inflammatory process of RA and psoriatic arthritis. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

SINCE THE PRODUCT WAS FIRST INTRODUCED, SERIOUS INFECTIONS, SOME INVOLVING DEATH, HAVE BEEN REPORTED IN PATIENTS USING ENBREL. MANY OF THESE INFECTIONS OCCURRED IN PATIENTS WHO WERE PRONE TO INFECTIONS, SUCH AS THOSE WITH ADVANCED OR POORLY CONTROLLED DIABETES. RARE CASES OF TUBERCULOSIS HAVE ALSO BEEN REPORTED. ENBREL SHOULD BE DISCONTINUED IN PATIENTS WITH SERIOUS INFECTIONS. DO NOT START ENBREL IF YOU HAVE AN INFECTION OF ANY TYPE OR IF YOU HAVE AN ALLERGY TO ENBREL OR ITS COMPONENTS. ENBREL SHOULD BE USED WITH CAUTION IN PATIENTS PRONE TO INFECTION. CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS ABOUT ENBREL OR INFECTIONS.

There have been reports of serious nervous system disorders such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your doctor if you have ever had any of these disorders or if you develop them after starting ENBREL(R) (etanercept). There have also been rare reports of serious blood disorders, some involving death. Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness. It is unclear if ENBREL has caused these nervous system or blood disorders. If your doctor confirms serious blood problems, you may need to stop using ENBREL.

The most frequent adverse events in placebo-controlled RA clinical trials involving 349 adults were injection site reactions (ISR) (37%), infections (35%), and headache (17%). Only the rate of ISR was higher than that of placebo. The most frequent adverse events in a methotrexate-controlled clinical trial of 415 adults with early-stage RA were infections (64%), ISR (34%), and headache (24%). Of these, only the rate of ISR was higher than that of methotrexate. In all 1,197 RA patients studied, malignancies were rare (1%).

Adverse events in the psoriatic arthritis trial were similar to those reported in RA clinical trials.

Immunex Corporation and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), market ENBREL in North America. Other Wyeth affiliates market ENBREL outside of

North America. Immunex manufactures ENBREL. Additional information about ENBREL, including full prescribing information, can be found on the company-sponsored Web site at (www.enbrel.com) or by calling toll-free 888-4ENBREL (888-436-2735).

Immunex Corporation is a leading biopharmaceutical company dedicated to improving lives through immune system science innovations.

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines.

Wyeth (NYSE: WYE) is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. Wyeth's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

NOTE: Except for the historical information contained herein, this news release contains forward-looking statements that involve substantial risks and uncertainties. Among the factors that could cause actual results or timelines to differ materially are risks associated with research and clinical development, regulatory approvals, our supply capabilities and reliance on third-party manufacturers, product commercialization, competition, litigation and other risk factors listed from time to time in reports filed by Immunex with the SEC, including but not limited to risks described under the caption "Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price" within our most recently filed Form 10-K. The forward-looking statements contained in this news release represent our judgment as of the date of this release. Immunex undertakes no obligation to publicly update any forward-looking statements. An electronic version of this news release -- as well as additional information about Immunex of interest to investors, customers, future employees and patients -- is available on the Immunex home page at www.immunex.com.

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