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

Form 8-K

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

Date of Report (Date of earliest event reported): August 9, 2022

Intra-Cellular Therapies, Inc.
(Exact name of registrant as specified in its charter)

Commission File Number: 001-36274

Delaware	**36-4742850**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

430 East 29th Street
New York, NY 10016
(Address of principal executive offices, including zip code)

(646) 440-9333
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

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

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**ITCI**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 2.02 Results of Operations and Financial Condition.

On August 9, 2022, Intra-Cellular Therapies, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2022, and provided a corporate update.

A copy of the Company's press release containing such announcements is attached hereto as Exhibit 99.1. The information in the press release set forth under the heading "Second Quarter Financial Highlights," together with the condensed consolidated financial information included in the press release, are incorporated by reference into this Item 2.02 of this Current Report on Form 8-K.

ITEM 8.01 Other Events.

In the press release dated August 9, 2022, the Company also provided a corporate update. The information set forth under the headings "Commercial Highlights," "Clinical Highlights," "About CAPLYTA (lumateperone)" and "About Intra-Cellular Therapies," together with the forward-looking statement disclaimer at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Explanatory Note

The Company is also filing this Form 8-K to transition an exhibit previously filed with the Securities and Exchange Commission (the "SEC") to the requirements set forth in Item 601(b) of Regulation S-K permitting registrants to omit confidential information from material contracts filed pursuant to Item 601(b)(10) without the need to submit a confidential treatment request to the SEC. The purpose of this filing is to attach and refile with the SEC a redacted version of the License Agreement dated as of May 31, 2005 by and between Bristol-Myers Squibb Company and the Company, originally filed with the Company's Current Report on Form 8-K on September 5, 2013 (Exhibit 10.1 hereto). This agreement was subject to an order granting confidential treatment by the SEC for certain confidential information contained therein. The order was issued on November 20, 2013, extended on September 6, 2016 and July 5, 2019, and expired on July 28, 2022. The confidential information omitted from Exhibit 10.1 is both (i) not material and (ii) is the type of information that the Company treats as private or confidential.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
10.1	License Agreement dated as of May 31, 2005 by and between Bristol-Myers Squibb Company and Intra-Cellular Therapies, Inc.
99.1	Press release dated August 9, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

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

INTRA-CELLULAR THERAPIES, INC.

By: /s/ Lawrence J. Hineline
Lawrence J. Hineline
Senior Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary

Date: August 9, 2022

Exhibit 10.1

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks as the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

LICENSE AGREEMENT

between

INTRA-CELLULAR THERAPIES, INC.

and

BRISTOL-MYERS SQUIBB COMPANY

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and entered into as of May 31, 2005 (the "Effective Date"), by and between **Bristol-Myers Squibb Company**, a Delaware corporation headquartered at 345 Park Avenue, New York, New York 10154 ("BMS"), and **Intra-Cellular Therapies, Inc.,** a Delaware corporation having its principal place of business at Audubon Biomedical Science and Technology Park, 3960 Broadway, New York, NY 10032 ("ITI"). BMS and ITI are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, BMS Controls (as defined below) certain patent rights and know-how rights with respect to the Licensed Compounds (as defined below); and

WHEREAS, ITI desires to obtain from BMS the licenses set forth herein, and BMS desires to grant such licenses to ITI, all on the terms and conditions set forth in this Agreement;

NOW, THEREFORE in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "Act" means the United States Food, Drug and Cosmetic Act, as amended.

1.2 "Affiliate" of a Person means any other Person which (directly or indirectly) is controlled by, controls or is under common control with such Person. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to a Person, shall mean the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise. "Control" shall be presumed to exist if either of the following conditions is met: (i) in the case of a corporate entity, direct or indirect ownership of voting securities entitled to cast at least fifty percent (50%) of the votes in the election of directors or (ii) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interests with the power to direct the management and policies of such entity.

1.3 "Agreement" means this Agreement, together with all Appendices attached hereto, as the same may be amended or supplemented from time to time.

1.4 "Approval" means, with respect to any Licensed Product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use and sale of the Licensed Product in such jurisdiction in accordance with applicable Laws. For purposes of the U.S., Approval means NDA Approval. For purposes of Japan, Approval means JNDA Approval. For purposes of the EU, Approval means MAA Approval.

1.5 "[***]" means (a) [***] (b) [***].

1.6 "BMS Core Patent Rights" means those patents and patent applications listed in Appendix 1 hereto, and (a) any foreign counterparts thereof, (b) all divisionals, continuations, continuations-in-part thereof or any other patent application claiming priority directly or indirectly to (i) any of the patents or patent applications identified on Appendix 1 or (ii) any patent or patent application from which the patents or patent applications identified on Appendix 1 claim direct or indirect priority, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, or extensions thereof, and any foreign counterparts thereof.

1.7 "BMS Know-How" means (a) Know-How that, as of the Effective Date, is Controlled by BMS and directly relates to and is reasonably necessary for, ITI's Development and Commercialization of the Licensed Compounds and Licensed Products in the Field, and (b) any Know-How that after the Effective Date is acquired or developed by BMS during the term of the Agreement, that is Controlled by BMS, and that directly relates to and is reasonably necessary for, ITI's Development and Commercialization of the Licensed Compounds and Licensed Products in the Field.

1.8 "BMS Other Patent Rights" means all Patent Rights other than those included in the BMS Core Patent Rights which are Controlled by BMS during the term of this Agreement and which (a) claim any Licensed Compound and/or Licensed Product and (b) are necessary for the research, discovery, Development, manufacture, marketing, use, export, import or sale of Licensed Compounds and/or Licensed Products in the Field. For the avoidance of doubt, the BMS Other Patent Rights do not include any claims in any Patent Rights Controlled by BMS covering the composition of matter of any compound that are not also covering the composition of matter of any Licensed Compound or an intermediate or starting material reasonably necessary in the manufacture of any Licensed Compound. Until a patent or patent application is identified in Appendix 9, it shall not be considered a BMS Other Patent Right for the purposes of this Agreement.

1.9 "BMS Patent Rights" means the BMS Core Patent Rights and the BMS Other Patent Rights.

1.10 "BMS Retained Field" means the prevention, treatment or control of obesity, diabetes, metabolic syndrome, or any related diseases, disorders or conditions or any cardiovascular disease, disorder and condition.

1.11 "Business Day" or "business day" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York are authorized or obligated by Law to close.

1.12 "Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.13 "Calendar Year" means each successive period of 12 months commencing on January 1 and ending on December 31.

1.14 "Combination Product" means a Licensed Product that includes at least one additional active ingredient other than the Licensed Compound. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized by the FDA as an active ingredient in accordance with 21 CFR 210.3(b)(7).

1.15 "Commercialization" or "Commercialize" means activities directed to commercially manufacturing, obtaining pricing and reimbursement approvals, carrying out Phase IV Studies, marketing, promoting, distributing, importing or selling a Licensed Product.

1.16 "Commercially Reasonable Efforts" means those efforts that a company within the bio-pharmaceutical industry would reasonably use, and specifically means, with respect to the Development and Commercialization of Licensed Compounds and Licensed Products, the carrying out of Development and Commercialization activities using efforts that a company within the bio-pharmaceutical industry would reasonably devote to a product [***]. Without limiting the foregoing, Commercially Reasonable Efforts require that ITI: (i) promptly assign responsibility for such Development and Commercialization activities to specific employees who are held accountable for progress and monitor such progress on an on-going basis, (ii) set and consistently seek to achieve specific and meaningful objectives and timelines for carrying out such Development and Commercialization activities, and (iii) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives and timelines.

1.17 "Competitive Compound" means [***].

1.18 "Confidential Information" means all trade secrets, processes, formulae, data, Know-How, improvements, inventions, chemical or biological materials, techniques, marketing plans, strategies, customer lists, or other information that has been created, discovered, or developed by a Party, or has otherwise become known to a Party, or to which rights have been assigned to a Party, as well as any other information and materials that are deemed confidential or proprietary to or by a Party (including, without limitation, all information and materials of a Party's customers and any other Third Party and their consultants), regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic, or electronic form. "Confidential Information" of BMS shall include, without limitation, the BMS Know-How.

1.19 "Controlled" or "Controls", when used in reference to intellectual property, shall mean the legal authority or right of a Party hereto (or any of its Affiliates) to grant a license or sublicense of intellectual property rights to the other Party or any Third Party, or to otherwise disclose proprietary or trade secret information to such other Party or to any Third Party, without breaching the terms of any agreement with any Third Party.

1.20 "Development" means non-clinical and clinical drug development activities reasonably related to the development and submission of information to a Regulatory Authority, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including, without limitation, pre-and post-approval studies and specifically excluding regulatory activities directed to obtaining pricing and reimbursement approvals). When used as a verb, "Develop" means to engage in Development.

1.21 "Development Plan" means, with respect to a Licensed Product, a comprehensive, multi-year plan specifying Development details for such Licensed Product (including, without limitation, the indications targeted, line of therapy, timelines for completing key activities, phasing of Development, primary endpoints, criteria for continuing activities, study size, comparator drugs, combination drugs, timelines for data preparation and filing of regulatory submissions, toxicology and pharmacology studies and manufacturing process development and scale up) for all applicable countries in the Territory, together with a detailed budget specifying the costs for all Development activities proposed to be undertaken by ITI. A summary of the initial Development Plan as of the Effective Date is attached hereto as Appendix 2.

1.22 "Documented BMS Know-How" means any BMS Know-How transferred to ITI under this Agreement in the form of written documentation or electronic files and any BMS Know-How that is initially disclosed verbally or visually to ITI and that is summarized in a written document provided to ITI within 30 days after such verbal or visual disclosure.

1.23 "Dollar" or "$" means the lawful currency of the United States.

1.24 "Effective Date" means the date specified in the initial paragraph of this Agreement.

1.25 "EMEA" means the European Agency for the Evaluation of Medicinal Products, or any successor agency thereto.

1.26 "EU" means the European Union, as its membership may be altered from time to time, and any successor thereto, and which, as of the Effective Date, consists of Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom, and that certain portion of Cyprus included in such organization.

1.27 "Excluded Compounds" means [***] identified in Appendix 3, and [***].

1.28 "FDA" means the U.S. Food and Drug Administration, or any successor agency thereto.

1.29 "Field" means the prevention, treatment or control of any human or animal disease, disorder or condition in any field except the BMS Retained Field.

1.30 "First Commercial Sale" means, with respect to any Licensed Product, the first sale for use or consumption by the general public of such Licensed Product in any country in the Territory after Approval of such Licensed Product has been granted, or such marketing and sale is otherwise permitted, by the Regulatory Authority of such country.

1.31 "GAAP" means generally accepted accounting principles in the United States.

1.32 "Generic Product" means any pharmaceutical product containing as an active ingredient a Licensed Compound (or any salt, solvate, crystalline or noncrystalline form of such Licensed Compound) that is also contained in a Licensed Product, and which pharmaceutical product is sold in the same country as such Licensed Product by any Third Party that is not a Sublicensee of ITI or its Affiliates for the same use as the Licensed Product is sold in that country.

1.33 "IND" means an Investigational New Drug Application, as defined in the Act, filed with the FDA or its foreign counterparts.

1.34 "Indemnification Claim" has the meaning set forth in Section 12.2.

1.35 "Indemnitee" has the meaning set forth in Section 12.2.

1.36 "Independent Evaluator" means an individual with relevant expertise in the commercialization of pharmaceutical products employed by an independent certified public accounting firm or investment bank of nationally recognized standing that, at the time of the evaluation set forth in Section 3.2, is not providing auditing or consulting services to either Party, and that is selected by ITI and reasonably acceptable to BMS, or such other qualified Person as the Parties may mutually agree to.

1.37 "ITI Improvement Patent Rights" means those Patent Rights owned or Controlled by ITI which claim inventions that arise out of activities under this Agreement and which would be infringed (absent a license from ITI) by the practice of the BMS Core Patent Rights or the BMS Other Patent Rights for the research, discovery, Development, manufacture, use or sale of compounds or pharmaceutical products in the BMS Retained Field or by the making, using or importing of the Licensed Compounds identified in Appendix 4 (except for the Excluded Compounds) for internal research purposes in the Field.

1.38 "JNDA" means a new drug application filed with the Koseisho required for marketing approval for the applicable Licensed Product in Japan.

1.39 "JNDA Approval" means the final approval of a JNDA by the Koseisho for the applicable Licensed Product in Japan.

1.40 "Know-How" means technical information (including, without limitation, all biological, chemical, pharmacological, toxicological, clinical, manufacturing assay and related data, know-how and trade secrets).

1.41 "Koseisho" means the Japanese Ministry of Health and Welfare, or any successor agency thereto.

1.42 "Laws" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.43 "Less Favorable to ITI" has the meaning set forth in Section 3.6.1.

1.44 "License" means a grant or transfer of rights with respect to the Development or Commercialization of any Licensed Compound or any Licensed Product. "License" also refers to the corresponding grant or transfer by ITI of rights back to BMS with respect to one or more Licensed Compound(s) or Licensed Product(s) pursuant to Article 3. For the avoidance of doubt, a License can, but does not necessarily have to, include a sublicense of the rights granted under Section 2.1.

1.45 "License Agreement" means a written, definitive agreement for a License.

1.46 "Licensed Compound" means (i) those compounds identified in Appendix 4, (ii) any compound that is an analog or derivative thereof and that satisfies the criteria described in Appendix 5, and (iii) any other compound that satisfies the criteria described in Appendix 5 and that was conceived or reduced to practice, in whole or in part, using any Documented BMS Know-How, BMS Core Patent Rights, BMS Other Patent Rights or any information generated in the research, discovery or Development of Licensed Compounds and Licensed Products that relates to the structure of a compound.

1.47 "Licensed Product" means any pharmaceutical product containing a Licensed Compound or a prodrug of a Licensed Compound (alone or with other active ingredients), in all forms, presentations, formulations and dosage forms.

1.48 "Losses and Claims" has the meaning set forth in Section 12.1.

1.49 "MAA Approval" means Approval by the EMEA of a marketing authorization application ("MAA") filed with the EMEA for the applicable Licensed Product under the centralized European procedure. If the centralized EMEA filing procedure is not used, MAA Approval shall be achieved upon the first Approval for the applicable Licensed Product in three of the following countries: France, Germany, Italy, Spain and the United Kingdom.

1.50 "Major Market Countries" means the following countries: [***]. "Major Market Country" means one of these countries.

1.51 "NDA" means a new drug application filed with the FDA required for marketing approval for the applicable Licensed Product in the U.S.

1.52 "NDA Approval" means the final approval of an NDA by the FDA for the applicable Licensed Product in the U.S.

1.53 "NDA Filing" means the acceptance by the FDA of the filing of an NDA for the applicable Licensed Product.

1.54 "Negotiation Period" has the meaning set forth in Section 3.1.2.

1.55 "Net Sales" means, with respect to any Licensed Product, the amount billed by a Party, an Affiliate of such Party, or any distributor or permitted Sublicensee for sales of such Licensed Product to a Third Party less:

(a) discounts (including, without limitation, cash discounts and quantity discounts), retroactive price reductions, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers (a "Discount"); *provided however*, that where any such Discount is based on sales of a bundled set of products in which such Licensed Product is included, the Discount shall be allocated to such Licensed Product on a pro rata basis based on the sales value (i.e., the unit average selling price multiplied by the unit volume) of the Licensed Product relative to the sales value contributed by the other constituent products in the bundled set, with respect to such sale;

(b) credits or allowances actually granted upon claims, damaged goods, rejections or returns of such Licensed Product, including such Licensed Product returned in connection with recalls or withdrawals;

(c) freight out, postage, shipping and insurance charges for delivery of such Licensed Product; and

(d) taxes or duties levied on, absorbed or otherwise imposed on the sale of such Licensed Product, including, without limitation, value-added taxes, or other governmental charges otherwise imposed upon the billed amount, as adjusted for rebates and refunds, to the extent not paid by the Third Party.

Net Sales shall be determined in accordance with GAAP. In the case of any Combination Product sold in the Territory, Net Sales for such Combination Product shall be calculated by [***]. If, [***] Net Sales for [***] shall be calculated by [***]. If [***], the Parties shall [***], or, [***] shall be [***] and [***], and shall [***].

Net Sales shall [***].

1.56 "Patent Rights" means (a) patents and patent applications, (b) any foreign counterparts thereof, (c) all divisionals, continuations, continuations-in-part thereof or any other patent application claiming priority directly or indirectly to (i) any of the patents or patent applications in (a) or (ii) any patent or patent application from which the patents or patent applications in (a) claim direct or indirect priority, and (d) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, or extensions thereof, and any foreign counterparts thereof.

1.57 "Person" means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity.

1.58 "Phase I Trial" means a human clinical trial of a Licensed Product in any country that is intended to initially evaluate the safety, pharmacokinetic and/or pharmacological effect of a Licensed Product in subjects, as more fully defined in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by a Regulatory Authority outside the U.S.

1.59 "Phase I/II Trial" means a human clinical trial of a Licensed Product on a limited number of subjects that is intended to establish that a pharmaceutical product is safe and to demonstrate initial indications of efficacy for its intended use.

1.60 "Phase II Trial" means a human clinical trial of a Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b), or a similar clinical study prescribed by a Regulatory Authority outside the U.S. For clarity, a Phase II Trial shall not include a Phase I/II Trial. A Phase IIa Trial is a Phase II Trial that is a human clinical trial in not less than 70 patients with the disease or indication under study and that is designed to provide an indication of the efficacy of the Licensed Product for its intended use, and a Phase IIb Trial is a Phase II Trial in patients with the disease or indication under study that is a well-controlled trial designed to be statistically significant.

1.61 "Phase III Trial" means a human clinical trial of a Licensed Product on a sufficient number of subjects that is designed to establish that a pharmaceutical product is safe and efficacious for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such pharmaceutical product in the dosage range to be prescribed, which trial is intended to support Approval of a Licensed Product, as described in 21 C.F.R. 312.21(c), or a similar clinical study prescribed by a Regulatory Authority outside the U.S. A Phase III Trial shall be deemed to have commenced when the first patient in such study has been dosed.

1.62 "Phase IIIb Trial" means (a) a product support human clinical trial of a Licensed Product (*i.e.*, a clinical trial that is not required for receipt of the first Approval of a Licensed Product for a particular indication in a country but which may be useful in providing additional drug profile data in support of such Approval of the Licensed Product for such indication) that is commenced before receipt of the first Approval of the Licensed Product for a particular indication in the country for which such trial is conducted or (b) a human clinical trial that is required or advised by a Regulatory Authority as a condition of or in connection with obtaining or maintaining the first Approval of a Licensed Product for a particular indication (whether commenced prior to or after receipt of such Approval).

1.63 "Phase IV Study" means a human clinical trial, or other test or study, of a Licensed Product commenced after receipt of the first Approval of the Licensed Product for a

particular indication in the country for which such trial is being conducted and that is (a) conducted within the parameters of the labeling approved for the Licensed Product, other than Phase IIIb Trials or (b) conducted outside the scope of the labeling approved for the Licensed Product. Phase IV Studies may include clinical trials, or other tests and studies, conducted in support of pricing/reimbursement for the first Approval of the Licensed Product, epidemiological studies, modeling and pharmacoeconomic studies, post-marketing surveillance studies, investigator sponsored clinical trials of a Licensed Product, and health economics studies.

1.64 "Qualified Study" means the first Phase IIa Trial for a Licensed Product anywhere in the world that is completed following the filing of a US IND for the Licensed Product wherein the doses in such Phase IIa Trial are based on the results of one or more Phase I Trials for the Licensed Product.

1.65 "Regulatory Authority" means any national or supranational governmental authority, including, without limitation, the FDA, EMEA or Koseisho, that has responsibility in countries in the Territory over the Development and/or Commercialization of the Licensed Compounds and Licensed Products.

1.66 "Restricted Mechanism of Action" means: [***].

1.67 "Sublicense Revenues" means all consideration in the form of cash ITI receives from a Sublicensee pursuant to any License, including without limitation [***]: (a) [***]; (b) [***]; (c) [***]; (d) [***]; and (e) [***].

1.68 "Sublicensee" means any Third Party to whom rights are transferred with respect to any Licensed Compound or Licensed Product, including through any license, sublicense, co-development, co-discovery, co-promotion, distribution, joint venture, Development and Commercialization collaboration or similar transaction between ITI (or an Affiliate of ITI) and a Third Party. "Sublicensee" shall also include any Third Party that is a party to a License Agreement.

1.69 "Term Sheet" has the meaning set forth in Section 3.6.2.

1.70 "Territory" means any country in the world.

1.71 "Third Party" means any Person other than ITI, BMS and their respective Affiliates.

1.72 "Third Party Term Sheet" means a Term Sheet summarizing the key terms and conditions on which ITI would be willing to enter into negotiations with a Third Party with a view to finalizing a mutually acceptable License Agreement that includes the terms contained in the Term Sheet.

1.73 "Title 11" has the meaning set forth in Section 13.10.

1.74 "Transferred Materials" has the meaning set forth in Section 4.3.

1.75 "United States" or "U.S." means the United States of America.

1.76 "Valid Claim" means a claim of (i) an issued and unexpired patent or a supplementary protection certificate, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise, or (ii) a pending patent application; *provided, however*, [***].

ARTICLE 2

LICENSE GRANT

2.1 BMS Patent Rights and BMS Know-How. Subject to all the terms and conditions set forth in this Agreement (including, without limitation, the restrictions in Section 2.2 and the reservation of rights in Section 2.6), BMS hereby grants to ITI a non-transferable (except in accordance with Section 15.4), exclusive license, with the right to sublicense in accordance with Section 2.3, under the BMS Patent Rights and BMS Know-How solely to the extent necessary to research, discover, Develop, make, have made, use, sell, offer to sell, export and import Licensed Compounds and Licensed Products in the Field in the Territory. For clarification, nothing in this Section 2.1 or this Agreement shall be interpreted as a grant of rights to co-formulate or use in combination a Licensed Compound with: (a) any compound that is not a Licensed Compound and that is, or the manufacture or use of which is, covered by a Patent Right owned by or licensed to BMS or any of its Affiliates; (b) a compound or product that is not a Licensed Compound or Licensed Product and that is or could be subject to a governmental grant providing marketing exclusivity with respect to such compound or such product (such as data exclusivity under the FDA's Orange Book or under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83), including but not limited to any such compound or such product that is being developed or sold (as of the Effective Date or in the future) by BMS or its Affiliates or by contractors or collaborators with or on behalf of BMS or its Affiliates, or (c) any Licensed Compound that is subject to Section 2.8 so that ITI cannot Develop or Commercialize a product containing such Licensed Compound.

2.2 Limitations. ITI may exercise the rights granted under Section 2.1 to (i) modify the Licensed Compounds identified in Appendix 4 (e.g., to prepare analogs or derivatives of those Licensed Compounds) and (ii) synthesize any compound using any BMS Know-How and any BMS Patent Rights or any information generated in the research, discovery or Development of Licensed Compounds and Licensed Products that relates to the structure of a compound; *provided, however*, that ITI may Develop and Commercialize only those resulting compounds that satisfy the criteria described in Appendix 5. Any compound resulting from activities permitted by this Section 2.2 and satisfying the definition of a Licensed Compound shall be a Licensed Compound, and any compound resulting from the activities permitted by this Section 2.2 that does not satisfy the criteria in Appendix 5 may not be Developed or Commercialized by ITI or licensed, sold or otherwise transferred to any Third Party by ITI for Development or Commercialization.

2.3 Sublicenses. ITI shall have the limited right to grant sublicenses to Third Parties with respect to the rights licensed to ITI under Section 2.1, solely in accordance with this Section 2.3.

2.3.1 Prior to the Completion of the Qualified Study, ITI may enter into a License Agreement only with the prior written consent of BMS. Regardless of the results of the Qualified Study, following the Completion of the Qualified Study, ITI shall have the right to enter into a License Agreement, subject to BMS' rights as set forth in Article 3. As used herein, "Completion of the Qualified Study" shall mean the submission to BMS of the preliminary clinical study report plus the clinical data and tables generated in connection with the Qualified Study after all patient dosing for the Qualified Study has been completed. ITI shall not have the right to enter into any License with a Third Party except in accordance with the procedure set forth in Article 3.

2.3.2 Subject to the foregoing and Article 3, ITI shall have the right to enter into a License Agreement with a Third Party, *provided* that:

(a) such License Agreement shall refer to this Agreement and shall be subordinate to and consistent with the terms and conditions of this Agreement, and, shall not limit ITI's ability to fully perform all of its obligations under this Agreement or BMS' rights under this Agreement;

(b) in such License agreement, the Sublicensee shall agree in writing to be bound to ITI by terms and conditions that are substantially similar to, or less favorable to the Sublicensee than, or otherwise allow ITI to fully perform, the corresponding terms and conditions of this Agreement;

(c) ITI shall take such actions as BMS reasonably requests, including but not limited to filing a lawsuit, in order to enforce against such Sublicensee provisions in the Sublicense relating to the protection of any intellectual property right of BMS licensed hereunder or any Confidential Information of BMS. ITI shall also take such actions as BMS reasonably requests, including but not limited to filing a lawsuit, in the event such Sublicensee is in breach of the rights granted to such Sublicensee under the intellectual property of BMS or in breach of any obligation under this Agreement that is binding upon the Sublicensee, including but not limited to, failing to maintain insurance coverage at the same levels and on the same terms and conditions as set forth in Section 12.4, failing to keep books and records in accordance with Section 8.7, failing to permit an independent auditor of ITI as to which BMS and such Sublicensee have no reasonable objection to review such books and records pursuant to the terms and conditions of Section 8.7, or failing to comply with the provisions corresponding to Sections 5.1, 5.2, and 5.3, such as failing to provide ITI with a copy of each Development Plan for a Licensed Product, failing to provide ITI with a copy of each development report due under Section 5.2, failing to maintain records in accordance with Section 5.3 or failing to allow an independent Third Party as to which such Sublicensee has no reasonable objection to review such records on behalf of ITI to verify that such Sublicensee is complying with Section 5.3;

(d) promptly after the execution of such License agreement, ITI shall provide a copy of such License agreement to BMS, with financial terms redacted;

(e) ITI shall remain responsible for the performance of this Agreement (including, without limitation, its obligations under Sections 5.1 and 6.1, the payment of all payments due, and making reports and keeping books and records), and shall use Commercially Reasonable Efforts to monitor such Sublicensee's compliance with the terms of such License;

(f) the Sublicensee shall agree in writing (i) to maintain insurance coverage at the same levels and on the same terms and conditions as set forth in Section 12.4, (ii) to keep books and records in accordance with Section 8.7, to permit an independent certified accountant of ITI as to which such Sublicensee has no reasonable objection to review such books and records pursuant to the terms and conditions of Section 8.7 and to permit ITI to inform BMS of the results of such review and to provide BMS with a copy of any report prepared by such accountant, and (iii) to comply with the provisions of the License Agreement between the Sublicensee and ITI corresponding to Sections 5.1, 5.2, and 5.3, including agreeing to provide ITI with a copy of each Development Plan for a Licensed Product, to provide ITI with a copy of each development report due under Section 5.2, to maintain records in accordance with Section 5.3, to allow an independent Third Party as to which such Sublicensee has no reasonable objection to review such records on behalf of ITI to verify that such Sublicensee is complying with Section 5.3, and to permit ITI to inform BMS of the results of such review and to provide BMS with a copy of any report prepared by such Third Party;

(g) any sublicense rights granted by ITI in a License (to the extent such sublicensed rights are granted to ITI in this Agreement) shall terminate effective upon the termination under Article 13 of the license from BMS to ITI with respect to such sublicensed rights, *provided* that such sublicensed rights shall not terminate if, as of the effective date of such termination under Article 13 the Sublicensee is not in material breach of its obligations to ITI under its License Agreement, and within sixty (60) days of such termination the Sublicensee agrees in writing to be bound directly to BMS under a license agreement substantially similar to this Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee (a "Surviving Sublicensee") for ITI, and *provided further* that (A) such license agreement shall not prejudice any remedy either Party may have against the other in connection with such termination of this Agreement (in whole or in part); (B) the scope of the rights granted to the Surviving Sublicensee under such license agreement (with respect to licensed activities, Licensed Products and territory) shall be less than or equal to the scope of the rights that had been sublicensed by ITI to the Surviving Sublicensee pursuant to the License Agreement; (C) such license agreement shall not include the provisions of Article 3 or Section 8.1 hereof; (D) ITI shall no longer be obligated under this Agreement to pay amounts set forth in this Agreement, to the extent such amounts are payable based on the activities of such Surviving Sublicensee, its Affiliates and its sublicensees from and after the effective date of such termination; (E) such license agreement shall obligate the Surviving Sublicensee to pay directly to BMS amounts corresponding to those set forth in Sections 8.2, 8.3 and 8.4 hereof which are payable based on the activities of such Surviving Sublicensee, its Affiliates and its sublicensees from and after the effective date of such termination; and (F) such license agreement shall not modify the rights and obligations of the Parties following any termination of this Agreement in whole or in part.

(h) such Sublicensees shall have the right to grant further sublicenses with respect to the Development or Commercialization of Licensed Products, *provided* that such further sublicenses shall be made in accordance with and subject to all of the terms and conditions of this Section 2.3 other than any reference to Article 3 contained therein (i.e., the Sublicensee shall be subject to this Section 2.3 in the same manner and to the same extent as ITI, but shall not be subject to Article 3).

2.3.3 For clarity, where provisions of this Agreement provide that ITI shall be "solely" responsible or the like with respect to a matter (for example, Sections 5.4, 5.5, or 7.1), it is understood that such responsibilities may be carried out or borne on ITI's behalf by a permitted Sublicensee or contractor of ITI.

2.3.4 It shall be a breach of this Agreement for ITI to enter into any License hereunder not in compliance with this Section 2.3.

2.3.5 Any purported License not entered into in compliance with the foregoing Sections 2.3.1 and 2.3.2 shall be null and void and without effect.

2.4 No Trademark License. No right or license, express or implied, is granted to ITI to use any trademark, trade name, trade dress or service mark owned or Controlled by BMS or any of its Affiliates. ITI, at its sole cost and expense, shall be responsible for the selection, registration and maintenance of all trademarks which it employs in connection with its activities conducted pursuant to this Agreement, if any, and shall own and Control such trademarks.

2.5 No Implied Licenses. No license or other right is or shall be created or granted hereunder by implication, estoppel or otherwise. All such licenses and rights are or shall be granted only as expressly provided in this Agreement.

2.6 Retained Rights. All rights not expressly granted hereunder are reserved by BMS and may be used by BMS for any purpose. Without limiting the foregoing, BMS retains [***]. BMS also expressly reserves and retains the right to make, have made and use any Licensed Compound for use as an intermediate or starting material in the manufacture of any compound that is not a Licensed Compound.

2.7 Grant to BMS. ITI grants to BMS a fully paid-up, worldwide, nonexclusive license to practice under and to utilize any ITI Improvement Patent Rights, solely to research, discover, Develop, make, have made, use, import, export, offer to sell, and sell compounds and pharmaceutical products in the BMS Retained Field and to make, have made, use, import and export any Licensed Compounds identified in Appendix 4 except for the Excluded Compounds for internal research purposes in the Field. Such nonexclusive license shall be sublicensable only together with any license with respect to the BMS Core Patent Rights or the BMS Other Patent Rights.

2.8 Compound Preemption. The first Party to file an IND for a product containing a Licensed Compound in that Party's field (i.e., in the case of ITI, in the Field, and in the case of BMS, in the BMS Retained Field, and subject to the provisions of Section 2.6), shall have the right to Develop and Commercialize that product and other products containing that Licensed Compound in that Party's field. Upon notification by the filing Party, the other Party shall no longer have the right to Develop or Commercialize a product containing that Licensed Compound in that Party's field until such time as the Party that first filed such an IND discontinues all Development and Commercialization efforts for products containing that Licensed Compound in that Party's field.

ARTICLE 3

BMS RIGHT OF FIRST NEGOTIATION

3.1 BMS Right of First Negotiation. BMS shall have a right of first negotiation with respect to Licensed Compounds and Licensed Products as follows:

3.1.1 ITI shall not enter into a License Agreement, or enter into discussions with any Third Party with respect to any License, until Completion of the Qualified Study except as otherwise provided for in Section 2.3.1. After Completion of the Qualified Study, ITI shall be free to license any or all Licensed Compounds and any or all Licensed Products to Third Parties subject to the following rights of BMS.

(a) After Completion of the Qualified Study, in the event that ITI desires to enter into a License Agreement for one or more Licensed Compounds and/or Licensed Products, before entering into discussions with any Third Party with respect to a License for such Licensed Compounds or Licensed Products, ITI shall provide BMS with written notice that a data room is open and available at ITI for BMS to review the data and information generated in connection with any clinical trials and any other Development performed with the Licensed Compounds or Licensed Products that ITI intends to out-license (such written notice, a "Data Room Notice"). ITI shall use its best efforts to inform BMS prior to the Data Room Notice being sent that ITI is preparing a data room in anticipation of a Data Room Notice. The Data Room Notice shall identify the Licensed Compound(s) and the Licensed Product(s) that would be the subject of such License and shall comply with Section 3.7.

(b) As of the date the Data Room Notice is provided to BMS, the data room shall include all relevant data then in existence and available to ITI regarding the applicable Licensed Compounds and Licensed Products, including, where applicable, copies of clinical protocols, case report forms, investigator brochures, regulatory submissions and correspondence from regulatory agencies with respect to the Licensed Compounds and Licensed Products that would be the subject of the License, and details of any Patent Rights owned or Controlled by ITI relating to the Licensed Compounds and Licensed Products that would be the subject of the License, any licenses obtained from Third Parties relating to the Licensed Compounds and Licensed Products that would be the subject of the License, and the cost of goods and source of goods for the Licensed Compounds and Licensed Products that would be the subject of the License. ITI shall also promptly provide BMS with any additional information available to ITI that is related to the Licensed Compound(s) and Licensed Product(s) that would be the subject of the License, and access to personnel and facilities, as reasonably requested by BMS as part of BMS' due diligence with respect to such License during the Negotiation Period (as defined below in Section 3.1.2).

(c) If BMS wishes to exercise its right of first negotiation and pursue license discussions, BMS shall so notify ITI thereof in writing (such notice, the "Exercise Notice") no later than [***] ([***]) [***] following the date the Data Room Notice is provided to BMS (the "Exercise Period"). The Parties shall thereafter during the Negotiation Period (defined below in Section 3.1.2) each use diligent efforts to conduct good faith negotiations with respect to such License. During the Negotiation Period, ITI shall provide BMS with an opportunity to make a proposal of terms and conditions in a Term Sheet with respect to such License and ITI shall either agree to the proposal (and such Term Sheet shall be deemed as "The Term Sheet ITI Delivered to BMS" for purposes of Section 3.2.1 below) and the Parties each shall use diligent efforts to negotiate a License Agreement in good faith based on the proposal, or ITI shall promptly provide a Term Sheet to BMS with a counter offer. During the Negotiation Period, ITI may revise the terms and conditions of the Term Sheet with respect to such License, and the last such Term Sheet that ITI delivers to BMS shall be deemed "The Term Sheet ITI Delivered to BMS" for the purposes of Section 3.2.1 below.

3.1.2 If ITI and BMS do not conclude a License Agreement with respect to such License during a period of [***] following the date the Data Room Notice is provided to BMS (the "Negotiation Period"), ITI shall then be free to enter into negotiations with any Third Party regarding a License for such Licensed Compound(s) and Licensed Product(s), and, subject to the provisions set forth in Sections 3.2, 3.3 and 3.4, to enter into such License with a Third Party. Such [***] Negotiation Period shall be extended by an additional [***] ([***]) [***] if during such [***] Negotiation Period (i) ITI and BMS reach agreement in principle with respect to a Term Sheet with respect to such License and (ii) BMS obtains internal approval of its executive committee to proceed with completing a License Agreement based on such Term Sheet.

3.1.3 Following delivery of the Data Room Notice, if BMS does not provide ITI with the Exercise Notice during the Exercise Period, ITI shall be free to enter into negotiations with any Third Party with respect to a License for the Licensed Compound(s) and Licensed Product(s) identified in the Data Room Notice, and ITI shall have the right to enter into a License Agreement with respect to the Licensed Compound(s) and Licensed Product(s) identified in the Data Room Notice without such Licensed Compound(s) and Licensed Product(s) being subject to Section 3.2 and Section 3.3, provided the geographic scope, the scope of licensed indications and the field of use in such License Agreement are the same as or narrower than those offered to BMS with respect to the Licensed Compounds and Licensed Products identified in the Data Room Notice.

3.1.4 ITI shall not enter into any License Agreement with any Third Party with respect to a License under terms and conditions which are Less Favorable to ITI (as defined in Section 3.6) than the terms and conditions set forth in The Term Sheet ITI Delivered to BMS, except in accordance with the procedure set forth in Section 3.2.

3.2 Process for Execution of License Agreement with Third Party following Expiration of Negotiation Period. If ITI and BMS have not concluded a License Agreement within the Negotiation Period, and if ITI thereafter intends to enter into a License Agreement with a Third Party, ITI shall follow the procedures set forth below:

3.2.1 Independent Evaluation; Re-Offer of Less Favorable Terms. If ITI desires to enter into a License Agreement with the Third Party, ITI shall notify BMS thereof and shall notify an Independent Evaluator for the purpose of this Section 3.2.1. ITI shall bear the costs of engaging the Independent Evaluator.

(a) ITI shall provide the Independent Evaluator with the Third Party Term Sheet, without revealing the identity of the Third Party, and shall also provide the Independent Evaluator with a copy of The Term Sheet ITI Delivered to BMS that is applicable.

(b) The Independent Evaluator shall promptly make a determination of whether the terms and conditions of the Third Party Term Sheet are Less Favorable to ITI (as defined below in Section 3.6) than the terms and conditions of the Term Sheet ITI Delivered To BMS, in accordance with Section 3.6.1 below. Unless the Parties agree otherwise, such determination shall be made by the Independent Evaluator within [***] ([***]) [***] of receipt of the relevant Term Sheets from ITI and the Independent Evaluator shall promptly notify the Parties of such determination. The Independent Evaluator shall be required to make a definite determination based on information provided to it as to whether or not the Third Party Term Sheet is Less Favorable to ITI than the last Term Sheet offered by ITI to BMS. The Independent Evaluator shall not have the authority to render any other determination or to respond without a decision, and the Parties agree to be bound by and not to challenge such determination, except in the case where a Party alleges that the Independent Evaluator did not act in good faith, breached a fiduciary duty or engaged in willful misconduct.

(c) If [***],[***] shall [***] and such [***]. For the avoidance of doubt, [***].

(d) If the Independent Evaluator determines that the terms and conditions set forth in the Third Party Term Sheet are Less Favorable to ITI than the Term Sheet ITI Delivered To BMS, ITI may at its discretion continue its negotiation with the Third Party, with the objective of obtaining financial terms and conditions which are more favorable to ITI than the financial terms and conditions last offered by ITI to BMS, *provided* that ITI shall not enter into a License Agreement with such Third Party without first following the above procedure set forth in this Section 3.2 with respect to submitting a revised Third Party Term Sheet to BMS or the Independent Evaluator. Alternatively, ITI may offer such financial terms and conditions set out in the Third Party Term Sheet to BMS (or ITI may offer BMS terms and conditions financially Less Favorable to ITI than those set out in the Third Party Term Sheet). In the event that ITI makes such offer to BMS, ITI shall also offer to BMS the same terms with respect to governance and decision-making as set out in the Third Party Term Sheet (or otherwise proposed by ITI to the Third Party). If ITI offers such terms and conditions for a License to BMS in accordance with this Section 3.2.1(d), BMS shall have an additional fifteen (15) business days to provide ITI with notice that BMS desires to enter into a License Agreement with ITI on substantially the same financial terms and conditions as set out in such Term Sheet (an "Acceptance Notice"). If an Acceptance Notice is provided by BMS, the Parties shall work diligently to expeditiously complete such a License Agreement within [***] ([***]) [***]. Such [***] ([***]) [***] negotiation period shall be extended by an additional [***] ([***]) [***] if during such [***] ([***]) [***] negotiation period (i) ITI and BMS reach agreement in principle with respect to a Term Sheet with respect to such License and (ii) BMS obtains internal approval of its executive committee to proceed with completing a License Agreement based on such Term Sheet.

(e) If an Acceptance Notice is not provided by BMS within such [***] ([***])[***] period, or if ITI and BMS do not execute a binding License Agreement within sixty (60) days after receipt of the Acceptance Notice, ITI shall be free to enter into a License Agreement with such Third Party having the terms and conditions set forth in the Third Party Term Sheet (or terms and conditions more favorable to ITI than the terms and conditions set forth in the Third Party Term Sheet) and such other terms and conditions as ITI and the Third Party agree. For the avoidance of doubt, [***].

3.3 License Agreement for Retained Rights. If, after Completion of the Qualified Study, BMS does not enter into a License Agreement for a License, and if ITI enters into a License Agreement for a License with a Third Party in accordance with Sections 3.1 or 3.2 above where the License is for less than all of the Licensed Compounds and all of the Licensed Products for all indications in the Field in all of the Territory (a "Limited Third Party License Agreement"), and BMS did not previously have an opportunity to negotiate for a License to such Licensed Compounds or Licensed Products for such indications in the Field in such country(ies) of the Territory in accordance with Section 3.1 and 3.2 that were not licensed to the Third Party in the Limited Third Party License Agreement (such unlicensed Licensed Compounds, Licensed Products, indications, and countries, the "Retained Rights"), then prior to offering a License to any Retained Rights to any Third Party, ITI shall offer a License to such Retained Rights to BMS first, and the procedure described above in Sections 3.1 and 3.2 shall apply to such Retained Rights (except that ITI shall not be required to complete any clinical trial for any compound that is part of such Retained Rights).

3.4 Resurrection of Right of First Negotiation. If ITI provides BMS the opportunity to obtain a License in accordance with Sections 3.1 through 3.3 for particular Licensed Compounds or Licensed Products and BMS does not enter into a License Agreement for such Licensed Compounds or Licensed Products, and if ITI has not entered into a License Agreement with a Third Party with respect to a License for such Licensed Compounds or Licensed Products prior to the earlier of: (i) [***]; or (ii) [***], [***] shall [***], *provided* that ITI shall be free to continue negotiations regarding such License with any Third Party (but not initiate any new negotiations with any other Third Party with whom ITI has not previously negotiated with respect to such License) during any such Negotiation Period pursuant to this Section 3.4, but may not enter into a License Agreement with a Third Party until after the end of such Negotiation Period, and then only in accordance with and following the procedure set forth in Section 3.2.

3.5 Except as provided in Section 3.4, BMS' right of first negotiation under this Article 3 shall be a one-time right per Licensed Product or Licensed Compound.

3.6 Certain Definitions. For the purposes of this Article 3, the following capitalized terms shall have the following meanings:

3.6.1 "[***]" means, with respect to [***], that [***].

3.6.2 "Term Sheet" means a non-binding term sheet summarizing the key terms and conditions on which a Party would be willing to enter into negotiations with a view to finalizing a mutually acceptable License Agreement that includes the terms contained in the Term Sheet. Such a Term Sheet shall contain a level of detail comparable to the term sheets exchanged between the Parties in connection with this Agreement, and shall include, without limitation, the financial terms and conditions and provisions for governance and decision-making authority with respect to the Development and Commercialization of the Licensed Product. It is understood that a Term Sheet need not specify all material terms, and as is customary, may provide a summary of only certain of the most significant terms.

3.7 In the Data Room Notice, ITI shall offer to BMS the right to negotiate for an exclusive license under any applicable Know -How and Patent Rights Controlled by ITI and the grant back of any applicable rights under BMS Patent Rights and BMS Know-How granted to ITI under this Agreement, for the further manufacture, Development and Commercialization in all of the Territory for all fields and all indications for all Licensed Compounds and Licensed Products identified in such notice and any likely backup Licensed Compounds and backup Licensed Products, except that ITI shall have the right to retain the right to co-develop and co-commercialize such Licensed Compounds and Licensed Products [***], and to limit the licenses and rights offered to BMS in the Data Room Notice for the U.S. to the right to co-develop and co-commercialize all such Licensed Compounds and Licensed Products [***] with BMS having at least equal participation in co-commercialization of such Licensed Products in the U.S. Any notice provided by ITI that does not comply with this Section 3.7 shall not be deemed a "Data Room Notice." Upon request of ITI, BMS shall confirm in writing whether a notice complies with this Section 3.7, and may waive in writing (in BMS's sole discretion) compliance of any Data Room Notice with this Section 3.7. Absent such written waiver from BMS, ITI may license any Licensed Compound or Licensed Product identified in a notice that does not comply with this Section 3.7 only after complying with Sections 3.1 and 3.2.

ARTICLE 4

TRANSFER OF KNOW-HOW AND MATERIALS

4.1 Documentation. During the sixty (60) day period following the Effective Date BMS shall provide ITI with one (1) electronic or paper copy of all documents, data or other information Controlled by BMS as of the Effective Date to the extent that such documents, data and information are the subject of the BMS Know-How license under Section 2.1 and are, in BMS' good faith judgment, reasonably necessary for the Development or manufacture of the Licensed Compounds or a Licensed Product and are reasonably available to BMS without undue searching; *provided, however*, that the foregoing shall in no event require BMS to provide originals of laboratory notebooks or pages thereof or manufacturing run records required to be maintained by BMS under applicable Law; *and provided further*, that with respect to BMS Know-How contained in laboratory notebooks, BMS shall only be required to provide ITI with copies of those laboratory notebook pages that can be located without undue searching and that contain BMS Know-How for the compounds identified in Appendix 3. Such documentation

shall not be used by ITI for any purpose other than for the research, discovery, Development, manufacture or Commercialization of Licensed Compounds and Licensed Products in accordance with this Agreement and is Confidential Information of BMS. ITI shall assume full responsibility and liability to BMS for any unauthorized use or disclosure of such Confidential Information. BMS shall be responsible for the cost of providing one (1) set of copies only. BMS shall have no obligation to reformat or otherwise alter or modify any materials, or to create materials in electronic form, in order to provide them to ITI. Any and all materials delivered to ITI pursuant to this Section 4.1 are and shall remain the sole property of BMS.

4.2 Technical Assistance. During the three (3) month period following the Effective Date, BMS shall reasonably cooperate with ITI to assist ITI with understanding and using the BMS Know-How provided to ITI under Section 4.1. Such cooperation shall include, without limitation, providing ITI with reasonable access by teleconference or in-person at BMS' facilities (subject to BMS' customary rules and restrictions with respect to site visits by non-BMS personnel) to BMS personnel directly involved in the research and Development of Licensed Compounds and Licensed Products to provide ITI with [***] ([***]) [***] of technical assistance and consultation in connection with the BMS Know-How transferred under Section 4.1, *provided, however*, that (i) such access shall be requested and coordinated through a single contact person to be designated by BMS, (ii) BMS makes no warranty, express or implied, that ITI shall be able to successfully implement and use the BMS Know-How, and (iii) BMS shall not be in default hereunder for any inadvertent failure to disclose all pertinent information related to the BMS Know-How, provided that such information shall be supplied to ITI promptly upon discovery of such failure to disclose or upon request of ITI specifically identifying the information to be disclosed. ITI shall be responsible for ensuring that its personnel who receive such assistance are appropriately qualified and experienced for such purpose.

4.3 Materials. Within thirty (30) days after the Effective Date, BMS shall transfer to ITI the Licensed Compounds and the intermediate compounds identified in Appendix 7 in the quantities set forth in Appendix 7 (the "Transferred Materials"). Other than the Transferred Materials, BMS shall have no obligation to provide ITI with any compounds or other materials, such as assays or biomaterials, under this Agreement. The samples of intermediate compounds identified in Appendix 7 provided to ITI by BMS as part of the Transferred Materials shall only be used by ITI and its Affiliates, Sublicensees and contractors to make Licensed Compounds. The Transferred Materials are provided "AS IS". ITI shall be fully responsible for its and its Affiliates', Sublicensees' and contractors' use, storage, handling and disposition of the Transferred Materials. Under no circumstances shall BMS be liable or responsible for ITI's or its Affiliates', Sublicensees' and contractors' use, storage, handling or disposition of the Transferred Materials, and ITI assumes sole responsibility for any claims, liabilities, damages and losses that might arise as a result of ITI's and its Affiliates', Sublicensees' and contractors' use, storage, handling or disposition of any Transferred Material. ITI shall indemnify, defend and hold harmless BMS and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all damages, liabilities, losses, costs and expenses (including, without limitation, reasonable legal expenses, costs of litigation and reasonable attorney's fees) arising in connection with any claims, suits, proceedings, whether for money damages or equitable relief, of any kind, arising out of or relating, directly or indirectly, to ITI's, or any of its Affiliates', Sublicensees' or contractors' use, storage, handling or disposition of any Transferred Material. Transferred Materials may only be provided to Affiliates, Sublicensees and contractors of ITI.

ARTICLE 5

DEVELOPMENT

5.1 Development. ITI shall itself or through its Affiliates or Sublicensees use Commercially Reasonable Efforts to [***]. A summary of the initial Development Plan as of the Effective Date is attached hereto as Appendix 2. [***]. Within sixty (60) days of the Effective Date, ITI shall provide BMS with a copy of the complete initial Development Plan. ITI shall promptly provide BMS with a copy of each Development Plan for a Licensed Product not covered by the initial Development Plan.

5.2 Development Reports. ITI shall provide BMS with written development reports within thirty (30) days following the end of the second and fourth Calendar Quarter each Calendar Year (i.e., every six (6) months) summarizing (but without disclosing specific data or results) the research and Development activities accomplished by ITI through the end of such six (6) month period with respect to Licensed Products, updates on ITI's progress against the existing Development Plans, any revisions to any Development Plan, and any significant challenges faced or anticipated with respect to Licensed Products. The obligations of ITI to provide information pursuant to this Section 5.2 shall be subject to its obligations under any License Agreement with a Sublicensee; provided that ITI shall provide to BMS a summary of the progress of the development of Licensed Products in sufficient detail for BMS to determine ITI's compliance its diligence obligation set forth in Section 5.1.

5.3 Records. ITI shall maintain complete and accurate records of all work conducted in furtherance of the research, Development and Commercialization of the Licensed Compounds and Licensed Products and all results, data and developments made in furtherance thereof. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. If BMS believes in good faith that ITI may not be complying with its obligations under this Section 5.3, BMS shall provide written notice thereof to ITI identifying the basis for BMS' good faith belief, and ITI shall allow an independent Third Party as to which ITI has no reasonable objection to review such records on behalf of BMS to verify that ITI is complying with this Section 5.3. Such review shall be at BMS' cost and upon reasonable advance notice at mutually agreed upon times and during normal business hours. Such Third Party shall be under an obligation of confidentiality at least equivalent to the terms contained in Article 11 of this Agreement. If BMS believes in good faith that a Sublicensee of ITI may not be complying with its obligations under the provision of the License Agreement between ITI and such Sublicensee corresponding to this Section 5.3, BMS shall provide written notice thereof to ITI identifying the basis for BMS' good faith belief, and ITI shall upon request of BMS have an independent Third Party selected by ITI as to which BMS and such Sublicensee have no reasonable objection to review such records to verify that such Sublicensee is complying with such provision, to be informed of the results of such review by ITI and to be provided with a copy by ITI of any report prepared by such Third Party.

5.4 Development Responsibilities and Costs. [***]. ITI shall research and Develop the Licensed Compounds and Licensed Products in compliance with all applicable legal and regulatory requirements, including, without limitation, all legal and regulatory requirements pertaining to the design and conduct of clinical studies.

5.5 Regulatory Responsibilities and Costs. As between the Parties, ITI shall have sole responsibility for, and shall bear the cost of preparing, all regulatory filings and related submissions with respect to the Licensed Compounds and Licensed Products. Except as set forth in Article 13, ITI shall own all INDs, Approvals and submissions in connection therewith and all Approvals shall be obtained by and in the name of ITI.

5.6 Subcontracting. ITI may perform certain activities in support of the Development of Licensed Compounds and Licensed Products through subcontracting to a Third Party contractor or contract service organization, *provided that*: (a) none of the rights of BMS hereunder are diminished or otherwise adversely affected as a result of such subcontracting; (b) any such Third Party subcontractor shall enter into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of confidential information that are no less restrictive than the obligations in this Agreement; (c) ITI shall use good faith and diligent efforts to secure an agreement from such Third Party to assign or license (with the right to sublicense) to ITI inventions (and patent rights covering such inventions) made by such Third Party in performing such services for ITI; and (d) ITI shall at all times be responsible for the performance of such subcontractor.

5.7 Competitive Compound. [***].

ARTICLE 6

COMMERCIALIZATION

6.1 ITI Obligations. ITI shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in the Territory. Without limiting the foregoing, ITI shall use Commercially Reasonable Efforts to obtain all Approvals with respect to at least one Licensed Product and to effect the First Commercial Sale of each Licensed Product for which such Approvals are obtained into each Major Market Country as soon as reasonably practicable after receipt of such Approvals.

6.2 Continued Availability. Following the First Commercial Sale of a Licensed Product in a country in the Territory and until the expiration or termination of this Agreement, ITI shall use Commercially Reasonable Efforts to maintain supplies of such Licensed Product sufficient to satisfy ITI's expected Commercialization efforts in such country.

6.3 Marking. Each Licensed Product Commercialized by ITI under this Agreement shall be marked with all patent and other intellectual property notices relating to the BMS Patent Rights in such a manner as may be required by applicable Law.

6.4 Reports. ITI shall provide BMS with a written report within thirty (30) days following the end of each Calendar Year summarizing significant commercial activities and events with respect to Licensed Products during the just ended Calendar Year.

ARTICLE 7

MANUFACTURE AND SUPPLY

7.1 Manufacture and Supply. As between the Parties, ITI shall be solely responsible at its expense for all of its requirements for making or having made all of its requirements of the Licensed Compounds and Licensed Products.

ARTICLE 8

FINANCIAL TERMS

In partial consideration of the rights granted by BMS to ITI pursuant to this Agreement, ITI shall make the payments provided for in this Article 8.

8.1 Initial Payment. [***], ITI shall pay to BMS a nonrefundable, noncreditable payment of one million Dollars ($1,000,000) in cash by wire transfer into an account designated in writing by BMS.

8.2 Development Milestone Payments. The following milestone payments are payable by ITI to BMS for each Licensed Product [***]:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The milestone payments set forth above shall be payable by ITI to BMS [***] of the achievement of the specified milestone event with respect to a Licensed Product. [***].

8.3 In addition to the milestone and royalty payments in this Article 8, ITI shall pay to BMS either (a) [***], or (b) [***].

8.4 Royalty Payments.

8.4.1 ITI shall pay to BMS in cash the following royalty payments on the total aggregate annual Net Sales in the Territory of all Licensed Products (including all indications and formulations for such Licensed Products) in a particular Calendar Year by ITI, its Affiliates, distributors and Sublicensees in the Territory:

Aggregate Annual Worldwide Net Sales of All Licensed Products in Calendar Year	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]

By way of example, [***].

8.4.2 Royalty Term. Royalties shall be payable on a product-by-product and country-by-country basis on Net Sales of Licensed Products [***] (i) [***], (ii) [***], or (iii) [***].

8.4.3 Royalty Reduction for Generic Competition. The royalty amounts otherwise payable under Section 8.4.1 shall be reduced [***] ([***]) on a country-by-country basis at any such time that there is no patent included in the BMS Patent Rights in effect for any reason that are infringed by the sale of a Generic Product or any other governmental grants (e.g., under the Hatch-Waxman Act) providing marketing exclusivity with respect to the applicable Licensed Product in such country that are violated by the sale of a Generic Product and [***]. For such purposes, the reduction shall [***]. Such reduction shall be first applied with respect to such country starting with [***] sales of the Generic Product(s) in such country [***] of the [***] of the [***].

8.4.4 Third Party Royalty Payments.

(a) If ITI, in its reasonable judgment, is required to obtain a license from any Third Party under any patent [***] or [***] for the prevention, treatment or control of any human or animal central nervous system disease, disorder or condition (i.e., [***], for example, [***] or [***]) in order to import, manufacture, use or sell any Licensed Product, and if ITI is required to pay to such Third Party a royalty under such license calculated on sales of a Licensed Product, and the infringement of such patent cannot reasonably be avoided by ITI, or if ITI is required by a court of competent jurisdiction to pay such a royalty to such a Third Party (and the infringement of such patent cannot reasonably be avoided by ITI), then the amount of ITI's royalty obligations under Section 8.4.1 hereof [***], *provided however*, that the royalties payable under Section 8.4.1 hereof [***].

(b) If (i) ITI, in its reasonable judgment, is required to obtain a license from any Third Party [***] or [***], and if ITI is required to pay to such Third Party a royalty under such license calculated on sales of a Licensed Product, and the infringement of such patent cannot reasonably be avoided by ITI, or if ITI is required by a court of competent jurisdiction to pay such a royalty to such a Third Party (and the infringement of such patent cannot reasonably be avoided by ITI), and (ii) [***], then the amount of ITI's royalty obligations under Section 8.4.1 hereof in each Calendar Year [***].

(c) [***] shall [***] to [***]. Prior to [***], [***] shall [***]. [***] shall [***] to [***], *provided* that [***] shall not [***] or [***]. [***] shall [***].

8.4.5 Royalty Conditions. The royalties under Section 8.4.1 shall be subject to the following conditions:

(a) Only one royalty shall be due with respect to the same unit of Licensed Product;

(b) no royalties shall be due upon the sale or other transfer among ITI, its Affiliates, distributors or Sublicensees, but in such cases the royalty shall be due and calculated upon ITI's or its Affiliate's or distributor's or Sublicensee's Net Sales of Licensed Product to the first independent Third Party; and

(c) no royalties shall accrue on the disposition of Licensed Product in reasonable quantities by ITI, its Affiliates, distributors or Sublicensees as part of an expanded access program or as *bona fide* samples or as donations to non-profit institutions or government agencies for non-commercial purposes or for the performance of clinical trials, provided, in each case, that neither ITI, its Affiliate, distributor or Sublicensee receives any payment for such Licensed Product exceeding the cost of goods.

8.4.6 Limit on Royalty Reductions. [***].

8.5 Manner of Payment. All payments to be made by ITI hereunder shall be made in Dollars by wire transfer of immediately available funds to such United States bank account as shall be designated by BMS. Late payments shall bear interest at the rate provided in Section 8.10.

8.6 Sales Reports and Royalty Payments. After the First Commercial Sale of a Licensed Product and during the term of this Agreement, ITI shall furnish to BMS a written report, within thirty (30) days after the end of each Calendar Quarter (or portion thereof, if this Agreement terminates during a Calendar Quarter), showing the amount of royalty due for such Calendar Quarter (or portion thereof). Royalty payments for each Calendar Quarter shall be due at the same time as such written report for the Calendar Quarter. With each quarterly payment, ITI shall deliver to BMS a full and accurate accounting to include at least the following information:

8.6.1 the quantity of each Licensed Product sold (by country) by ITI, its Affiliates, distributors and Sublicensees;

8.6.2 the total gross sales and total Net Sales for each Licensed Product (by country) by ITI, its Affiliates, distributors and Sublicensees, and the calculation of Net Sales from such gross sales;

8.6.3 the quantities of each Licensed Product used by ITI and its Affiliates, distributors or Sublicensees or sold to the U.S. Government;

8.6.4 the names and addresses of all distributors and Sublicensees of ITI;

8.6.5 the royalties payable in Dollars which shall have accrued hereunder in respect of such Net Sales;

8.6.6 withholding taxes, if any, required by applicable Law to be deducted in respect of such royalties; and

8.6.7 the dates of the First Commercial Sales of Licensed Products in any country during the reporting period; and the exchange rates used in determining the amount of Dollars payable hereunder.

If no royalty or payment is due for any royalty period hereunder, ITI shall so report.

8.7 Sales Record Audit.

8.7.1 ITI shall keep, and shall cause each of its Affiliates, distributors and Sublicensees, if any, to keep, full and accurate books of accounting in accordance with GAAP containing all particulars that may be necessary for the purpose of calculating all royalties payable to BMS.

8.7.2 Such books of accounting of ITI and its Affiliates shall be kept at their principal place of business and, with all necessary supporting data and records, shall during all reasonable times for [***] ([***]) [***] next following the end of the Calendar Year to which each shall pertain, be open for inspection not more than once during any 12 month period at reasonable times by an independent certified accountant selected by BMS and as to which ITI has no reasonable objection, at BMS' expense, for the purpose of verifying royalty statements and payments for compliance with this Agreement.

8.7.3 Such books of accounting of ITI's distributors and Sublicensees (if any) shall be kept at their principal place of business and, with all necessary supporting data and records, shall during all reasonable times for [***] ([***]) [***] next following the end of the Calendar Year to which each shall pertain, be open for inspection at reasonable times by an independent certified accountant selected by ITI and as to which BMS and such distributor or Sublicensee have no reasonable objection, at BMS' expense, for the purpose of verifying royalty statements and payments for compliance with this Agreement. ITI shall, upon request of BMS but not more than once during any 12 month period, have such an accountant inspect such books of accounting and such supporting data and records for such purpose. BMS shall be informed of the results of such audit by ITI, and to be provided by ITI with a copy of any report prepared by such accountant.

8.7.4 Such accountant must have agreed in writing to maintain all information learned in confidence, except as necessary to disclose to BMS such compliance or noncompliance by ITI, its Affiliates, distributors or Sublicensees (who must agree in the License Agreement that such audit report may be disclosed to BMS). The results of each inspection, if any, shall be binding on both Parties. BMS shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for any year shown by such inspection of more than [***] ([***]) of the amount paid, ITI shall pay for such inspection. Any underpayments shall be paid by ITI within ten (10) Business Days of notification of the results of such inspection. Any overpayments shall be fully creditable against amounts payable in subsequent payment periods.

8.8 Currency Exchange. With respect to Net Sales invoiced in Dollars, the Net Sales and the amounts due to BMS hereunder shall be expressed in Dollars. With respect to Net Sales invoiced in a currency other than Dollars, the Net Sales shall be expressed in the domestic currency of the entity making the sale, together with the Dollar equivalent, [***]. The "closing mid-point rates" found in the "dollar spot forward against the dollar" table published by The Financial Times or any other publication as agreed to by the Parties shall be used as the source of spot rates to calculate the average as defined in the preceding sentence. All payments shall be made in Dollars.

8.9 Tax Withholding. The withholding tax, duties, and other levies (if any) applied by a government of any country of the Territory on payments made by ITI to BMS hereunder shall be borne by BMS. ITI, its Affiliates and Sublicensees shall cooperate with BMS to enable BMS to claim exemption therefrom under any double taxation or similar agreement in force and shall provide to BMS proper evidence of payments of withholding tax and assist BMS by obtaining or providing in as far as possible the required documentation for the purpose of BMS' tax returns.

8.10 Interest Due. Without limiting any other rights or remedies available to BMS, ITI shall pay BMS interest on any payments that are not paid on or before the date such payments are due under this Agreement at a rate of [***] ([***]) [***] or the maximum applicable legal rate, if less, calculated on the total number of days payment is delinquent.

8.11 Statement by ITI. Within 120 days of the close of each fiscal year of ITI, ITI shall provide BMS with a written summary of ITI's business activities for the just ended fiscal year along with a written statement signed by the chief executive officer of ITI certifying that substantially all of ITI's business activities in the just ended fiscal year were not on behalf of Licensed Compounds and/or Licensed Products, if that is the case. If that is not the case, then ITI shall promptly provide BMS will all information required by BMS to comply with FIN 46, which was issued by the Financial Accounting Standards Board.

ARTICLE 9

REPRESENTATIONS AND WARRANTIES; DISCLAIMER;

LIMITATION OF LIABILITY

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that (i) it has all requisite corporate power and authority to enter into this Agreement and to perform its obligations under this Agreement, (ii) execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized, (iii) this Agreement is legally binding and enforceable on each Party in accordance with its terms, and (iv) the performance of this Agreement by it does not create a breach or default under any other agreement to which it is a Party.

9.2 Representations and Warranties of BMS. BMS represents, warrants and covenants to ITI that:

9.2.1 to the actual knowledge of its in-house patent department and legal department, as of the Effective Date, there is no pending litigation which alleges, or any written communication alleging, that BMS' activities with respect to the BMS Patent Rights or the Licensed Compounds have infringed or misappropriated any of the intellectual property rights of any Third Party;

9.2.2 all fees required to be paid by BMS in order to maintain the BMS Patent Rights have been paid as of the Effective Date;

9.2.3 as of the Effective Date, BMS has good and valid title to the BMS Patent Rights or the BMS Know-How existing as of the Effective Date, free and clear of any encumbrance, lien, mortgage, charge, restriction or liability of any kind whatsoever, whether equitable or legal, that would conflict with or impair the rights granted to ITI under this Agreement or that would require the payment by ITI of any royalty to any Third Party, including, without limitation, any person or entity listed on Appendix 8;

9.2.4 it has not granted, and shall not grant during the term of this Agreement, any right to any Third Party relating to the BMS Patent Rights or the BMS Know-How that would conflict with the rights granted to ITI under this Agreement;

9.2.5 BMS has the right to grant to ITI the rights and licenses in and to the BMS Patent Rights or the BMS Know-How as set forth in this Agreement;

9.2.6 to the actual knowledge of its in-house patent department and legal department, as of the Effective Date, the manufacture of the Licensed Compounds identified in Appendix 4 does not infringe or misappropriate the intellectual property rights of any Third Party;

9.2.7 to the actual knowledge of its in-house patent department and legal department, as of the Effective Date, BMS has not received any written request or demand from any Third Party (or, to the actual knowledge of its in-house patent department and legal department, any other request or demand from any Third Party) for the licensing of any intellectual property rights of such party in connection with the development, manufacture or commercialization of the Licensed Compounds identified in Appendix 4;

9.2.8 to the actual knowledge of its in-house patent department and legal department, as of the Effective Date, none of the BMS Patent Rights is involved in any interference or opposition proceeding, and BMS has not received any written request, demand or notice from any Third Party (including the United States Patent and Trademark Office) threatening or disclosing such a proceeding with respect to any of the BMS Patent Rights; and

9.2.9 to the actual knowledge of its in-house patent department and legal department, except as set forth in Appendix 8, as of the Effective Date, BMS has not received any statement or assertion that (i) any claim in any of the BMS Patent Rights is, or may be or become rendered, invalid or unenforceable, (ii) any Third Party is aware of any basis as to the future potential invalidity or unenforceability of any claim of any of the BMS Patent Rights, or (iii) the BMS Patent Rights do not list all required inventors.

9.3 Representations and Warranties of ITI. ITI represents, warrants and covenants that (i) it shall not engage in any activities that use the BMS Patent Rights and/or Documented BMS Know-How in a manner that is outside the scope of the license rights granted to it hereunder, (ii) all of its activities related to its use of the BMS Patent Rights and Documented BMS Know-How, and the research, Development and Commercialization of the Licensed Compounds and Licensed Products, pursuant to this Agreement shall comply with all applicable material legal and regulatory requirements, and (iii) prior to filing the first drug application (i.e., an NDA or its foreign equivalent) for a Licensed Product, ITI shall have all licenses that are necessary in order for the manufacture, use or sale of such Licensed Product not to infringe the intellectual property of any Third Party known to ITI as of such date, but excluding licenses applicable to any Third Party issued patents for which ITI has obtained a well-reasoned, written opinion of an outside patent attorney that ITI's activities under the scope of this Agreement are not reasonably likely to infringe any Valid Claim of such Third Party issued patent.

9.4 The Parties agree that ITI shall not be in breach of the warranty in Section 9.3(ii) in the event that ITI cures a breach of such warranty within sixty (60) days of the date ITI becomes aware of such breach, or if such breach is not capable of being cured during such sixty (60) day period, if ITI commences to cure such breach during such sixty (60) day period and diligently cures such breach as soon as possible after such sixty (60) day period.

9.5 DISCLAIMER. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING IN THE CASE OF BMS ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE BMS PATENT RIGHTS OR BMS KNOW-HOW OR ANY LICENSE GRANTED BY BMS HEREUNDER, OR WITH RESPECT TO ANY COMPOUNDS, INCLUDING BUT NOT LIMITED TO THE TRANSFERRED MATERIALS, OR PRODUCTS. FURTHERMORE, NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION OR WARRANTY BY BMS THAT ANY PATENT OR OTHER PROPRIETARY RIGHTS INCLUDED IN THE BMS PATENT RIGHTS ARE VALID OR ENFORCEABLE OR THAT USE OF THE BMS PATENT RIGHTS, BMS KNOW-HOW AND TRANSFERRED MATERIALS CONTEMPLATED HEREUNDER DOES NOT INFRINGE ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

9.6 Limitation of Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, [***]. The Parties agree that in the event that there is a final judicial determination (or a determination by an arbitrator in the event the Parties submit a matter to binding arbitration) that absent the limitation under this Section 9.6 of BMS' liability to the amounts paid by ITI to BMS under Sections 8.1, 8.2, 8.3 and 8.4, BMS would be liable to ITI in an amount greater than the amounts paid by ITI to BMS under Sections 8.1, 8.2, 8.3 and 8.4 of this Agreement [***] then [***].

ARTICLE 10

PATENT MAINTENANCE; INFRINGEMENT; PATENT EXTENSIONS

10.1 Inventions. Inventorship of inventions conceived or reduced to practice in the course of Development activities under this Agreement shall be determined by application of United States patent Laws pertaining to inventorship. If such inventions are jointly invented in the course of Development activities by one or more employees or consultants or contractors of both Parties, such inventions shall be jointly owned ("Joint Invention"), and if one or more claims included in an issued patent or pending patent application which is filed in a patent office in the Territory claim such Joint Invention, such patent or patent application shall be jointly owned ("Joint Patent Rights"). If such an invention is solely invented in the course of Development activities by an employee or consultant of a Party, such invention shall be solely owned by such Party, and any patent filed claiming such solely owned invention shall also be solely owned by such Party. This Agreement shall be understood to be a joint research agreement in accordance with 35 U.S.C. § 103(c)(3) to develop the Licensed Compounds and Licensed Products. Each Party shall enter into binding agreements obligating all employees and consultants performing activities under or contemplated by this Agreement, including activities related to the BMS Patent Rights, Licensed Compounds or Licensed Products, to assign his/her interest in any invention conceived or reduced to practice in the course of such activities to the Party for which such employee or consultant is providing its services. With respect to contractors, ITI shall use good faith and diligent efforts to secure an agreement from such contractor to assign or license (with the right to sublicense) to ITI inventions (and patent rights covering such inventions) made by such contractor in performing such services for ITI.

10.2 Filing, Prosecution and Maintenance of BMS Patent Rights. ITI shall notify BMS in writing as soon as practicable of any Patent Rights Controlled by BMS during the term of this Agreement that are not included in the BMS Core Patent Rights and that ITI reasonably believes should be included in the BMS Other Patent Rights and the basis for ITI's belief that such Patent Rights should be included in the BMS Other Patent Rights. Upon agreement by BMS that such Patent Rights should be included in the BMS Other Patent Rights (such agreement not be unreasonably withheld), the parties shall amend Appendix 9 to identify such Patent Rights in Appendix 9, such amended Appendix 9 shall become a part of this Agreement, and such Patent Rights identified in Appendix 9 by way of such amendment shall be included within the BMS Other Patent Rights. BMS shall be responsible, using its in-house patent counsel or outside patent counsel selected by BMS (such selection to be subject to ITI's approval, such approval not to be unreasonably withheld), for the preparation, prosecution (including, without limitation, any interferences, reissue proceedings and reexaminations) and maintenance of the BMS Patent Rights. BMS shall be responsible for the costs incurred by BMS with respect to the filing, prosecution and maintenance of the BMS Core Patent Rights and the BMS Other Patent Rights, provided that BMS remains responsible for such filing, preparation, prosecution and maintenance, and provided further that in the event that BMS grants rights to ITI in the BMS

Retained Field or grants ITI rights under this Agreement to Develop or Commercialize any compound that does not meet the criteria described in Appendix 5 (other than any Licensed Compound identified in Appendix 4 that does not meet those criteria) ITI shall be responsible for all such costs relating to Patent Rights specifically covering the applicable compound. BMS shall provide ITI with an update of the filing, prosecution and maintenance status for each of the BMS Patent Rights, including copies of any material official correspondence to or from patent offices. BMS shall reasonably consult with and cooperate with ITI with respect to the preparation, prosecution and maintenance of the BMS Patent Rights. BMS shall not take any action during prosecution and maintenance of the BMS Patent Rights that would materially adversely affect them (including any reduction in claim scope), without ITI's prior consent. ITI may file a notice with governmental patent offices of the exclusive license to the BMS Patent Rights granted to ITI hereunder.

10.3 Patent Abandonment.

10.3.1 In no event for [***] ([***]) [***] from [***] shall BMS permit any of the BMS Patent Rights (other than the BMS Core Patent Rights under Part II of Appendix 1) to be abandoned in any Major Market Country, or elect not to file a new patent application claiming priority to a patent application within the BMS Patent Rights (other than the BMS Core Patent Rights under Part II of Appendix 1) either before such patent application's issuance or within the time period required for the filing of an international (i.e., Patent Cooperation Treaty), regional (including European Patent Office) or national application in any Major Market Country, without ITI's written consent. BMS shall provide ITI with notice of the allowance and expected issuance date of any such patent within the BMS Patent Rights, or any of the aforementioned filing deadlines, and ITI shall provide BMS with prompt notice as to whether ITI desires BMS to file such new patent application.

10.3.2 Following [***] of [***] with respect to BMS Patent Rights (other than the BMS Core Patent Rights under Part II of Appendix 1) in any Major Market Country, as of the Effective Date with respect to the BMS Core Patent Rights under Part II of Appendix 1 in any Major Market Country, and as of the Effective Date with respect to the BMS Patent Rights in any non-Major Market Country in the Territory, in no event shall BMS permit any of the BMS Patent Rights to be abandoned, or elect not to file a new patent application claiming priority to a patent application within the BMS Patent Rights either before such patent application's issuance or within the time period required for the filing of an international (i.e., Patent Cooperation Treaty), regional (including European Patent Office) or national application, without ITI first being given an opportunity to assume full responsibility for the continued prosecution and maintenance of such BMS Patent Rights, or the filing of such new patent application. BMS shall provide ITI with notice of the allowance and expected issuance date of any such patent within the BMS Patent Rights, or any of the aforementioned filing deadlines, and ITI shall provide BMS with prompt notice as to whether ITI desires BMS to file such new patent application. In the event that BMS decides either (i) not to continue the prosecution or maintenance of a patent application or patent within the BMS Patent Rights in any country as permitted in this Section 10.3.2, or (ii) not to file such new patent application requested to be filed by ITI, BMS shall provide ITI with notice of this decision at least thirty (30) days prior to any pending lapse or abandonment thereof. In such event, BMS shall provide ITI with an opportunity to assume

responsibility for all external costs reasonably associated with the filing and/or further prosecution and maintenance of such patent application and any patent issuing thereon (such filing to occur prior to the issuance of the patent to which the application claims priority or expiration of the applicable filing deadline, as set forth above). In the event that ITI assumes such responsibility for such filing, prosecution and maintenance costs, BMS shall transfer the responsibility for such filing, prosecution and maintenance of such patent applications and patents to patent counsel selected by ITI and reasonably acceptable to BMS, [***]. In such case, ITI shall provide BMS with an update of the filing, prosecution and maintenance status for each of such patent applications and patents, including copies of any material official correspondence to or from patent offices. ITI shall reasonably consult with and cooperate with BMS with respect to the preparation, prosecution and maintenance of such patent applications and patents. ITI shall not take any action during prosecution and maintenance of such patent applications and patents that would materially adversely affect them (including any reduction in claim scope), without BMS' prior consent. Such patent applications and patents shall otherwise continue to be subject to all of the terms and conditions of the Agreement in the same way as the other BMS Patent Rights.

10.4 Enforcement of BMS Patent Rights Against Infringers.

10.4.1 Enforcement by BMS. In the event that BMS or ITI becomes aware of a suspected infringement of any BMS Patent Right in the Field, such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. BMS shall have the right, but shall not be obligated, to bring an infringement action for suspected infringement in the Field at its own expense, in its own name and entirely under its own direction and control, subject to the following. BMS shall include in any such action a claim agreed upon by the Parties for reasonable damages suffered by ITI as a result of such infringement in an amount to be agreed upon by the Parties ("ITI Infringement Damages"). ITI shall reasonably assist BMS (at BMS' expense) in any action or proceeding being prosecuted for suspected infringement in the Field if so requested, including by being named or joined as a plaintiff to such actions or proceedings if requested by BMS or required by Law. ITI shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or proceeding which restricts the scope, or adversely affects the enforceability, of a BMS Patent Right in the Field may be entered into by BMS without the prior written consent of ITI, which consent shall not be unreasonably withheld, delayed or conditioned. Further, no settlement of any such action or proceeding which pertains to the infringement of the BMS Patent Rights by virtue of the Development or Commercialization of a Licensed Compound in the Field by a Third Party that is not a Sublicensee may be entered into by BMS without the prior written consent of ITI, which consent shall not be unreasonably withheld, delayed or conditioned.

10.4.2 Enforcement by ITI. If BMS elects not to bring any action for infringement described in Section 10.4.1 and so notifies ITI, then ITI may bring such action at its own expense, in its own name and entirely under its own direction and control, subject to the following. BMS shall reasonably assist ITI (at ITI's expense) in any action or proceeding being prosecuted if so requested, including by being named or joined as a plaintiff to such actions or proceedings if requested by ITI or required by Law. BMS shall have the right to participate and be represented in any such suit by its own counsel at its own expense. No settlement of any such action or proceeding which restricts the scope, or adversely affects the enforceability, of a BMS Patent Right may be entered into by ITI without the prior written consent of BMS, which consent shall not be unreasonably withheld, delayed or conditioned.

10.4.3 Withdrawal. If either Party brings an action or proceeding under this Section 10.4 and subsequently ceases to pursue or withdraws from such action or proceeding, it shall promptly notify the other Party and the other Party may substitute itself for the withdrawing Party under the terms of this Section 10.4.

10.4.4 Damages. In the event that either Party exercises the rights conferred in this Section 10.4 and recovers any damages or other sums in such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith, including, without limitation, attorney's fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party. If after such reimbursement any funds shall remain from such damages or other sums recovered, [***].

10.5 Patent Extensions. BMS and ITI shall each cooperate with one another and shall use Commercially Reasonable Efforts in obtaining patent term extension (including without limitation, any pediatric exclusivity extensions as may be available) or supplemental protection certificates or their equivalents in any country with respect to patent rights covering the Licensed Products. if elections with respect to obtaining such patent term extensions are to be made, ITI shall have the right to make the election to seek patent term extension or supplemental protection, *provided* that such election shall be made so as to maximize the period of marketing exclusivity for the Licensed Product. For such purpose, for all Approvals ITI shall provide BMS with written notice of any expected Approval at least thirty (30) days prior to the expected date of Approval, as well as notice within three (3) business days of receiving each Approval confirming the date of such Approval. Notification of the receipt of an Approval shall be in accordance with Section 15.2 except that the notification shall be sent to:

Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Vice President and Chief Patent Counsel
Telephone: 609-252-4825
Facsimile: 609-252-7884

10.6 Data Exclusivity and Orange Book Listings. With respect to data exclusivity periods (such as those periods listed in the FDA's Orange Book (including without limitation any available pediatric extensions) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83, and all international equivalents), ITI shall use Commercially Reasonable Efforts consistent with its obligations under applicable Law to seek, maintain and enforce all such data exclusivity periods available for the Licensed Products. With respect to

filings in the FDA Orange Book (and foreign equivalents) for issued patents for a Licensed Product, ITI shall, consistent with its obligations under applicable Law, list in a timely manner and maintain all applicable BMS Patent Rights and other patents Controlled by ITI required to be filed by it, or that it is permitted to file, under applicable Law. At least sixty (60) days prior to an anticipated deadline for the filing of patent listing information for BMS Patent Rights, ITI shall consult with BMS regarding the content of such filing. In the event of a dispute between the Parties as to whether a BMS Patent Right can be filed and/or the content of such filing, the Parties shall take expedited steps to resolve the dispute as promptly as possible, including seeking advice of an independent legal counsel to guide their decision. BMS shall provide, consistent with its obligations under applicable Law, reasonable cooperation to ITI in filing and maintaining such Orange Book (and foreign equivalent) listings.

10.7 Notification of Patent Certification. ITI shall notify and provide BMS with copies of any allegations of alleged patent invalidity, unenforceability or non-infringement of a BMS Patent Right pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, an application under §505(b)(2) or other similar patent certification by a Third Party, and any foreign equivalent thereof. Such notification and copies shall be provided to BMS within two (2) days after ITI receives such certification, and shall be sent to the address set forth in Section 10.4. In addition, upon request by BMS, ITI shall provide reasonable assistance and cooperation (including, without limitation, making available to BMS documents possessed by ITI that are reasonably required by BMS and making available personnel for interviews and testimony) in any actions reasonably undertaken by BMS to contest any such patent certification.

10.8 BMS shall not be required to take any action pursuant to Sections 10.4, 10.6 or 10.7 that BMS reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree that BMS is then subject to or otherwise may create legal liability on the part of BMS.

10.9 Assignment of BMS Patent Rights. Notwithstanding any provision in this Agreement to the contrary, BMS shall have the right to transfer or assign ownership of any BMS Patent Rights as long as any such transfer or assignment is made expressly subject to the rights and licenses granted to ITI under this Agreement and the transferee or assignee of the transferred or assigned BMS Patent Rights agrees in writing to prosecute and maintain such BMS Patent Rights in accordance with the terms of this Article 10.

ARTICLE 11

NONDISCLOSURE OF CONFIDENTIAL INFORMATION

11.1 Nondisclosure. Each Party agrees that, for so long as this Agreement is in effect and for a period of [***] ([***]) [***], a Party receiving Confidential Information of the other Party (or that has received any such Confidential Information from the other Party prior to the Effective Date) shall (1) maintain in confidence such Confidential Information using not less than the efforts such Party uses to maintain in confidence its own proprietary industrial information of similar kind and value, (ii) not disclose such Confidential Information to any Third Party without the prior written consent of the other Party, except for disclosures expressly permitted below, and (iii) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (iii) shall not create or imply any rights or licenses not expressly granted under Article 2 hereof).

11.2 Exceptions. The obligations in Section 11.1 shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent proof:

11.2.1 is publicly disclosed by the disclosing Party, either before or after it is disclosed to the receiving Party hereunder; or

11.2.2 was known to the receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the disclosing Party; or

11.2.3 is subsequently disclosed to the receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and is disclosed without any obligation to keep it confidential or any restriction on its use; or

11.2.4 is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the receiving Party; or

11.2.5 has been independently developed by employees or contractors of the receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the disclosing Party.

11.3 Authorized Disclosure. The receiving Party may disclose Confidential Information belonging to the other Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

11.3.1 filing or prosecuting patents;

11.3.2 regulatory filings, including any Approvals or applications therefor;

11.3.3 prosecuting or defending litigation, provided it has used good faith and diligent efforts to obtain a protective order for such Confidential Information;

11.3.4 subject to Section 11.4, complying with applicable Laws (including, without limitation, the rules and regulations of the Securities and Exchange Commission or any national securities exchange) and with judicial process, if in the reasonable opinion of the receiving Party's counsel, such disclosure is necessary for such compliance; *provided*, *however*, that except where impracticable, the receiving Party shall give the disclosing Party reasonable advance notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall afford the disclosing Party a reasonable opportunity to oppose, limit or secure confidential treatment for such required disclosure, and in the event of any such required disclosure, the receiving Party shall disclose only that portion of the Confidential Information of the disclosing Party that the receiving Party is legally required to disclose;

11.3.5 disclosure, in connection with the performance of this Agreement and solely on a "need to know basis", to Affiliates, potential collaborators (including potential co-marketing and co-promotion contractors), research collaborators, employees, consultants, or agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Article 11; *provided*, *however*, that the receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Article 11 to treat such Confidential Information as required under this Article 11; and

11.3.6 made by such Party to existing or potential acquirers or merger candidates; investment bankers; public and private sources of funding; existing or potential investors, venture capital firms or other financial institutions or investors for purposes of obtaining financing, *provided* that such Party has used good faith and diligent efforts to secure an agreement from any such Third Party to be bound by obligations of confidentiality and restrictions on use of Confidential Information that are no less restrictive than the obligations in this Agreement.

If and whenever any Confidential Information is disclosed in accordance with this Section 11.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and subject to Section 11.4, the receiving Party shall notify the disclosing Party of the receiving Party's intent to make such disclosure pursuant to this Section 11.3 sufficiently prior to making such disclosure so as to allow the disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information.

11.4 Terms of this Agreement. The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. For the avoidance of doubt, this Section 11.4 shall in no way prevent a Party from disclosing the existence of this Agreement or any terms of this Agreement in order to seek legal advice whenever deemed appropriate by such Party or to enforce such Party's rights under this Agreement, whether through arbitral proceedings, court proceedings or otherwise, or to defend itself against allegations or claims relating to this Agreement, or to comply with Applicable Law (except as provided in Section 11.5 below) when advised in a written opinion of outside counsel that terms of the Agreement are required to be disclosed to comply with Applicable Law (a copy of which opinion shall be provided to the other Party).

11.5 Securities Filings. Notwithstanding anything to the contrary in this Agreement, in the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document which describes or refers to this Agreement under the Securities Act of 1933, as amended, the Securities Exchange Act, of 1934, as amended, any other applicable securities Law or the rules of any national securities exchange, the Party shall notify the other Party of such intention and shall provide such other Party with a copy of relevant portions of the proposed filing [***] ([***]) [***]prior to such filing (and any revisions to such portions of the proposed filing a reasonable time prior to the filing thereof), including any exhibits thereto

relating to this Agreement, and shall use reasonable efforts to obtain confidential treatment of any information concerning this Agreement that such other Party requests be kept confidential, and shall only disclose Confidential Information which it is advised by counsel is legally required to be disclosed. No such notice shall be required under this Section 11.5 if the substance of the description of or reference to this Agreement contained in the proposed filing has been included in any previous filing made by the either Party hereunder or otherwise approved by the other Party.

11.6 Publication.

11.6.1 Publication by BMS. BMS may publish or present data and/or results relating to a Licensed Compound or Licensed Product developed in the BMS Retained Field in scientific journals and/or at scientific conferences, subject to the prior review and comment by ITI as follows. BMS shall provide ITI with the opportunity to review any proposed abstract, manuscript or presentation which discloses information relating to a Licensed Compound or Licensed Product by delivering a copy thereof to ITI [***] ([***]) [***] before its intended submission for publication or presentation. ITI shall have [***] ([***]) [***] from its receipt of any such abstract, manuscript or presentation in which to notify BMS in writing of any specific objections to the disclosure, based on either the need to seek patent protection or concern regarding the specific disclosure of Confidential Information of ITI, BMS Know-How or the identity of any Licensed Compound or Licensed Product. In the event ITI objects to the disclosure in writing within such [***] ([***]) [***] period, BMS shall delete from the proposed disclosure any ITI Confidential Information, any BMS Know-How and the identity of any Licensed Compound or Licensed Product (other than Licensed Compounds for which BMS has first filed an IND pursuant to Section 2.8) upon request by ITI and, in the event of an objection based on the need to seek patent protection, BMS shall not submit the publication or abstract or make the presentation containing the objected-to information for a period of [***] ([***]) [***] to provide an opportunity to seek patent protection. Once any such abstract or manuscript is accepted for publication, BMS shall provide ITI with a copy of the final version of the manuscript or abstract. For clarification, this Section 11.6.1 shall not limit or restrict BMS' ability to publish or present publicly information on compounds which are not Licensed Compounds or Licensed Products*, provided* such publication or presentation does not contain ITI Confidential Information or identify any Licensed Compound or Licensed Product. Notwithstanding anything in this Section 11.6.1, BMS shall not have the right to make any publications with respect to Licensed Compounds for which ITI has first filed an IND as provided in Section 2.8, or with respect to Excluded Compounds.

11.6.2 Publication by ITI. ITI may publish or present data and/or results relating to a Licensed Compound or Licensed Product developed in the Field in scientific journals and/or at scientific conferences, subject to the prior review and comment by BMS as follows. ITI shall provide BMS with the opportunity to review any proposed abstract, manuscript or presentation which discloses information relating to a Licensed Compound or Licensed Product by delivering a copy thereof to BMS [***] ([***])[***] before its intended submission for publication or presentation. BMS shall have [***] ([***])[***] from its receipt of any such abstract, manuscript or presentation in which to notify ITI in writing of any specific objections to the disclosure, based on either the need to seek patent protection or concern

regarding the specific disclosure of Confidential Information of BMS or BMS Know-How or the identity of any Licensed Compound or Licensed Product. In the event BMS objects to the disclosure in writing within such [***] ([***]) [***] period, ITI shall delete from the proposed disclosure any BMS Confidential Information, any BMS Know-How and the identity of any Licensed Compound or Licensed Product upon request by BMS (other than Licensed Compounds for which ITI has first filed an IND pursuant to Section 2.8, or Excluded Compounds) and, in the event of an objection based on the need to seek patent protection, ITI shall not submit the publication or abstract or make the presentation containing the objected-to information for a period of [***] ([***]) [***] to provide an opportunity to seek patent protection. Once any such abstract or manuscript is accepted for publication, ITI shall provide BMS with a copy of the final version of the manuscript or abstract. Notwithstanding anything in this Section 11.6.2, ITI shall not have the right to make any publications with respect to Licensed Compounds for which BMS has first filed an IND pursuant to Section 2.8.

ARTICLE 12

INDEMNITY

12.1 ITI Indemnity. ITI shall indemnify, defend and hold harmless BMS and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all damages, liabilities, losses, costs and expenses (including, without limitation, reasonable legal expenses, costs of litigation and reasonable attorney's fees) arising in connection with any claims, suits, proceedings, whether for money damages or equitable relief, of any kind brought by any Third Party (collectively "Losses and Claims") and arising out of or relating, directly or indirectly, (i) to the research, discovery Development, Commercialization (including, without limitation, promotion, advertising, offering for sale, sale or other disposition), transfer, importation or exportation, manufacture, labeling, handling or storage, or use of, or exposure to, any Licensed Compound or any Licensed Product by or for ITI or any of its Affiliates, distributors, Sublicensees, agents and contractors or any consumer of any Licensed Compound or any Licensed Product or (ii) to ITI's (or its Affiliates' and Sublicensees') use and practice otherwise of the BMS Patent Rights and BMS Know-How, including, without limitation, for each of clauses (i) and (ii), claims and threatened claims based on product liability, bodily injury, risk of bodily injury, death or property damage, infringement or misappropriation of Third Party patents, copyrights, trademarks or other intellectual property rights, or the failure to comply with applicable Law related to the matters referred to in the foregoing clauses (i) and (ii) with respect to any Licensed Compound or any Licensed Product; [***].

12.2 BMS Indemnity. BMS shall indemnify, defend and hold harmless ITI and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives, from and against any and all Losses and Claims arising out of or relating, directly or indirectly, [***].

12.3 Indemnification Procedure. A claim to which indemnification applies under Section 12.1 shall be referred to herein as an "Indemnification Claim". If any Person or Persons (collectively, the "Indemnitee") intends to claim indemnification under this Article 12, the Indemnitee shall notify the Party subject to the indemnification obligation (the "Indemnitor") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee, *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as aforesaid, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim in any manner which would have an adverse effect on the Indemnitee's interests (including without limitation any rights under this Agreement or the scope or enforceability of the BMS Patents Rights or BMS Know-How), without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld or delayed. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to Article 11.

12.4 Insurance. ITI shall, beginning with the initiation of the first clinical trial for a Licensed Product, maintain at all times thereafter during the term of this Agreement, and until the later of (i) [***] ([***]) [***] or (ii) [***], [***], [***], [***], and with [***] and [***]. Within [***] ([***]) [***] following written request from BMS, ITI shall furnish to BMS a certificate of insurance evidencing such coverage as of the date. Each such certificate of insurance, as well as any certificates evidencing new or modified coverages of ITI, shall include a provision whereby [***] ([***]) [***] written notice must be received by BMS prior to coverage modification or cancellation by either ITI or the insurer and of any new or modified coverage. In the case of a modification or cancellation of such coverage, ITI shall promptly provide BMS with a new certificate of insurance evidencing that ITI's coverage meets the requirements in the first sentence of this Section 12.3.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement shall commence as of the Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, shall continue until ITI no longer has any obligation under this Agreement to make payments to BMS.

13.2 Termination by BMS. BMS shall have the right to terminate this Agreement, at BMS' sole discretion, as follows:

13.2.1 Insolvency. BMS shall have the right to terminate this Agreement, at BMS' sole discretion, upon delivery of written notice to ITI upon the filing by ITI in any court or agency pursuant to any statute or regulation of the United States or any other jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of ITI or its assets, upon the proposal by ITI of a written agreement of composition or extension of its debts, or if ITI is served by a Third Party (and not by BMS) with an involuntary petition against it in any insolvency proceeding, upon the ninety-first (91st) day after such service if such involuntary petition has not previously been stayed or dismissed, or upon the making by ITI of an assignment for the benefit of its creditors.

13.2.2 Breach. BMS shall have the right to terminate this Agreement, at BMS' sole discretion, upon delivery of written notice to ITI in the event of any material breach by ITI of this Agreement (except, the failure to use Commercially Reasonable Efforts to Develop or Commercialize at least one Licensed Compound and Licensed Product, which is covered under Section 13.2.3), *provided* that such breach has not been cured [***] ([***]) [***] after written notice thereof is given by BMS to ITI; *provided, however*, that if such breach relates to the failure to make a payment when due, such breach must be cured [***] ([***]) [***] after written notice thereof is given by BMS.

13.2.3 [***]. [***].

13.2.4 Termination for Competitive Compound. BMS shall have the right to terminate this Agreement, at BMS' sole discretion, upon delivery of written notice to ITI effective [***] ([***]) [***] in the event that ITI or an Affiliate or Sublicensee of ITI violates Section 5.7.

13.2.5 Disputed Breach. If ITI disputes in good faith the existence or materiality of a breach specified in a notice provided by BMS pursuant to Section 13.2.2, or a failure to use Commercially Reasonable Efforts specified in a notice provided by BMS pursuant to Section 13.2.3, or that a compound or product is a Competitive Compound as alleged in a notice provided by BMS pursuant to Section 13.2.4, and ITI provides notice to BMS of such dispute within the applicable thirty (30) day, sixty (60) day or three (3) month period, BMS shall not have the right to terminate this Agreement unless and until the existence of such material breach or failure by ITI has been agreed upon by the Parties pursuant to the dispute resolution procedure in Section 14.1 or there is a final judicial determination of such material breach or such failure (or a determination of such material breach or such failure by an arbitrator in the event the Parties submit such dispute to binding arbitration) and ITI fails to cure such breach or failure within sixty (60) days following such determination (except to the extent such breach involves the failure to make a payment when due, which breach must be cured within ten (10) days following such determination). It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.3 Termination by ITI. ITI shall have the right to terminate this Agreement, at ITI's sole discretion, as follows.

13.3.1 On a country-by-country and product-by-product basis, effective upon [***] ([***]) [***] prior written notice in the case where Approval has not been obtained for the applicable Licensed Product or upon [***] ([***]) [***] prior written notice in the case where Approval has been obtained for the applicable Licensed Product, ITI may terminate this Agreement for any reason; *provided, however*, that (i) no such termination right may be exercised as to a Major Market Country in the EU unless all countries in the EU are so terminated and (ii) no such termination right may be exercised as to all of the Major Market Countries excluding Japan unless all countries in the Territory are so terminated (i.e., the entire Agreement is terminated).

13.3.2 ITI may terminate this Agreement in the event of a material breach by BMS, *provided* that such breach has not been cured within [***] ([***]) [***] following written notice by ITI. If BMS disputes in good faith the existence or materiality of such breach and provides notice to ITI of such dispute within such [***] ([***]) [***] period, ITI shall not have the right to terminate this Agreement in accordance with this Section 13.3.2 unless and until the existence of such material breach has been agreed upon by the Parties pursuant to the dispute resolution procedure in Section 14.1 or there is a final judicial determination of such material breach (or a determination of such material breach by an arbitrator in the event the Parties submit such dispute to binding arbitration) and BMS fails to cure such breach within [***] ([***]) [***] following such determination. It is understood and acknowledged that during the pendency of such a dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.

13.4 Effect of Termination by BMS. Upon termination of this Agreement by BMS under Section 13.2:

13.4.1 All rights and licenses granted to ITI in Article 2 shall terminate, all rights of ITI under the BMS Patent Rights and BMS Know-How shall revert to BMS, and ITI and its Affiliates shall cease all use of the BMS Patent Rights, the BMS Know-How and the Transferred Materials, and shall return to BMS all unused portions of the Transferred Materials.

13.4.2 All regulatory filings (including, without limitation, all INDs and NDAs) and Approvals and all other documents relating to or necessary to further Develop and Commercialize the Licensed Compounds and the Licensed Products, as they exist as of the date of such termination, (and all of ITI's right, title and interest therein and thereto) shall be assigned to BMS, and ITI shall provide to BMS one (1) copy of the foregoing documents and filings, all documents and filings contained in or referenced in any such filings, together with the raw and summarized data for any preclinical and clinical studies of the Licensed Compounds and such Licensed Products. BMS shall have the right to obtain specific performance of ITI's obligations referenced in this Section 13.4.2 and/or in the event of failure to obtain assignment, ITI hereby consents and grants to BMS the right to access and reference (without any further action required on the part of ITI, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose in the Territory. Without limiting the foregoing in this paragraph, to the extent applicable, ITI's obligations under Section 10.6 shall continue with respect to all countries in the Territory for which there is a failure to obtain assignment of all regulatory filings and Approvals.

13.4.3 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of termination shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of termination.

13.4.4 BMS shall have the right to retain all amounts previously paid to BMS by ITI.

13.4.5 Should ITI have any inventory of any Licensed Compound suitable for use in clinical trials, ITI shall offer to sell such Licensed Compound to BMS at ITI's out-of-pocket cost (but BMS shall be under no obligation to purchase same unless it agrees to do so in writing at such time).

13.4.6 Should ITI have any inventory of any Licensed Product approved and allocated prior to termination for sale in a terminated country, ITI shall have [***] ([***]) [***] thereafter in which to dispose of such inventory (subject to the payment to BMS of any royalties due hereunder thereon), *provided however*, that (i) such right shall terminate at such time that BMS or a Third Party has taken over responsibility for the sale of such Licensed Product in such country and (ii) such Licensed Product shall not be sold [***].

13.4.7 ITI shall provide to BMS all Know-How owned or Controlled by ITI and its Affiliates that is necessary for the Development and Commercialization of the Licensed Compounds and the Licensed Products in existence as of the date of such termination, including but not limited to ITI's manufacturing processes, techniques and trade secrets for making such Licensed Compounds and Licensed Products and all Know-How relating to any composition, formulation, method of use or manufacture of such Licensed Compounds and such Licensed Products, and BMS shall automatically have an exclusive, perpetual, worldwide, transferable, sublicensable right and license under such Know-How solely for (i) researching, Developing, using, importing, selling and offering for sale Licensed Compounds and Licensed Products in the Territory and (ii) making and having made Licensed Compounds and Licensed Products anywhere in the Territory for use, importation, sale and offer for sale in the Territory. ITI shall, at no charge, provide such training and assistance as is necessary to enable BMS to use such Know-How to make the Licensed Compounds and Licensed Products in existence as of the date of such termination.

13.4.8 ITI shall assign (or, if applicable, cause its Affiliate to assign) to BMS all of ITI's (and such Affiliate's) right, title and interest in and to any registered or unregistered trademark, trademark application, trade name or internet domain name that is specific to a Licensed Product (it being understood that the foregoing shall not include any trademarks or trade names that contain the corporate name of ITI) in each terminated country.

13.4.9 ITI shall assign (or, if applicable, cause its Affiliate to assign) to BMS all of ITI's (and such Affiliate's) entire right, title and interest in and to any Patent Rights owned or Controlled by ITI or its Affiliates in existence as of the date of such termination to the extent covering the composition of matter, use, or manufacture of Licensed Compounds and Licensed Products and all Patent Rights owned or Controlled by ITI or its Affiliates after the date of such termination claiming any invention conceived or reduced to practice by or on behalf of ITI during the term of this Agreement to the extent covering the composition of matter, use, or manufacture of Licensed Compounds and Licensed Products.

13.4.10 ITI shall provide to BMS all data generated during the term of this Agreement relating to the Licensed Compounds and the Licensed Products and assign (or, if applicable, cause its Affiliate to assign) to BMS all of ITI's (and such Affiliate's) entire right, title and interest in and to all such data.

13.4.11 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination.

13.4.12 BMS shall not owe any royalty or other compensation to ITI for the research, Development and Commercialization of any Licensed Compound or any Licensed Product in the event of any such termination of the Agreement by BMS, except as expressly provided in Section 13.4.16.

13.4.13 [***].

13.4.14 It is understood and agreed that BMS shall be entitled to specific performance as a remedy to enforce the provisions of this Section 13.4, in addition to any other remedy to which it may be entitled by applicable Law.

13.4.15 The license granted under Section 2.7 shall remain in effect and shall be fully paid up.

13.4.16 If ITI has the capability in place as of the date of such termination to commercially manufacture and supply to BMS all or part of BMS' requirements of the applicable Licensed Compounds and/or Licensed Products for use and sale in the Territory, if BMS so elects in its sole discretion, ITI shall supply to BMS for a period not to exceed [***] ([***]) [***] (with the period of time being within the sole discretion of BMS) as much of BMS' requirements of such Licensed Compounds and/or Licensed Products as possible (not to exceed amounts then manufactured by ITI) for use and sale in the Territory, at a price equal to [***] for such Licensed Compounds and/or Licensed Products, under terms and conditions as may be mutually agreed between the Parties. In such event, ITI shall manufacture and supply as much of BMS' requirements as possible (not to exceed amounts then manufactured by ITI) of such Licensed Compounds and/or Licensed Products until, as BMS may elect at its sole discretion, BMS assumes responsibility for its own manufacture and supply of such Licensed Compounds and/or Licensed Products for the Territory. In the event that ITI has, prior to the date of such termination, engaged a Third Party to manufacture and supply any Licensed Compounds or Licensed Products, ITI shall use diligent efforts to provide in any agreement with such Third Party a requirement for such Third Party to supply BMS' requirements of all such Licensed Compounds and Licensed Products in the event BMS terminates this Agreement under Section 13.2. In the event that BMS terminates this Agreement under Section 13.2, ITI shall supply BMS' requirements of all such Licensed Compounds and Licensed Products in quantities manufactured for and supplied to ITI by such Third Party for a period [***] ([***]) [***] (with the

period of time being within the sole discretion of BMS); provided however, if there are restrictions in the agreement between ITI and such Third Party governing the manufacture and supply of such Licensed Compounds and Licensed Products that would preclude the period from being [***] ([***]) [***], then such period shall be up to as long a time as permitted under such agreement. Where ITI has engaged a Third Party to manufacture and supply any Licensed Compounds or Licensed Products to ITI and BMS elects to have ITI supply any portion of BMS' requirements of such Licensed Compounds or Licensed Products, then ITI shall supply such Licensed Compounds and Licensed Products at the cost paid by ITI to such Third Party plus ITI's shipping, handling and other reasonable costs associated with providing such Licensed Compounds and Licensed Products to BMS.

13.4.17 Nothing in this Section 13.4 shall be deemed to limit any remedy to which BMS may be entitled by applicable Law.

13.5 Effect of Termination by ITI for Breach. Upon termination of this Agreement by ITI pursuant to Section 13.3.2:

13.5.1 All rights and licenses granted to ITI in Article 2 shall terminate, all rights of ITI under the BMS Patent Rights and BMS Know-How shall revert to BMS, and ITI and its Affiliates shall cease all use of the BMS Patent Rights, the BMS Know-How and the Transferred Materials, and shall return to BMS all unused portions of the Transferred Materials.

13.5.2 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of termination or expiration shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of termination or expiration.

13.5.3 BMS shall have the right to retain all amounts previously paid to BMS by ITI.

13.5.4 Should ITI have any inventory of any Licensed Product approved and allocated prior to termination for sale in a terminated country, ITI shall have [***] ([***]) [***] in which to dispose of such inventory (subject to the payment to BMS of any royalties due hereunder thereon).

13.5.5 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination or expiration.

13.5.6 Nothing in this Section 13.5 shall be deemed to limit any remedy to which ITI may be entitled by applicable Law.

13.6 Effect of Termination by ITI Under Section 13.3.1. Upon termination of this Agreement under Section 13.3.1 or, with respect to each applicable country as to which termination occurs pursuant to Section 13.3.1 hereof (the rights and obligations of the Parties as to the remaining countries of the Territory in which termination under Section 13,3.1 has not occurred, being unaffected by such termination):

13.6.1 All rights and licenses granted to ITI in Article 2 shall terminate with respect to each terminated country, all rights of ITI under the BMS Patent Rights and BMS Know-How shall revert to BMS with respect to each terminated country, and ITI and its Affiliates shall cease all use of the BMS Patent Rights and BMS Know-How with respect to each terminated country. In the event that the entire Agreement is terminated under Section 13.3.1, ITI and its Affiliates shall cease all use of the Transferred Materials and shall return to BMS all unused portions of the Transferred Materials.

13.6.2 All regulatory filings (including, without limitation, all INDs and NDAs) and Approvals and other documents relating to or necessary to further Develop and Commercialize Licensed Compounds and Licensed Products, as they exist as of the date of such termination, (and all of ITI's right, title and interest therein and thereto) in each terminated country shall be assigned to BMS, and ITI shall provide to BMS one (1) copy of the foregoing documents and filings and all documents and filings contained in or referenced in any such filings, together with the raw and summarized data for any preclinical and clinical studies of the Licensed Compounds and such Licensed Product (and where reasonably available, electronic copies thereof). BMS shall have the right to obtain specific performance of ITI's obligations referenced in this Section 13.6.2 and/or in the event of failure to obtain assignment, ITI hereby consents and grants to BMS the right to access and reference (without any further action required on the part of ITI, whose authorization to file this consent with any Regulatory Authority is hereby granted) any and all such regulatory filings for any regulatory or other use or purpose in each terminated country. Without limiting the foregoing in this paragraph, to the extent applicable, ITI's obligations under Section 10.6 shall continue with respect to each terminated country for which there is a failure to obtain assignment of all regulatory filings and Approvals.

13.6.3 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of termination or expiration shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of termination or expiration.

13.6.4 BMS shall have the right to retain all amounts previously paid to BMS by ITI.

13.6.5 13.6.5 Should ITI have any inventory of any Licensed Compound suitable for use in clinical trials in each terminated country, ITI shall offer to sell such Licensed Compound to BMS at ITI's out-of-pocket cost (but BMS shall be under no obligation to purchase same unless it agrees to do so in writing at such time).

13.6.6 Should ITI have any inventory of any Licensed Product approved and allocated prior to termination for sale in a terminated country, ITI shall have [***] ([***]) [***] in which to dispose of such inventory (subject to the payment to BMS of any royalties due hereunder thereon), provided however, that (i) such right shall terminate at such time that BMS or a Third Party has taken over responsibility for the sale of such Licensed Product in such country and (ii) such Licensed Product shall not be sold [***].

13.6.7 ITI shall provide to BMS all Know-How owned or Controlled by ITI and its Affiliates that is necessary for the Development and Commercialization of the Licensed Compounds and the Licensed Products subject to such termination, including but not limited to ITI's manufacturing processes, techniques and trade secrets for making such Licensed Compounds and Licensed Products and all Know-How relating to any composition, formulation, method of use or manufacture of such Licensed Compounds and such Licensed Products, and provide BMS all data generated during the term of this Agreement relating to such Licensed Compounds and Licensed Products, and BMS shall automatically have an exclusive, perpetual, worldwide, transferable, sublicensable right and license to use all such Know-How and data solely for (i) researching, Developing, using, importing, selling and offering for sale such Licensed Compounds and Licensed Products in each terminated country and (ii) making and having made such Licensed Compounds and Licensed Products anywhere in the world for use, importation, sale and offer for sale in each terminated country. Each time ITI terminates pursuant to Section 13.3.1 any rights and obligations it has under this Agreement, ITI shall reasonably cooperate with BMS to assist BMS with understanding and using the Know-How provided to BMS under this Section 13.6.7. Each such time, such cooperation shall include, without limitation, providing BMS with reasonable access by teleconference or in-person at ITI's facilities (subject to ITI's customary rules and restrictions with respect to site visits by non-ITI personnel) to ITI personnel directly involved in the research and Development of Licensed Compounds and Licensed Products to provide BMS, [***] in connection with the Know-How transferred to BMS under this Section 13.6.7. Any additional technical assistance and consultation shall be charged to BMS at ITI's cost for rendering such assistance and consultation.

13.6.8 ITI shall assign (or, if applicable, cause its Affiliate to assign) to BMS all of ITI's (and such Affiliates') right, title and interest in and to any registered or unregistered trademark, trademark application, trade name or internet domain name that is specific to a Licensed Product (it being understood that the foregoing shall not include any trademarks or trade names that contain the corporate name of ITI) in each terminated country.

13.6.9 ITI shall grant to BMS an exclusive license under all Patent Rights owned or Controlled by ITI or its Affiliates covering the composition of matter, use, or manufacture of the Licensed Compounds and Licensed Products subject to such termination solely for the purposes of the further research, Development and Commercialization of such Licensed Compounds and Licensed Products and to make and have made such Licensed Compounds and Licensed Products anywhere in the world for use, importation, sale and offer for sale in each terminated country. [***].

13.6.10 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination or expiration.

13.6.11 [***].

13.6.12 It is understood and agreed that BMS shall be entitled to specific performance as a remedy to enforce the provisions of this Section 13.6, in addition to any other remedy to which it may be entitled by applicable Law.

13.6.13 In the event that ITI terminates the entire Agreement pursuant to Section 13.3.1, the license granted under Section 2.7 shall remain in effect and shall be fully paid up.

13.6.14 If ITI has the capability in place as of the date of such termination to commercially manufacture and supply to BMS all or part of BMS' requirements of the applicable Licensed Compounds and/or Licensed Products for use and sale in the terminated countries, if BMS so elects in its sole discretion, ITI shall supply as much of BMS' requirements as possible (not to exceed amounts then manufactured by ITI) of such Licensed Compounds and/or Licensed Products for a period not to exceed [***] ([***]) [***] (with the period of time being within the sole discretion of BMS) for use and sale in the terminated countries, at a price equal to [***] ([***]) of ITI's documented fully-burdened manufacturing cost (determined in accordance with GAAP) for such Licensed Compounds and/or Licensed Products, under terms and conditions as may be mutually agreed between the Parties. In such event, ITI shall manufacture and supply as much of BMS' requirements as possible (not to exceed amounts then manufactured by ITI) of such Licensed Compounds and/or Licensed Products until, as BMS may elect at its sole discretion, BMS assumes responsibility for its own manufacture and supply of such Licensed Compounds and/or Licensed Products for the terminated countries. In the event that ITI has, prior to the date of such termination, engaged a Third Party to manufacture and supply any of the applicable Licensed Compounds or Licensed Products, ITI shall use diligent efforts to provide in any agreement with such Third Party a requirement for such Third Party to supply BMS' requirements of all such Licensed Compounds and Licensed Products manufactured for and supplied to ITI by such Third Party each time ITI terminates any of its rights pursuant to Section 13.3.1. Each time BMS terminates any of its rights pursuant to Section 13.3.1, ITI shall supply BMS' requirements of all such Licensed Compounds and Licensed Products in quantities manufactured for and supplied to ITI by such Third Party for a period [***] ([***]) [***] (with the period of time being within the sole discretion of BMS); provided however, if there are restrictions in the agreement between ITI and such Third Party governing the manufacture and supply of such Licensed Compounds and Licensed Products that would preclude the period from being [***] ([***]) [***], then such period shall be up to as long as the period permitted under such agreement. Where ITI has engaged a Third Party to manufacture and supply any applicable Licensed Compounds or Licensed Products to ITI and BMS elects to have ITI supply any portion of BMS' requirements of such Licensed Compounds or Licensed Products, then ITI shall supply such Licensed Compounds and Licensed Products at the cost paid by ITI to such Third Party plus ITI's shipping, handling and other reasonable costs associated with providing such Licensed Compounds and Licensed Products to BMS.

13.6.15 Nothing in this Section 13.6 shall be deemed to limit any remedy to which ITI may be entitled by applicable Law.

13.7 Effect of Expiration of this Agreement. Upon expiration of this Agreement:

13.7.1 All amounts due or payable to BMS that were accrued, or that arise out of acts or events occurring, prior to the effective date of expiration shall remain due and payable; but (except as otherwise expressly provided herein) no additional amounts shall be payable based on events occurring after the effective date of expiration.

13.7.2 BMS shall have the right to retain all amounts previously paid to BMS by ITI.

13.7.3 Neither Party shall be relieved of any obligation that accrued prior to the effective date of such termination.

13.7.4 The license with respect to BMS Know-How granted under Section 2.1 shall remain in effect and shall be fully paid up.

13.7.5 The license granted under Section 2.7 shall remain in effect and shall be fully paid up.

13.8 Scope of Termination. Except as otherwise expressly provided herein, termination of this Agreement shall be as to all countries in the Territory and all Licensed Compounds and all Licensed Products.

13.9 Survival. The following provisions shall survive termination of this Agreement, as well as any other provisions which by their nature are intended to survive termination: Article 1 (as applicable), Section 4.3 (except for the first sentence), Sections 8.6 through 8.10, Section 9.5, Section 9.6, Section 10.1, Section 10.4.4 (with respect to an action, suit or proceeding commenced prior to termination), Section 10.7, Article 11, Article 12, whichever one of Sections 13.4, 13.5, 13.6 or 13.7 applies, this Section 13.9, Section 13.10, Article 14 and Article 15.

13.10 Bankruptcy. The Parties agree that in the event a Party becomes a debtor under Title 11 of the U.S. Code ("Title 11"), this Agreement shall be deemed to be, for purposes of Section 365(n) of Title 11, a license to rights to "intellectual property" as defined therein. Each Party as a licensee hereunder shall have the rights and elections as specified in Title 11. Any agreements supplemental hereto shall be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of Title 11.

ARTICLE 14

DISPUTE RESOLUTION

14.1 Resolution by Senior Executives. Except as provided in Sections 8.7 and 14.3, in the event of any dispute between the Parties in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party hereunder, the Parties shall first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within ten (10) Business Days, either Party may, by written notice to the other Party, refer the dispute to the Chief Executive Officer of ITI and the President, Pharmaceutical Research Institute of BMS or other designated officer of BMS for attempted resolution by good faith negotiation within thirty (30) days after such notice is received; provided, however, the Chief Executive Officer of ITI and the President, Pharmaceutical Research Institute of BMS or other designated officer of BMS may each designate a senior manager of his or her company to whom such dispute is delegated for attempted resolution.

14.2 Remedies. Except as provided in Sections 8.7 and 14.3, if any dispute between the Parties relating to or arising out this Agreement cannot be resolved in accordance with Section 14.1, each Party shall be free to pursue any or all available remedies at law or in equity.

14.3 Notwithstanding anything in this Article 14, each Party shall have the right to seek injunctive or other equitable relief from a court of competent jurisdiction pursuant to Section 15.8 that may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the dispute, including any breach or threatened breach of Article 11, Section 13.4 or Section 13.6.

ARTICLE 15

MISCELLANEOUS

15.1 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

15.2 Notices. Any notice required or permitted to be given by this Agreement shall be in writing and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by first class, registered or certified mail addressed as set forth below unless changed by notice so given:

If to ITI:

Intra-Cellular Therapies, Inc.
Audubon Biomedical Science and Technology Park
3960 Broadway
New York, NY 10032
Telephone: (212) 923-3344
Facsimile: (212) 923-3388

With a copy to:

Cooley Godward LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190-5601
Attn. Matthias Alder, Esq.
Telephone: 703-456-8689
Facsimile: 703-456-8100

If to BMS:

Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Senior Vice President for Business Development
Telephone: 609-252-4712
Facsimile: 609-252-7212

With a copy to:

Bristol-Myers Squibb Company
P.O. Box 4000
Route 206 & Province Line Road
Princeton, New Jersey 08543-4000
Attention: Senior Counsel, Business Development and Licensing
Telephone: 609-252-5328
Facsimile: 609-252-4232

Any such notice shall be deemed delivered on the date received. A Party may add, delete, or change the person or address to whom notices should be sent at any time upon written notice delivered to the Party's notices in accordance with this Section 15.2.

15.3 Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including, without limitation, acts of God, fires, earthquakes, strikes and labor disputes, acts of war, terrorism, civil unrest or intervention of any governmental authority ("Force Majeure"); *provided, however*, that the affected Party promptly notifies the other Party and further provided that the affected Party shall use Commercially Reasonable Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

15.4 Assignment.

15.4.1 BMS may, without ITI's consent, assign or transfer all of its rights and obligations hereunder, in connection with any transfer of all of the BMS Patent Rights and BMS Know-How, to any Affiliate of BMS or to any Third Party (including, without limitation, a successor in interest); *provided, however*, that such assignee or transferee agrees in a writing provided to ITI to be bound by the terms of this Agreement.

15.4.2 Upon thirty (30) days advance written notice to BMS and subject to BMS' approval, not to be unreasonably withheld, delayed or conditioned, ITI may assign or transfer all of its rights and obligations hereunder to a Third Party of equal or superior financial condition as ITI or to an Affiliate (and so long as such assignment includes, without limitation, all Approvals, all manufacturing assets relating to this Agreement, and all rights and obligations

under this Agreement); *provided, however*, that such Third Party or Affiliate shall have agreed prior to such assignment or transfer to be bound by the terms of this Agreement in a writing provided to BMS; and, *provided, further*, that ITI remains jointly and severally liable with such Third Party or Affiliate for the performance of this Agreement where assigned or transferred to a Third Party or an Affiliate.

15.4.3 ITI may assign or transfer all of its rights and obligations hereunder without such consent to a successor in interest by reason of merger, consolidation or sale of substantially all of the assets of ITI (and so long as such assignment or transfer includes, without limitation, all Approvals, all manufacturing assets relating to this Agreement, and all rights and obligations under this Agreement); *provided, however*, that such successor in interest shall have agreed prior to such assignment or transfer to be bound by the terms of this Agreement in a writing provided to BMS.

15.4.4 Subject to the foregoing, this Agreement shall inure to the benefit of and be binding on the Parties' successors and assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, the assignee or transferee in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning non-transferring Party shall not recognize, nor shall it be required to recognize, such assignment or transfer.

15.5 Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

15.6 Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, release or amendment of any obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.

15.7 Choice of Law. This Agreement shall be governed by, enforced, and shall be construed in accordance with the laws of the State of New York without regard to its conflicts of law provisions (other than section 5-1401 of the New York General Obligations Law).

15.8 Jurisdiction.

15.8.1 Each Party irrevocably submits to the exclusive jurisdiction of (i) the Supreme Court of the State of New York, New York County, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, action or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit or proceeding either in the United States District Court for the Southern District of New York or if such suit, action or other proceeding may not be brought in such court for jurisdictional reasons, in the Supreme Court of the State of New

York, New York County. Each Party further agrees that service of any process, summons, notice or document by personal delivery, by registered mail, or by a recognized international express delivery service to such Party's respective address set forth above shall be effective service of process for any action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 15.8. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) the Supreme Court of the State of New York, New York County or (ii) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

15.8.2 Each Party hereto hereby waives to the fullest extent permitted by applicable Law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement. Each Party hereto (i) certifies that no representative, agent or attorney of the other Party has represented, expressly or otherwise, that such other Party would not, in the event of litigation, seek to enforce that foregoing waiver and (ii) acknowledges that it and the other Party hereto have been induced to enter into this Agreement, as applicable, by, among other things, the mutual waivers and certifications in this Section 15.8.

15.9 Publicity. Upon execution of this Agreement, ITI may issue the press release announcing the existence of this Agreement in the form and substance as set forth in Appendix 6 hereof. Each Party agrees not to issue any other press release or other public statement disclosing other information relating to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, *provided, however*, that any disclosure which is required by Law or the rules of a securities exchange, as reasonably advised by the disclosing Party's outside counsel in a written opinion, a copy of which shall be provided to the other Party, may be made subject to the following terms of this Section 15.9, and *provided, further*, that ITI may from time to time issue public statements relating to the ongoing Development and/or Commercialization of Licensed Compounds (excluding disclosure of the financial terms of this Agreement) pursuant to this Agreement without the prior written consent of BMS. The Parties agree that any such required disclosure shall not contain confidential business or technical information and, if disclosure of confidential business or technical information is required by Law, the Parties shall use appropriate diligent efforts to minimize such disclosure and obtain confidential treatment for any such information which is disclosed to a governmental agency. Each Party agrees to provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter thereof as soon as reasonably practicable under the circumstances prior to its scheduled release. Except under extraordinary circumstances, each Party shall provide the other with an advance copy of any such announcement at least five (5) business days prior to its scheduled release. Each Party shall have the right to expeditiously review and recommend changes to any such announcement and, except as otherwise required by Law, the Party whose announcement has been reviewed shall remove any information the reviewing Party reasonably deems to be inappropriate for disclosure. The contents of any announcement or similar publicity which has been reviewed and approved by the reviewing Party can be re-released by either Party without a requirement for re-approval.

15.10 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute BMS and ITI as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

15.11 Headings. Headings and captions are for convenience only and are not be used in the interpretation of this Agreement.

15.12 Entire Agreement. This Agreement constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

15.13 Counterparts. This Agreement may be executed in counter-parts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument.

15.14 Nonsolicitation. During the first five (5) years of the term of this Agreement, each party agrees that neither it nor any of its Affiliates shall recruit, solicit or induce, directly or indirectly, any employee of the other party or any of its Affiliates that has at any time been directly involved in the research and Development activities with respect to Licensed Compounds to terminate his or her employment with the other party or such Affiliate and become employed by or consult for such party or any of its Affiliates. For purposes of the foregoing, "recruit", "solicit" or "induce" shall not be deemed to mean (i) circumstances where an employee of the other party or any of its Affiliates initiates contact with such party or any of its Affiliates with regard to possible employment, or (ii) general solicitations of employment not specifically targeted at employees of the other party or any of its Affiliates, including responses to general advertisements.

15.15 Exports. ITI agrees not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples or equipment received or generated under this Agreement in violation of any applicable export control Laws.

15.16 Interpretation.

15.16.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party hereto as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

15.16.2 The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation". The word "will" shall be construed to have the same meaning and effect as the word "shall". The word "any" shall mean "any and all" unless otherwise clearly indicated by context.

15.16.3 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (e) all references herein to Articles, Sections or Appendices, unless otherwise specifically provided, shall be construed to refer to Articles, Sections and Appendices of this Agreement.

* * *

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized officers.

INTRA-CELLULAR THERAPIES, INC.

By: /s/ Sharon Mates
(Signature)
Name: Sharon Mates
Title: Chairman and Chief Executive Officer
Date: May 31, 2005

BRISTOL-MYERS SQUIBB COMPANY

By: /s/ Tamar Howson
(Signature)
Name: Tamar Howson
Title: Sr. VP, Corporate and Business Development
Date: May 31, 2005

Appendix 1

BMS Core Patent Rights

[***]

Appendix 2

Summary of Initial Development Plan

[***] Appendix 2 pg.

Appendix 3

Excluded Compounds

[***]

Appendix 4

Licensed Compounds

[***] Appendix 4 pg.

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Appendix 6

Press Release

FOR IMMEDIATE RELEASE

INTRA-CELLULAR THERAPIES, INC. RECEIVES EXCLUSIVE LICENSE FOR CENTRAL NERVOUS SYSTEM COMPOUNDS FROM BRISTOL-MYERS SQUIBB COMPANY

NEW YORK, NY—May XXth, 2005- Intra-Cellular Therapies, Inc., (ITI) a privately held biopharmaceutical company focusing on the development of new therapeutics for neuropsychiatric and neurodegenerative disorders, today announced that it has been granted an exclusive, worldwide license to a family of pre-clinical compounds from Bristol-Myers Squibb Company.

"This agreement provides ITI with a portfolio of compounds with potential to be effective treatments for schizophrenia and other therapies for CNS indications such as Tourette's. syndrome, Bipolar Disorder, and Obsessive-Compulsive Disorder," said CEO and Chairman of ITI, Sharon Mates, Ph.D. "The compounds complement our internal pipeline of small molecule therapeutics developed using ITI's drug discovery platform."

Under the terms of the agreement, ITI will pay to Bristol-Myers Squibb an upfront license fee, development-based milestone payments and royalties should the compound receive regulatory approval for commercialization. Additional financial terms were not disclosed.

About Intra-Cellular Therapies

Intra-cellular Therapies, Inc. (ITI) is developing novel drugs for the treatment of schizophrenia, depression, Parkinson's and Alzheimer's disease and other disorders of the Central Nervous System (CNS). The Company is uniquely focusing on the signaling pathways inside nerve cells, as elucidated by Nobel-Prize winning scientist and Rockefeller University Professor Dr. Paul Greengard. ITI has exclusively licensed a platform of technologies from The Rockefeller University. Using this platform ITI has developed a pre-clinical pipeline of small molecule therapeutics for the treatment of CNS disorders. The first product under development discovered using the Company's proprietary technology platform is a small molecule therapeutic for the treatment of Parkinson's disease and other CNS disorders.

About Schizophrenia

Schizophrenia is a devastating brain disorder that affects approximately 2.2 million American adults, or 1.1 percent of the population age 18 and older. Schizophrenia interferes with a person's ability to think clearly, to distinguish reality from fantasy, to manage emotions, make decisions, and relate to others. The first signs of schizophrenia typically emerge in the teenage years or early twenties. Because of the early onset and chronic nature of the disorder schizophrenia exerts a heavy burden on the nation's medical care system. It is estimated that $33 Billion/year is spent in the US on direct medical costs related to schizophrenia.

Except for the historical information presented herein, matters discussed herein may constitute forward-looking statements that are subject to certain risks and uncertainties that could cause

actual results to differ materially from any future results, performance or achievements expressed or implied by such statements. Statements that are not historical facts are forward-looking statements. ITI disclaims, however, any intent or obligation to update these forward-looking statements. There can be no assurance that ITI's development efforts will succeed, that products will receive required regulatory approval or that, even if such regulatory approval were received, such products would ultimately achieve commercial success.

For more information
Sharon Mates, Ph.D., CEO
Intra-Cellular Therapies
212-923-3344

Appendix 7

Compound Samples to be Provided by BMS

[***]

Appendix 8

Exceptions to Warranties

[***]

Appendix 9

BMS Other Patent Rights

[***]

INTRA-CELLULAR THERAPIES REPORTS SECOND QUARTER 2022 FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

Total revenues for the second quarter 2022 were $55.6 million, compared to $20.0 million for the same period in 2021, representing a 178% increase

CAPLYTA net product revenues for the second quarter 2022 were $55.1 million, representing a 190% increase over the same period in 2021 and a 58% increase over the first quarter 2022

Second quarter 2022 CAPLYTA new and total prescriptions increased 225% and 191%, respectively, versus the same period in 2021

Second quarter 2022 CAPLYTA new and total prescriptions increased 55% and 51%, respectively, versus the first quarter 2022

NEW YORK, August 9, 2022 /GLOBE NEWSWIRE/ — Intra-Cellular Therapies, Inc. (Nasdaq: ITCI), a biopharmaceutical company focused on the development and commercialization of therapeutics for central nervous system (CNS) disorders, today announced its financial results for the second quarter ended June 30, 2022 and provided a corporate update.

“In this quarter, CAPLYTA experienced significant revenue growth, increasing nearly 60% over the first quarter of 2022, driven by strong uptake in bipolar depression. We expect to continue to deliver strong revenue growth throughout 2022 and also look forward to advancing our development programs,” said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies.

SECOND QUARTER FINANCIAL HIGHLIGHTS

- Total revenues were $55.6 million for the second quarter of 2022, compared to $20.0 million for the second quarter of 2021. Net product revenues of CAPLYTA were $55.1 million for the second quarter of 2022, compared to $19.0 million for the same period in 2021, representing a year-over-year increase of 190% and a 58% increase over the first quarter of 2022.

- Cost of product sales were $4.7 million in the second quarter of 2022, compared to $2.0 million for the second quarter of 2021.
- Selling, general and administrative (SG&A) expenses were $100.3 million for the second quarter of 2022, compared to $69.9 million for the second quarter of 2021. This increase is primarily due to an increase in marketing and advertising expenses and labor related costs.
- Research and development (R&D) expenses for the second quarter of 2022 were $38.5 million, compared to $17.3 million for the second quarter of 2021. This increase is due to higher lumateperone clinical trial and non-clinical related costs and an increase in non-lumateperone project costs.
- Net loss for the quarter ended June 30, 2022 was $86.6 million, compared to a net loss of $68.7 million for the quarter ended June 30, 2021.
- Cash, cash equivalents, restricted cash and investment securities totaled $679.2 million at June 30, 2022, compared to $413.7 million at December 31, 2021. In January 2022, the Company completed a $460.0 million public offering resulting in net proceeds to the Company of approximately $433.7 million from the sale of 10,952,381 shares of its common stock, after deducting underwriting discounts and commissions and offering expenses.

COMMERCIAL HIGHLIGHTS

- Q2 2022 marks the second full quarter of the launch of the CAPLYTA's bipolar depression indication following U.S. Food and Drug Administration (FDA) approval in late December 2021. CAPLYTA is the first and only FDA-approved treatment for depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults as monotherapy and as adjunctive therapy with lithium or valproate.
- The significant launch inflection continued in both new and total prescriptions, reflecting sustained robust growth following approval in bipolar depression. Second quarter CAPLYTA new and total prescriptions increased by 55% and 51%, respectively, versus the first quarter of 2022. Second quarter CAPLYTA new and total prescriptions increased by 225% and 191%, respectively, versus the second quarter of 2021.
- Following FDA approval during the second quarter of 2022, two new dosage strengths of CAPLYTA, 10.5 mg and 21 mg, are expected to be available in pharmacies this month. This will expand the patient population who has access to CAPLYTA, specifically for patients taking strong or moderate CYP3A4 inhibitors and patients with moderate or severe hepatic impairment.
- CAPLYTA maintained broad coverage in the Medicare Part D and Medicaid channels, with greater than 98% of lives covered and, during the quarter, we further expanded coverage in the Commercial channel to approximately 85% of lives covered. Our LytaLink patient support program continues to be highly effective in supporting patient access.

CLINICAL HIGHLIGHTS

Lumateperone:

- Mixed Features program: Patient enrollment is progressing well in Study 403, a global clinical trial evaluating lumateperone 42 mg in patients with major depressive disorder (MDD) and in patients with bipolar depression who exhibit mixed features. The primary endpoint is change from baseline versus placebo on the MADRS total score at week 6, and the CGI-S scale is the key secondary endpoint. We expect to complete clinical conduct in this study in late 2022.
- Adjunctive MDD program: Patient enrollment in pivotal global studies 501 and 502 evaluating lumateperone 42 mg as adjunctive treatment to anti-depressants is ongoing. We expect to file a supplemental New Drug Application (sNDA) with the FDA for lumateperone as an adjunctive therapy to antidepressants for the treatment of MDD in 2024.
- Presentations: In the second quarter of 2022, there were lumateperone research presentations at the American Psychiatric Association (APA) Meeting, the International Conference for Bipolar Disorders (ISBD) Annual Meeting, the American Society of Clinical Psychopharmacology (ASCP), and the Schizophrenia International Research Society (SIRS). The presentations included additional analyses from our lumateperone bipolar depression program including findings consistent with broad antidepressant effects, marked improvements in patients' daily functioning, and further evidence of a favorable metabolic profile.

  At SIRS, we presented safety analyses from our open-label safety switching study evaluating lumateperone 42 mg in patients with stable schizophrenia. Overall, data from this post-hoc analysis further support the favorable safety and tolerability profile of lumateperone 42 mg in patients with schizophrenia who switched from another antipsychotic, irrespective of the previous antipsychotic. In addition, patients switching from risperidone/paliperidone or olanzapine to lumateperone had significant improvements in cardiometabolic parameters and prolactin concentrations.
- Lumateperone Long Acting Injectable (LAI) formulation: We have completed the preclinical development of an LAI formulation, and we have conducted a Phase 1 single ascending dose study with this formulation. This study evaluated the pharmacokinetics, safety and tolerability of lumateperone LAI in patients with stable symptoms of schizophrenia. We are exploring alternate sites of injection with this formulation as well as progressing other formulations. This will assist us in evaluating dosing strategies and formulation for our efficacy studies. The goal of our program is to develop LAI formulations that are effective, safe and well-tolerated with treatment durations of one month and longer.

Other Programs:

- ITI-1284-ODT-SL program: ITI-1284 is a deuterated form of lumateperone, a new chemical entity formulated as an oral disintegrating tablet for sublingual administration. We are presently evaluating ITI-1284-ODT-SL in Phase 1 studies including drug-drug interaction studies. We expect to commence clinical conduct in Phase 2 clinical trials in agitation in patients with probable Alzheimer's disease, in dementia-related psychosis and certain depressive disorders in the elderly in 2023.
- Phosphodiesterase type I inhibitor (PDE1) program: We have initiated our Phase 2 clinical program with lenrispodun for Parkinson's disease and expect to commence patient enrollment in the second half of 2022.

  We continue to investigate the anti-cancer effects of PDE1 inhibitors. In April of this year, we presented preclinical data at the AACR Annual meeting describing the antitumor effects of PDE1 inhibitors, when administered in conjunction with checkpoint inhibitor immunotherapy in an animal model of triple negative breast cancer. We have now shown that our PDE1 inhibitors can potentiate the action of checkpoint inhibitors in various models of colorectal, kidney, breast and glioblastoma cancers. We plan to present additional data from this program at future scientific meetings.
- ITI-333 program in Opioid Use Disorder: We continue to advance the development of ITI-333. Following the recent completion of our single ascending dose study, we have commenced a neuroimaging study to investigate brain occupancy for receptors that play a role in substance use disorder and also have applicability for pain. The results of this study will support the dose selection for future studies.

Conference Call and Webcast Details

The Company will host a live conference call and webcast today at 8:30 AM Eastern Time to discuss the Company's financial results and provide a corporate update. The live webcast and subsequent replay may be accessed by visiting the Company's website at www.intracellulartherapies.com. Please connect to the Company's website at least 5-10 minutes prior to the live webcast to ensure adequate time for any necessary software download. Alternatively, please call 1-(877) 407-8291 (U.S.) or 1-(201) 689-8345 (international) to listen to the live conference call. The conference ID number for the live call is 13731923. Please dial in approximately 10 minutes prior to the call.

CAPLYTA® (lumateperone) is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate.

Important Safety Information

Boxed Warnings:

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. All antidepressant-treated patients should be closely monitored for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.**

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis**, including stroke and transient ischemic attack. See Boxed Warning above.
- **Neuroleptic Malignant Syndrome (NMS)**, which is a potentially fatal reaction. Signs and symptoms include: high fever, stiff muscles, confusion, changes in breathing, heart rate, and blood pressure, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Patients who experience signs and symptoms of NMS should immediately contact their doctor or go to the emergency room.
- **Tardive Dyskinesia**, a syndrome of uncontrolled body movements in the face, tongue, or other body parts, which may increase with duration of treatment and total cumulative dose. TD may not go away, even if CAPLYTA is discontinued. It can also occur after CAPLYTA is discontinued.
- **Metabolic Changes**, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases)**. Complete blood counts should be performed in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. CAPLYTA should be discontinued if clinically significant decline in WBC occurs in absence of other causative factors.
- **Decreased Blood Pressure & Dizziness**. Patients may feel lightheaded, dizzy or faint when they rise too quickly from a sitting or lying position (orthostatic hypotension). Heart rate and blood pressure should be monitored and patients should be warned with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls**. CAPLYTA may cause sleepiness or dizziness and can slow thinking and motor skills, which may lead to falls and, consequently, fractures and other injuries. Patients should be assessed for risk when using CAPLYTA.
- **Seizures**. CAPLYTA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment**. Patients should use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.

- **Body Temperature Dysregulation**. CAPLYTA should be used with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.
- **Dysphagia**. CAPLYTA should be used with caution in patients at risk for aspiration.

Drug Interactions: CAPLYTA should not be used with CYP3A4 inducers. Dose reduction is recommended for concomitant use with strong CYP3A4 inhibitors or moderate CYP3A4 inhibitors.

Special Populations: Newborn infants exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Breastfeeding is not recommended. Dose reduction is recommended for patients with moderate or severe hepatic impairment.

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs. placebo were somnolence/sedation, dizziness, nausea, and dry mouth.

Please click here to see full Prescribing Information including **Boxed Warning**.

About CAPLYTA (lumateperone)

CAPLYTA 42 mg is an oral, once daily atypical antipsychotic approved in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression) as monotherapy and as adjunctive therapy with lithium or valproate. While the mechanism of action of CAPLYTA is unknown, the efficacy of CAPLYTA could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Lumateperone is being studied for the treatment of major depressive disorder, and other neuropsychiatric and neurological disorders. Lumateperone is not FDA-approved for these disorders.

About Intra-Cellular Therapies

Intra-Cellular Therapies is a biopharmaceutical company founded on Nobel prize-winning research that allows us to understand how therapies affect the inner-workings of cells in the body. The company leverages this intracellular approach to develop innovative treatments for people living with complex psychiatric and neurologic diseases. For more information, please visit www.intracellulartherapies.com.

Forward-Looking Statements

This news release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements

include statements regarding, among other things, our expectations regarding the commercialization of CAPLYTA, including the availability of two new dosage strengths of CAPLYTA; our plans to conduct clinical or nonclinical trials and the timing of those trials, including enrollment, initiation or completion of clinical conduct, or the availability of results; plans to make regulatory submissions to the FDA and the timing of such submissions; whether clinical trial results will be predictive of future real-world results; whether CAPLYTA will serve an unmet need; our beliefs about the potential utility of our product candidates; future financial results; and development efforts and plans under the caption "About Intra-Cellular Therapies." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to, the following: there are no guarantees that CAPLYTA will be commercially successful; we may encounter issues, delays or other challenges in commercializing CAPLYTA; the COVID-19 pandemic may negatively impact our commercial plans and sales for CAPLYTA; the COVID-19 pandemic may negatively impact the conduct of, and the timing of enrollment, completion and reporting with respect to, our clinical trials; whether CAPLYTA receives adequate reimbursement from third-party payors; the degree to which CAPLYTA receives acceptance from patients and physicians for its approved indications; challenges associated with execution of our sales activities, which in each case could limit the potential of our product; results achieved in CAPLYTA in the treatment of schizophrenia and bipolar depression following commercial launch of the product may be different than observed in clinical trials, and may vary among patients; any other impacts on our business as a result of or related to the COVID-19 pandemic; challenges associated with supply and manufacturing activities, which in each case could limit our sales and the availability of our product; impacts on our business, including on the commercialization of CAPLYTA and our clinical trials, as a result of the conflict in Ukraine; risks associated with our current and planned clinical trials; we may encounter unexpected safety or tolerability issues with CAPLYTA following commercial launch for the treatment of schizophrenia or bipolar depression or in ongoing or future trials and other development activities; our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; our proposals with respect to the regulatory path for our product candidates may not be acceptable to the FDA; our reliance on collaborative partners and other third parties for development of our product candidates; and the other risk factors detailed in our public filings with the Securities and Exchange Commission. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

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INTRA-CELLULAR THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share amounts) (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	**2022**	2021
Revenues				
Product sales, net	**$ 55,074**	$ 19,007	**$ 89,829**	$ 34,586
Grant revenue	**505**	1,040	**746**	1,339
Total revenues	**55,579**	20,047	**90,575**	35,925
Operating expenses:				
Cost of product sales	**4,650**	2,040	**7,805**	3,495
Selling, general and administrative	**100,316**	69,851	**175,776**	122,435
Research and development	**38,536**	17,297	**67,579**	32,355
Total operating expenses	**143,502**	89,188	**251,160**	158,285
Loss from operations	**(87,923)**	(69,141)	**(160,585)**	(122,360)
Interest income	**1,320**	421	**1,868**	905
Loss before provision for income taxes	**(86,603)**	(68,720)	**(158,717)**	(121,455)
Income tax expense	**—**	24	**5**	29
Net loss	**$ (86,603)**	$ (68,744)	**$ (158,722)**	$ (121,484)
Net loss per common share:				
Basic & Diluted	**$ (0.92)**	$ (0.85)	**$ (1.70)**	$ (1.50)
Weighted average number of common shares:				
Basic & Diluted	**94,285,117**	81,229,788	**93,449,424**	81,088,900

The condensed consolidated statements of operations for the three and six months ended June 30, 2022 and 2021 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

INTRA-CELLULAR THERAPIES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands except share and per share amounts)

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	**$ 77,235**	$ 92,365
Investment securities, available-for-sale	**600,594**	319,968
Restricted cash	**1,400**	1,400
Accounts receivable, net	**46,976**	20,156
Inventory	**25,022**	7,948
Prepaid expenses and other current assets	**37,979**	25,444
Total current assets	**789,206**	467,281
Property and equipment, net	**2,137**	1,791
Right of use assets, net	**20,477**	20,764
Other assets	**86**	86
Total assets	**$ 811,906**	$ 489,922
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 10,749**	$ 8,691
Accrued and other current liabilities	**17,274**	11,073
Accrued customer programs	**16,483**	5,964
Accrued employee benefits	**18,385**	20,897
Lease liabilities, short-term	**7,743**	6,732
Total current liabilities	**70,634**	53,357
Lease liabilities	**19,075**	18,675
Total liabilities	**89,709**	72,032
Stockholders' equity:		
Common stock, $0.0001 par value: 175,000,000 shares authorized at June 30, 2022 and December 31, 2021, 94,367,233 and 81,886,965 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	**9**	8
Additional paid-in capital	**2,106,942**	1,639,476
Accumulated deficit	**(1,379,952)**	(1,221,230)
Accumulated comprehensive loss	**(4,802)**	(364)
Total stockholders' equity	**722,197**	417,890
Total liabilities and stockholders' equity	**$ 811,906**	$ 489,922

The condensed consolidated balance sheets at June 30, 2022 and December 31, 2021 have been derived from the financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.