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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K/A  
Amendment No. 2**

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**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 29, 2013**

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**INTRA-CELLULAR THERAPIES, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-54896**  
(Commission  
File Number)

**36-4742850**  
(IRS Employer  
Identification No.)

**3960 Broadway**  
**New York, New York 10032**  
(Address of principal executive offices) (Zip Code)

**(212) 923-3344**  
(Registrant's telephone number, including area code)

**Oneida Resources Corp.**  
**c/o Samir Masri CPA Firm P.C., 175 Great Neck Road, Suite 403, Great Neck, NY 11021**  
(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- 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))
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**Item 1.01. Entry into a Material Definitive Agreement.**

The disclosures set forth in Item 2.01 hereof are hereby incorporated by reference into this Item 1.01.

**Item 2.01. Completion of Acquisition or Disposition of Assets.**

Pursuant to an Agreement and Plan of Merger dated August 23, 2013, or the Merger Agreement, by and among Oneida Resources Corp., which we refer to as the Company, we, our and us; ITI, Inc., a Delaware corporation and wholly-owned subsidiary of the Company, or Merger Sub; and Intra-Cellular Therapies, Inc., a Delaware corporation, which we refer to as ITI; Merger Sub merged with and into ITI, with ITI remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. This transaction is referred to throughout this report as the “Merger.” The Merger was effective on August 29, 2013, upon the filing of a Certificate of Merger with the Secretary of State of the State of Delaware. As part of the Merger, ITI changed its name to ITI, Inc. A copy of the Merger Agreement is filed herewith as Exhibit 2.1, and is incorporated herein by reference.

Immediately following the Merger, a newly organized wholly-owned subsidiary of the Company named “Intra-Cellular Therapies, Inc.,” or Name Change Merger Sub, merged with and into the Company, leaving the Company as the surviving corporation. We refer to this transaction as the “Name Change Merger.” In connection with the Name Change Merger, we relinquished our corporate name “Oneida Resources Corp.” and assumed in its place the name “Intra-Cellular Therapies, Inc.” The Name Change Merger and name change became effective on August 29, 2013, upon the filing of a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware. A copy of the Certificate of Ownership and Merger is filed herewith as Exhibit 3.4, and is incorporated herein by reference.

At the effective time of the Merger, or the Effective Time, the legal existence of Merger Sub ceased and each share of ITI common stock and each share of ITI preferred stock that was issued and outstanding immediately prior to the Effective Time was automatically exchanged for 0.5 shares of our common stock, which we refer to as the Exchange. We issued an aggregate of 22,134,647 shares of our common stock upon such exchange of the outstanding shares of ITI common stock and preferred stock. In addition, at the Effective Time, we assumed ITI’s 2003 Equity Incentive Plan, as amended, or the 2003 Equity Incentive Plan, and all options to purchase ITI common stock then outstanding under the 2003 Equity Incentive Plan, and such options became exercisable for an aggregate of 1,462,380 shares of our common stock, subject to the vesting and other terms of such options. The vesting of such options was not accelerated as a result of the Merger. At the Effective Time, we also assumed the outstanding warrant to purchase ITI common stock, and such warrant became exercisable for 1,822 shares of our common stock.

Immediately following the Effective Time, pursuant to the terms of a Redemption Agreement dated August 29, 2013, or the Redemption Agreement, by and among the Company and its then-current sole stockholder, we completed the closing of a redemption of 5,000,000 shares of our common stock, or the Redemption, from our then-current sole stockholder in consideration of \$60,000, plus professional costs related to the transaction not to exceed \$20,000. The 5,000,000 shares constituted all of the issued and outstanding shares of our capital stock, on a fully-diluted basis, immediately prior to the Merger. A copy of the Redemption Agreement is filed herewith as Exhibit 10.17, and is incorporated herein by reference.

Upon completion of the Merger and the Redemption, the former stockholders of ITI held 100% of the outstanding shares of our capital stock. Unless otherwise indicated in this Current Report on Form 8-K, or this report, all share and per share figures reflect the exchange of each share of ITI common stock and each share of ITI preferred stock then outstanding for 0.5 shares of our common stock at the Effective Time of the Merger; however, the share and per share numbers in the financial statements of ITI filed herewith as Exhibit 99.1 are not adjusted to give effect to the Merger.

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As a condition to the Merger, we entered into an Indemnity Agreement with our former sole officer and director, or the Indemnity Agreement, pursuant to which we agreed to indemnify such former officer and director for actions taken by him in his official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions. A copy of the Indemnity Agreement is filed herewith as Exhibit 10.18, and is incorporated herein by reference.

The Merger is being accounted for as a capital transaction. Upon the effectiveness of the Merger, the Company's business became the operation of ITI and its business. Immediately following the Effective Time, our board of directors, which immediately prior to the Effective Time consisted of Samir N. Masri as our sole director, appointed Sharon Mates, Ph.D., who was Chairman, President and Chief Executive Officer of ITI, as our Chairman, President and Chief Executive Officer, to serve on our board of directors with Mr. Masri. At the Effective Time, Mr. Masri resigned from all of his positions as an officer of the Company. In addition, immediately following the Effective Time, our board of directors appointed Lawrence J. Himeline, who was the Vice President of Finance, Chief Financial Officer and Secretary of ITI, as our Vice President of Finance, Chief Financial Officer and Secretary; Allen A. Fienberg, Ph.D., who was the Vice President of Business Development of ITI, as our Vice President of Business Development; Lawrence P. Wennogle, Ph.D., who was the Vice President, Drug Discovery of ITI, as our Vice President, Drug Discovery; and Kimberly E. Vanover, Ph.D., who was the Vice President, Clinical Development of ITI, as our Vice President, Clinical Development. On September 9, 2013, which was the eleventh day following the date that we filed with the Securities and Exchange Commission, or SEC, and transmitted to our sole stockholder prior to the Merger, a Schedule 14f-1 reporting a change in the majority of our directors, Christopher Alafi, Ph.D., Richard Lerner, M.D., Joel S. Marcus and Sir Michael Rawlins, M.D., FRCP, FMedSci, were appointed to our board of directors to serve on our board of directors with Dr. Mates, and Mr. Masri resigned from our board of directors as of such date. Each of Dr. Mates, Dr. Alafi, Dr. Lerner, Mr. Marcus, and Sir Michael were directors of ITI immediately prior to the Merger.

Prior to the Merger, ITI sold to accredited investors approximately \$60.0 million of its shares of common stock, or 18,889,307 shares at a price of \$3.1764 per share, which included \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes, or Notes. We refer to this transaction as the Private Placement and the number of shares stated in the preceding sentence does not reflect the Exchange in the Merger. The price per share in the Private Placement, as adjusted for the Exchange in the Merger, would be \$6.3528 per share of our post-Merger common stock. Also, ITI granted the investors in the Private Placement registration rights requiring ITI or any successor to register those shares of

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ITI common stock (which were exchanged for shares of our common stock, along with the rest of the outstanding shares of ITI capital stock, except for dissenting shares, at the Effective Time) for public resale, as described in more detail below. The then existing stockholders of ITI who agreed to become parties to the registration rights agreement also became entitled to such registration rights, subject to specified differences in the agreement between the rights of new investors and existing stockholders. The existing Second Amended and Restated Investor Rights Agreement, by and among ITI and the investors listed therein, dated as of October 25, 2007, as amended, was terminated at the Effective Time. The Private Placement closed immediately prior to the filing of a Certificate of Merger with the Secretary of State of the State of Delaware, on August 29, 2013.

The Merger Agreement has been filed as Exhibit 2.1 to this Current Report on Form 8-K to provide investors and security holders with information regarding its terms. It is not intended to provide any other factual information about the Company or ITI. The representations, warranties and covenants contained in the Merger Agreement were made only for the purposes of such agreement and as of specified dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties. The representations and warranties may have been made for the purposes of allocating contractual risk between the parties to the agreement instead of establishing these matters as facts, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors are not third-party beneficiaries under the Merger Agreement and should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company, ITI or any of their respective subsidiaries or affiliates. In addition, the assertions embodied in the representations and warranties contained in the Merger Agreement are qualified by information in a confidential disclosure schedule provided by ITI, which is not being filed with this Current Report on Form 8-K as permitted by the SEC's rules and regulations. Accordingly, investors should not rely on the representations and warranties as characterizations of the actual state of facts, since (i) they were made only as of the date of such agreement or a prior, specified date, (ii) in some cases they are subject to qualifications with respect to materiality, knowledge and/or other matters, and (iii) they may be modified in important part by the underlying disclosure schedule. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Merger Agreement, which subsequent information may or may not be fully reflected in the Company's public disclosures.

ITI announced the Private Placement and the Merger in a press release dated September 3, 2013, which has been filed as Exhibit 99.3 to this Current Report on Form 8-K.

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## DESCRIPTION OF THE BUSINESS OF INTRA-CELLULAR THERAPIES, INC.

### Overview

We were originally incorporated in the State of Delaware in August 2012 under the name “Oneida Resources Corp.” Prior to the Merger, Oneida Resources Corp., or the Shell Company, was a “shell” company registered under the Securities Exchange Act of 1934, as amended, or the Exchange Act, with no specific business plan or purpose until it began operating the business of ITI through the Merger transaction on August 29, 2013. ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for the treatment of neuropsychiatric and neurologic diseases and other disorders of the central nervous system. Effective upon the Merger, a wholly-owned subsidiary of the Company merged with and into ITI, and ITI continues as the operating subsidiary of the Company. As used herein, the words the “Company,” “we,” “us,” and “our” refer to the current Delaware corporation operating the business of ITI as a wholly-owned subsidiary, which business will continue as the business of the Company.

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. Our lead product candidate, ITI-007, is in Phase 2 clinical trials as a first-in-class treatment for schizophrenia. Current medications available for the treatment of schizophrenia do not adequately address the broad array of symptoms associated with this CNS disorder. Use of these current medications also is limited by their substantial side effects. ITI-007 is designed to be effective across a wider range of symptoms, treating both the acute and residual phases of schizophrenia, with improved safety and tolerability.

ITI-007 is currently being studied in a randomized, placebo and active controlled Phase 2 clinical trial. In this Phase 2 trial, approximately 320 patients with an acutely exacerbated episode of schizophrenia are randomized to receive one of four treatments: 60 mg of ITI-007, 120 mg of ITI-007, 4 mg of risperidone (active control) or placebo in a 1:1:1:1 ratio, orally once daily for 28 days. The primary efficacy endpoint for this clinical trial is change from baseline to Day 28 on the total Positive and Negative Syndrome Scale, or PANSS. As part of the trial protocol, we performed an interim analysis of the data after approximately 30 patients in each arm had received treatment for 28 days. Based on the interim analysis, we observed an antipsychotic signal as measured by an average improvement in change from baseline on the total PANSS score at both doses of ITI-007 (60 mg and 120 mg) compared to placebo. Additionally, signals for improvement in both the Positive Symptom subscale and Negative Symptom subscale were observed. Patient enrollment has completed, and we currently anticipate that the full results from this trial will be available in the fourth quarter of 2013. Additional interim data from the Phase 2 trial are set forth below in the section entitled “Our Clinical Programs—ITI-007 Program—ITI-007 for the treatment of exacerbated and residual schizophrenia—Phase 2 Clinical Trial (ITI-007-005).”

We are also pursuing clinical development of ITI-007 for the treatment of additional CNS diseases and disorders. At the lowest doses, ITI-007 has been demonstrated to act primarily as a potent 5-HT<sub>2A</sub> serotonin receptor antagonist. As the dose is increased, additional benefits are derived from the engagement of additional drug targets, including modest dopamine receptor modulation and modest inhibition of serotonin transporters. We believe that combined interactions at these receptors may provide additional benefits above and beyond selective 5-HT<sub>2A</sub> antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer’s disease and autism spectrum disorders, while avoiding many of the side effects associated with more robust dopamine receptor antagonism. As the dose of ITI-007 is further increased, leading to moderate dopamine receptor modulation, inhibition of serotonin transporters, and indirect glutamate modulation, these actions complement the complete blockade of 5-HT<sub>2A</sub> serotonin receptors. In this dose range, we believe that ITI-007 will be useful in treating the symptoms associated with schizophrenia, bipolar disorder, major depressive disorder and other neuropsychiatric diseases.

Given the potential utility for ITI-007 and follow-on compounds to treat these additional indications, we may investigate, either on our own or with a partner, agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer’s disease and autism spectrum disorders; major depressive disorder; intermittent explosive disorder; non-motor symptoms and motor complications associated with Parkinson’s disease; and post-traumatic stress disorder. We hold exclusive, worldwide commercialization rights to ITI-007 and a family of compounds from Bristol-Myers Squibb Company pursuant to an exclusive license.

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We have a second major program that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase 1, or PDE1. PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. We have licensed the lead compound in this portfolio, ITI-214, and other compounds in this portfolio, to Takeda Pharmaceutical Company Limited, or Takeda. ITI-214 is the first compound in its class to successfully advance into Phase I clinical trials and is being developed for the treatment of cognitive impairment associated with schizophrenia, or CIAS, and other disorders. The results of our first Phase I clinical trial in 70 subjects in a randomized, double-blind, placebo-controlled study indicate that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Other compounds in the PDE1 portfolio outside the Takeda collaboration are being advanced for the treatment of other indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical programs that are focused on advancing drug candidates for the treatment of cognitive dysfunction, in both schizophrenia and Alzheimer's disease, and for disease modification and the treatment of neurodegenerative disorders, including Alzheimer's disease.

We have assembled a management team with significant industry experience to lead the discovery and development of our product candidates. We complement our management team with a group of scientific and clinical advisors that includes recognized experts in the fields of schizophrenia and other central nervous system disorders, including Nobel Laureate, Dr. Paul Greengard, one of our co-founders.

Our corporate headquarters and laboratory are located at 3960 Broadway, New York, New York, and our telephone number is (212) 923-3344. We also have an office in Towson, Maryland. We maintain a website at [www.intracellulartherapies.com](http://www.intracellulartherapies.com), to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission, or SEC, will be available free of charge through the website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

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### **Our Strategy**

Our goal is to discover and develop novel small molecule therapeutics for the treatment of CNS diseases in order to improve the lives of people suffering from such illnesses. Using our key understanding of intracellular signaling, we seek to accomplish our goal, using our in-house expert drug discovery and clinical development teams, in two ways:

- we seek to have the capability to develop first-in-class medications with novel mechanisms that have the potential to treat CNS diseases for which there are no previously marketed drugs; and

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- we seek to develop drugs that can differentiate themselves in competitive markets by addressing aspects of CNS disease which are either not treated by currently marketed drugs or can be effective with fewer side effects.

The key elements of our strategy are to:

- complete the development of ITI-007 for its lead indication, treatment of acute symptoms in schizophrenia, and for additional neuropsychiatric indications, such as bipolar disorder and residual symptoms in schizophrenia;
- expand the commercial potential of ITI-007 by investigating its usefulness in neurological areas, such as behavioral disturbances in dementia, including Alzheimer's disease and autism spectrum disorder, and in additional neuropsychiatric indications, such as sleep disorders associated with neuropsychiatric and neurological disorders and major depressive disorder;
- continue to develop with our collaboration partner, Takeda, PDE inhibitor compounds, such as ITI-214, for CNS indications such as CIAS; and
- advance earlier stage product candidates in our pipeline.

#### **Our Drug Discovery Platform and Capabilities**

Based on the pioneering efforts of ITI co-founder and Nobel laureate, Dr. Paul Greengard, we have developed a detailed understanding of intracellular signaling pathways and intracellular targets. We have used that knowledge to develop several state of the art technology platforms, including one called CNSProfile™. This technology monitors the phosphoprotein changes elicited by major psychotropic drug classes and subclasses, and generates a unique molecular signature for drug compounds. By monitoring how the levels of these phosphoproteins change *in vivo*, we identify intracellular signaling pathways through which several major drug classes operate. Along with what we believe to be state of the art drug discovery efforts, we have used, and may continue to use, this information as a tool to validate our selection of preclinical candidate molecules.

During the years ended December 31, 2012 and 2011, we incurred \$15.5 million and \$7.7 million in research and development expenses, respectively.

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## Disease and Market Overview

Our programs for small molecule therapeutics are designed to address various CNS diseases that we believe are underserved or unmet by currently available therapies and that represent large potential commercial market opportunities for us. Background information on the CNS diseases and related commercial markets that may be addressed by our programs is set forth below.

### *Schizophrenia*

Schizophrenia is a disabling and chronic mental illness that is characterized by multiple symptoms during an acute phase of the disorder that can include so-called “positive” symptoms, such as hearing voices, grandiose beliefs and suspiciousness or paranoia. These symptoms can be accompanied by additional, harder to treat symptoms, such as social withdrawal, blunted emotional response and speech deficits, collectively referred to as “negative” symptoms, difficulty concentrating and disorganized thoughts, or cognitive impairment, depression and insomnia. Such symptoms often persist even after the acute positive symptoms subside, and contribute substantially to the social and employment disability associated with schizophrenia. Current antipsychotic medications provide some relief for the symptoms associated with the acute phase of the disorder, but they do not effectively treat the residual phase symptoms associated with chronic schizophrenia. Moreover, currently available medications used to treat acute schizophrenia are limited in their use due to side effects that can include movement disorders, weight gain, metabolic disturbances, and cardiovascular disorders.

According to the National Institute of Mental Health, over 1% of the world’s population suffers from schizophrenia, and more than 3 million Americans suffer from the illness in any given year. Worldwide sales of antipsychotic drugs used to treat schizophrenia and other CNS related disorders exceeded \$40 billion in 2012. These drugs have been increasingly used by physicians to address a range of disorders in addition to schizophrenia, including bipolar disorder and a variety of psychoses and related conditions in elderly patients. Despite their commercial success, current antipsychotic drugs have substantial limitations, including inadequate efficacy and severe side effects.

The first-generation, or typical, antipsychotics that were introduced in the late-1950s block dopamine receptors. While typical antipsychotics are effective against positive symptoms of schizophrenia in many patients, these drugs often induce disabling motor disturbances, and they fail to address or worsen most of the negative symptoms and cognitive disturbances associated with schizophrenia.

Most schizophrenia patients in the United States are treated today with second-generation, or atypical, antipsychotics, which induce fewer motor disturbances than typical antipsychotics, but still fail to address most of the negative symptoms of schizophrenia. In addition, currently prescribed treatments do not effectively address or may exacerbate cognitive disturbances associated with schizophrenia. It is believed that the efficacy of atypical antipsychotics is due to their interactions with dopamine and 5-HT<sub>2A</sub> receptors. The side effects induced by the atypical agents may include weight gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, sleep disturbances, and motor disturbances. We believe that these side effects generally arise either from non-essential receptor interactions or from excessive dopamine blockade.



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The limitations of currently available antipsychotics result in poor patient compliance. A landmark study funded by the National Institute of Mental Health, the Clinical Antipsychotic Trials of Intervention Effectiveness, also referred to as CATIE, which was published in The New England Journal of Medicine in September 2005, found that 74% of patients taking typical or atypical antipsychotics discontinued treatment within 18 months because of side effects or lack of efficacy. We believe there is a large underserved medical need for new therapies that have improved side effect and efficacy profiles.

### ***Bipolar Disorder***

Bipolar disorder, commonly referred to as manic-depressive illness, is characterized by extreme shifts in mood. Individuals with bipolar disorder may experience intense feelings of over-excitement, irritability, and impulsivity with grandiose beliefs and racing thoughts, referred to as a manic episode. Symptoms of depression may include feeling tired, hopeless and sad, with difficulty concentrating and thoughts of suicide. Some people experience both types of symptoms in the same “mixed” episode. Severe symptoms of bipolar disorder can be associated with hallucinations or delusions, otherwise referred to as psychosis.

Bipolar disorder affects 4.4% of the adult United States population, or approximately 13 million adults, with a worldwide prevalence of 2.4%. In 2012, therapeutics used to treat bipolar disorder had global sales of approximately \$6 billion.

Bipolar disorder is often treated with antipsychotic medications alone or in combination with mood stabilizers. The side effects and safety risks associated with antipsychotic drugs in patients with bipolar disorder are similar to those experienced by patients with schizophrenia. Moreover, a large national research program conducted from 1998 to 2005 called the Systematic Treatment Enhancement Program for Bipolar Disorder, or STEP-BD, followed 4,360 patients with bipolar disorder long term and showed that about half of patients who were treated for bipolar disorder still experienced lingering and recurrent symptoms, indicating a clear need for improved treatments.

### ***Alzheimer’s Disease***

Alzheimer’s disease is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, and eventually even the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living, and a host of behavioral and neuropsychiatric symptoms. Alzheimer’s disease primarily affects older people and, in most cases, symptoms first appear after age 60. Alzheimer’s disease gets worse over time and is fatal.

The market for Alzheimer’s disease therapeutics is categorized into two segments: acetylcholinesterase inhibitors and NMDA receptor antagonists, which include Aricept®, Namenda®, Exelon® and Ebixa®. Acetylcholinesterase inhibitors, which account for 40% of the total worldwide market, had total sales of \$4.1 billion in 2011. In 2012, global sales of CNS therapeutics for dementia and Alzheimer’s disease reached \$8 billion.

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According to the Alzheimer's Association, 5.2 million people in the United States are living with Alzheimer's disease, and it is currently the fifth leading cause of death for people age 65 and older. It has been estimated that 35.6 million people worldwide were living with dementia in 2010. This number is expected to nearly double to 65.7 million by 2030 and to 115.4 million by 2050. While the diagnostic criteria for Alzheimer's disease mostly focus on the related cognitive deficits, it is often the behavioral and psychiatric symptoms that are most troublesome for caregivers and lead to poor quality of life for patients. These symptoms include agitation, aggressive behaviors, and psychosis. Studies have suggested that approximately 20% to 51% of Alzheimer's disease patients may develop psychosis, commonly consisting of hallucinations and delusions. The diagnosis of Alzheimer's disease psychosis is associated with more rapid cognitive and functional decline and institutionalization.

The U.S. Food and Drug Administration, or FDA, has not approved any drug to treat the behavioral symptoms of Alzheimer's disease. As symptoms progress and become more severe, physicians often resort to off-label use of antipsychotic medications in these patients. Current antipsychotic drugs are associated with a number of side effects, which can be problematic for elderly patients with Alzheimer's disease. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with Alzheimer's disease. Current antipsychotic drugs also have a boxed warning for use in elderly patients with dementia-related psychosis due to increased mortality and morbidity. There is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with Alzheimer's disease.

### ***Parkinson's Disease***

Parkinson's disease is a chronic and progressive neurodegenerative disorder that involves malfunction and death of neurons in a region of the brain that controls movement. This neurodegeneration creates a shortage of an important brain signaling chemical, or neurotransmitter, known as dopamine, thereby rendering patients unable to direct or control their movements in a normal manner. Parkinson's disease is characterized by well-known motor symptoms, including tremors, limb stiffness, slowness of movements, and difficulties with posture and balance, as well as by non-motor symptoms, which include sleep disturbances, mood disorders, cognitive impairment and psychosis. Parkinson's disease progresses slowly in most people and the severity of symptoms tends to worsen over time.

Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. According to the National Parkinson Foundation, about 1 million people in the United States and from approximately 4 to 6 million people worldwide suffer from this disease. Parkinson's disease is more common in people over 60 years of age, and the prevalence of this disease is expected to increase significantly as the average age of the population increases. Parkinson's disease patients are commonly treated with dopamine replacement therapies, such as levodopa, commonly referred to as L-DOPA, which is metabolized to dopamine, and dopamine agonists, which are molecules that mimic the action of dopamine. Sales of therapeutics such as L-DOPA and dopamine agonists used to treat the motor symptoms of the disease reached \$2.5 billion in 2012.

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Non-motor symptoms can be particularly distressing and even more troublesome to patients with Parkinson's disease than the primary motor disturbances. Non-motor symptoms substantially contribute to the burden of Parkinson's disease and deeply affect the quality of life of patients and their caregivers. Non-motor symptoms of Parkinson's disease are associated with increased caregiver stress and burden, nursing home placement, and increased morbidity and mortality.

Treatment of non-motor symptoms associated with Parkinson's disease poses a challenge to physicians. Current dopamine replacement drugs used to treat the motor symptoms of Parkinson's disease do not help, and sometimes worsen, the non-motor symptoms. No drugs are currently approved by the FDA for treating the broad non-motor symptoms associated with Parkinson's disease, and this remains a large unmet medical need.

### ***Depression***

Major depressive disorder, or MDD, is a brain disorder that can be associated with symptoms of sadness, hopelessness, helplessness, feelings of guilt, irritability, loss of interest in formerly pleasurable activities, cognitive impairment, disturbed sleep patterns, and suicide ideation or behavior. Different people may experience different symptoms, but everyone with major depression experiences symptoms that are severe enough to interfere with everyday functioning, such as the ability to concentrate at work or school, social interactions, eating and sleeping. Sometimes the depressive episode can be so severe it is accompanied by psychosis (hallucinations and delusions). According to the National Institute of Mental Health, approximately 3% of teenagers and approximately 7% of adults experience MDD each year. Worldwide sales of antidepressant drugs reached \$11.9 billion in 2011. The antidepressant market is primarily composed of selective serotonin reuptake inhibitors such as Lexapro® (marketed by Forest Laboratories and Lundbeck) and selective norepinephrine reuptake inhibitors, or SNRIs, such as Cymbalta® (marketed by Eli Lilly). Antipsychotics such as Seroquel® (marketed by Astrazeneca) and Abilify® (marketed jointly by Bristol Myers Squibb and Otsuka Pharmaceutical) are also used as adjunctive treatments with antidepressant treatment. The National Institute of Mental Health-funded Sequenced Treatment Alternatives to Relieve Depression, or STAR\*D, study showed that only one-third of treated patients experience complete remission of depressive symptoms. Nearly two-thirds of patients were considered treatment-resistant.

## Our Clinical Programs

Our pipeline includes two product candidates in clinical development and two product candidates in advanced pre-clinical testing. We believe that our product candidates offer innovative therapeutic approaches and may provide significant advantages relative to current therapies. The following table summarizes our product candidates and programs:

### ITI Therapeutic Pipeline

Program/Indication	Discovery	EDC	Preclinical	Phase 1	Phase 2	Phase 3
<b>ITI-007 Program</b>						
▪ Schizophrenia						
▪ Bipolar Disorder *						
▪ Sleep Maintenance Insomnia & Sleep Disturbances associated with Neurologic & Psychiatric Disorders						
▪ Behavioral Disturbances associated with Dementia, including Alzheimer's disease (AD) *						
▪ Sleep & Behavioral Disturbances associated with Autism Spectrum Disorder *						
▪ Depression and other Mood Disorders, including MDD, PTSD, IED *						
<b>ITI-002 (PDE1) Program</b>						
☐ <b>ITI-214 Partnered with Takeda</b>						
▪ Cognitive Impairment associated with Schizophrenia (CIAS)						} Partnered with Takeda
▪ Parkinson's Disease (PD)						
▪ Cognitive Impairment in Alzheimer's disease (AD)						
▪ Attention Deficit and Hyperactivity Disorders						
☐ <b>ITI-002 Internal Program</b>						
▪ Cardiovascular and Other Diseases						
<b>Additional PDE Programs</b>						
▪ PDE2: Cognition/neurodegenerative disorders						
▪ PDE9: AD/cognition						
<b>Alzheimer's Disease</b>						
▪ ITI-012: Casein Kinase 1 Inhibitors						
▪ ITI-009: gSAP Inhibitors						

\* We have not conducted separate Phase 1 clinical trials of ITI-007 dedicated to these indications. We plan to use data from our completed Phase 1 trials of ITI-007 in healthy volunteers to advance the product candidate into Phase 2 and other trials for these indications.

#### ITI-007 Program

Our lead product candidate, ITI-007, possesses a mechanism of action that we believe targets multiple neurobiological pathways and could be developed to allow fine tuning of the drug candidate's action in the brain by simple dose adjustments. At the lowest doses, ITI-007 has been demonstrated to act primarily as a potent 5-HT<sub>2A</sub> receptor antagonist, blocking the activity of this receptor with minimal interaction with dopamine receptors and serotonin transporters. As the dose is increased, ITI-007 interacts more robustly with dopamine receptors and serotonin transporters and indirectly modulates glutamate signaling. We believe that the dose response pattern demonstrated by ITI-007 in clinical trials to date may make it possible to select a clinical dose capable of treating an array of symptoms associated with schizophrenia and other CNS disorders that is broader than that addressable by other antipsychotic drugs, yet without causing the side effects commonly experienced with use of such drugs. We also believe that the differential pharmacology of ITI-007 at different doses could allow customized dosing based on an individual patient's symptoms.

We believe these features of ITI-007 may be able to improve the quality of life of patients with schizophrenia to allow them to more fully integrate into their families and their workplace.

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In addition, ITI-007 may be shown to treat disorders at either low-doses (e.g., sleep, aggression and agitation) or high-doses (e.g., acute exacerbated and residual schizophrenia, bipolar disorders, and mood disorders).

#### *Phase 1 studies to support multiple clinical indications*

We have conducted a series of Phase 1 safety studies of ITI-007 in Europe and the United States during the period from 2007 to 2011. All of the studies conducted to date in the United States have been conducted under an Investigational New Drug, or IND, filed in 2007 by ITI. Data from these studies are being used to support the clinical development of ITI-007 in multiple indications, including acute exacerbated schizophrenia, sleep disorders in neuropsychiatric and neurodegenerative disease, major depressive disorders, bipolar disorders, behavioral disturbances in dementia and Alzheimer's disease, autism, posttraumatic stress disorder, or PTSD, and intermittent explosive disorder, or IED. We have completed the following three Phase 1 trials in healthy volunteers:

- A Phase 1, double-blind placebo controlled, single ascending dose study in 40 healthy volunteers in Europe in 2007. ITI-007 was generally well tolerated at all doses. Most adverse events, or AEs, were mild to moderate and all treatment related AEs resolved. The most frequent AE was headache.
- A Phase 1, placebo controlled multiple ascending dose study in 25 healthy volunteers in Europe from 2007 to 2008. ITI-007 was generally well tolerated at all doses. Most AEs were mild to moderate and all treatment related AEs resolved.
- A Phase 1, open-label positron emission tomography, or PET, study to demonstrate receptor occupancy, safety, tolerability and pharmacokinetics after single oral dose administration of ITI-007 in 16 healthy male volunteers. This study was conducted in the United States from 2007 to 2009. ITI-007 was well tolerated, all AEs were of mild or moderate intensity and all treatment related AEs resolved. Dose related increases in receptor occupancy at dopamine D2 receptors in the striatum were demonstrated after ITI-007 administration. Brain occupancy at 5-HT2A and serotonin reuptake transporters also was demonstrated after single doses of ITI-007.

We continued Phase 1 development of ITI-007 in patients with schizophrenia in order to advance ITI-007 in this target therapeutic indication. Specifically, we conducted the following additional studies:

- A Phase 1b/2, placebo controlled multiple ascending dose study in 45 patients with stable schizophrenia in the United States during 2009 to 2010. ITI-007 was generally well tolerated at all doses. All AEs were mild to moderate and all treatment related AEs resolved. The overall percentage of patients reporting treatment related AEs was similar for those treated with ITI-007 (83.3% to 100%, across dose groups) and placebo (72.7%). The majority of the treatment related AEs that occurred at the commencement of the study decreased in terms of frequency and/or severity with repeated administration. We observed signs consistent with clinical efficacy in stable patients with schizophrenia in this study.
- A Phase 1, randomized study to determine the tolerability, safety and pharmacokinetics of ITI-007 using different dosing regimens in 11 patients with schizophrenia. This study was conducted in the United States in 2011. In this study, we showed that administration of ITI-007 in a capsule dosage form taken with food reduced the incidence of treatment related AEs and all treatment related AEs resolved. The most commonly reported treatment related AE in this study was somnolence, commonly known as drowsiness.

#### *ITI-007 for the treatment of exacerbated and residual schizophrenia*

In multiple clinical trials of ITI-007 in patients with schizophrenia, the drug candidate has demonstrated clinical signals consistent with reductions in psychosis, depression and insomnia. Reductions in psychosis are consistent with the potential to treat acute schizophrenia, whereas reductions in depression and insomnia are consistent with the potential to treat residual phase schizophrenia. ITI-007 has been shown to be safe and well-tolerated across a wide range of doses in these studies. Further, at doses that have demonstrated clinical activity, ITI-007 has caused fewer adverse effects than those typically associated with antipsychotic drug treatment, such as impaired motor function. These adverse side effects can be a major cause of patient noncompliance with current antipsychotic therapies.

#### Phase 2 Clinical Trial (ITI-007-005)

Based on the successful completion of these studies in patients with schizophrenia, ITI-007 has advanced in development and is currently being studied in ITI-007-005, a randomized, placebo and active controlled Phase 2 clinical trial in approximately 320 patients with acute exacerbated schizophrenia at multiple sites in the United States. In this Phase 2 trial, patients with an acutely exacerbated episode of schizophrenia are randomized to receive one of four treatments: 60 mg of ITI-007, 120 mg of ITI-007, 4 mg of risperidone (active control) or placebo in a 1:1:1:1 ratio. Patients receive study treatment orally once daily in the morning for 28 days. Subject participation lasts approximately 7 to 8 weeks, including a one week screening period, a four week treatment period followed by stabilization on standard of care, and a safety follow up visit approximately two weeks after stabilization. The primary efficacy endpoint for this clinical trial is change from baseline to Day 28 on the total Positive and Negative Syndrome Scale, or PANSS. The PANSS is a well-validated 30-item rating scale that measures the ability of a drug to reduce schizophrenia symptom severity. The PANSS measures the Positive Symptoms, such as delusions and hallucinations; the Negative Symptoms, such as blunted affect and emotional withdrawal; and General Psychopathology, such as anxiety, depression, and uncooperativeness.

Secondary efficacy endpoints in this trial include weekly assessments of the total PANSS as well as its subscales (Positive Symptom Subscale, Negative Symptom Subscale, and General Psychopathology Subscale) and the Negative Symptom Factor (based on a subset of PANSS questions). Safety and tolerability are also assessed.

#### *Planned Interim Analysis*

As part of the trial protocol, an interim analysis of the data was planned to be conducted after approximately 30 patients per treatment arm had completed 28 days of treatment. The goal of the interim analysis was to validate the study assumptions on treatment effect of ITI-007 compared to placebo. Based on the results of the interim analysis, the trial may have proceeded as planned, been terminated prematurely or modified, such as terminating one of the treatment arms.

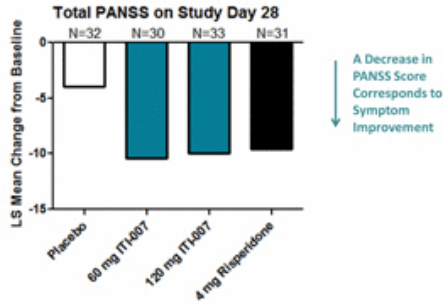
The interim analysis was conducted on select group data unblinded to treatment with 126 patients included in the intent-to-treat analysis. Individual data were kept blinded to preserve the integrity of this trial.

*Results of Interim Analysis*

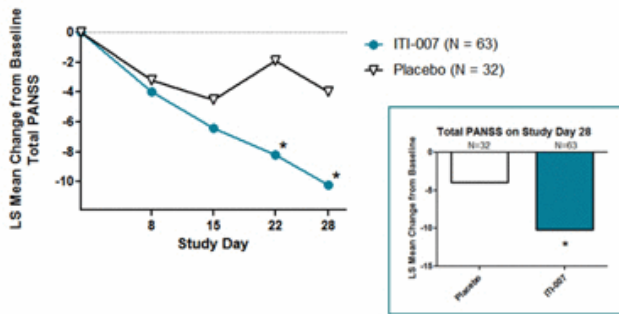
The results of the interim analysis indicated that the study assumptions were validated and the study was continued as planned. In particular, the interim results indicated an antipsychotic signal as measured by an average improvement in change from baseline on the total PANSS at both doses of ITI-007 (60 mg and 120 mg) compared to placebo. As expected, risperidone, as the treatment control, also exhibited an antipsychotic signal by demonstrating assay sensitivity. When the two ITI-007 treatment arms (60 mg and 120 mg) were combined to increase statistical power in comparison to placebo, ITI-007 demonstrated statistically significant improvement after three and four weeks of treatment (Least Squares Mean Change from Baseline on total PANSS,  $p < 0.05$  versus Placebo at a 0.05 (two-sided) level of significance based on ANCOVA-LOCF for Intent-to-Treat, or ITT, population). Both doses of ITI-007 and risperidone exhibited signals indicating improvement in the Positive Symptom Subscale and the General Psychopathology Subscale.

These interim data are demonstrated in the graphs set forth below. Investors should be cautioned that preliminary and interim results of a clinical trial are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available.

**ITI-007-005 Interim: Antipsychotic Signal at Both Doses Measured by Total PANSS**

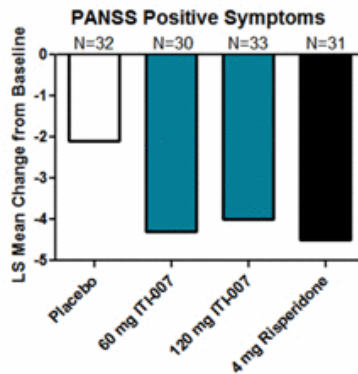


**ITI-007-005 Interim: Statistically Significant Antipsychotic Efficacy When the Two ITI-007 Dose Arms Are Combined**

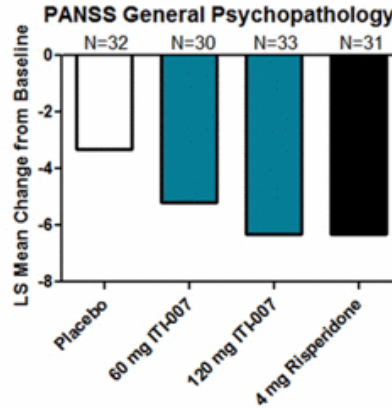


\*  $p < 0.05$ ; Statistically significant for PANSS Total versus Placebo at a 0.05 (two-sided) level of significance based on ANCOVA-LOCF for Intent-to-Treat (ITT) population

**ITI-007-005 Interim: Improved Positive Symptoms**

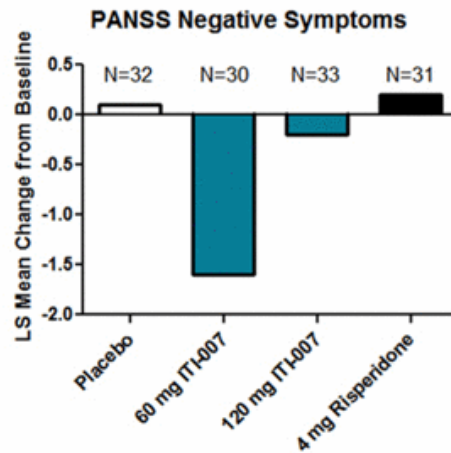


## ITI-007-005 Interim: Improved General Psychopathology

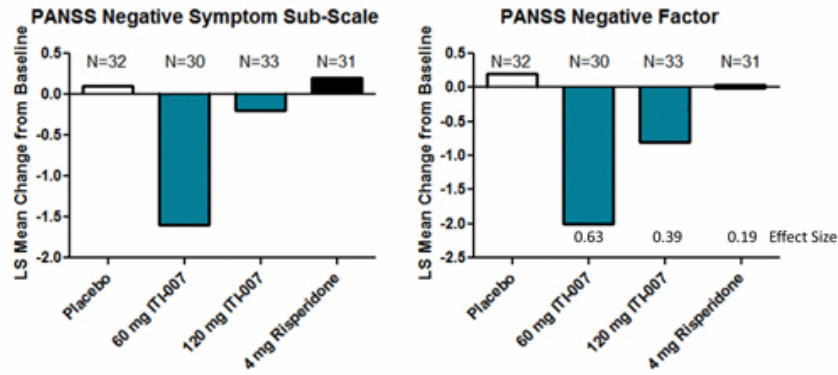


ITI-007, especially at the 60 mg dose, exhibited a signal indicating improvement in the Negative Symptom Subscale. An even greater signal was observed with 60 mg of ITI-007 on the Negative Symptom Factor. The Negative Symptom Factor includes symptoms of blunted affect, emotional withdrawal, poor rapport, passive social withdrawal, lack of spontaneity, motor retardation, uncooperativeness and active social avoidance. The 60 mg dose of ITI-007 improved Negative Symptom Factor scores with an effect size of 0.63 (the closer the effect size is to a value of 1, the better the Negative Symptom Factor score), whereas the 120 mg dose of ITI-007 exhibited an effect size of 0.39 on this endpoint. In contrast, risperidone, the treatment control, exhibited an effect size of 0.19 on this measure. We believe that ITI-007 may have utility in broadly treating the symptoms associated with acute exacerbated schizophrenia, in addition to targeting negative and other residual symptoms in this disease.

## ITI-007-005 Interim: Improved Negative Symptoms



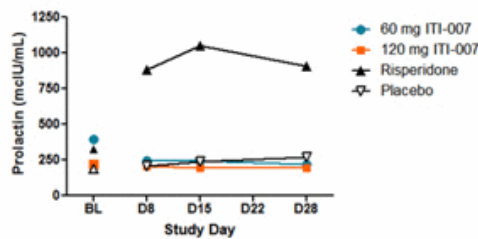
## ITI-007-005 Interim: Improvement in Negative Symptoms with ITI-007 Confirmed with Improved Negative 'Factor'<sup>1</sup>



<sup>1</sup>van der Gaag et al., 2006

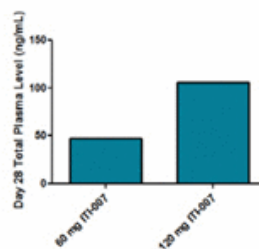
At the interim analysis, ITI-007 was also demonstrated to be safe and well-tolerated in patients with acute schizophrenia. There were no treatment related serious adverse events. The most frequent AE reported was sedation, which occurred in all treatment arms, including placebo. The frequency of sedation at the interim analysis was similar in the 120 mg ITI-007 group and the risperidone group and less in the 60 mg ITI-007 and placebo groups. There were no safety concerns with respect to 12-lead electrocardiograms, or ECG's, vital signs, body weight, clinical chemistry values, and extrapyramidal side effects (including no akathisia associated with ITI-007), and no suicidal ideation or behavior. Unlike risperidone, ITI-007 did not increase blood levels of prolactin. Overall, we believe that the group pharmacodynamic data at the interim analysis indicates a good oral pharmacokinetic profile of ITI-007 with predictable exposures, supporting the potential appropriateness of a once-a-day administration.

## ITI-007-005 Interim: Unlike Risperidone and Many Other Antipsychotics, ITI-007 Does Not Cause Hyperprolactinemia



Plasma prolactin levels were determined from samples collected before dose administration (trough) after overnight fast

## ITI-007-005 Interim: Good Oral Availability & Predictable Exposure



Patient enrollment has completed, and we currently anticipate that the full results of the ITI-007-005 Phase 2 trial will be available in the fourth quarter of 2013. We are planning additional clinical trials to explore ITI-007's mechanism of action for addressing chronic residual phase schizophrenia. We believe that ITI-007's pharmacological profile may expand its therapeutic potential beyond the treatment of acutely exacerbated schizophrenia to also include chronic residual schizophrenia by improving negative symptoms, mood, sleep and cognition.



The pharmacological profile of ITI-007 offers the potential to treat bipolar mania, depression, and mixed symptoms at doses similar to those targeted for the treatment of schizophrenia. We believe that ITI-007 may be effective alone or in combination with mood stabilizers. Given that many patients with bipolar disorder also experience disturbed sleep and cognitive impairment similar to that observed in schizophrenia, we believe that ITI-007 may treat a wide array of symptoms in patients with bipolar disorder, including improvement of cognition and sleep. We expect that data from our completed Phase 1 studies and data from our on-going Phase 2 trial in acute exacerbated schizophrenia will be used to advance ITI-007 directly into well-controlled clinical trials for the treatment of bipolar disorder. If our Phase 2 trial in acute exacerbated schizophrenia successfully meets its endpoints, we intend to initiate Phase 3 trials in schizophrenia in the second half of 2014 and plan to initiate separate additional trials in bipolar disorder in 2015. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. After the completion of the ITI-007-005 Phase 2 trial in schizophrenia, we plan to request a meeting with the FDA to discuss our clinical development plan for ITI-007, including our plan to conduct separate, but overlapping, well-controlled clinical efficacy trials in schizophrenia and bipolar disorder.

The FDA may not agree with our clinical development plans to advance ITI-007 for the treatment of schizophrenia and bipolar disorder with separate, but overlapping, well-controlled clinical trials in both indications. Our clinical plans may change based on the outcome of the ITI-007-005 Phase 2 trial in schizophrenia and based on any discussions with the FDA.

*ITI-007 for the treatment of sleep disturbances associated with neurologic and psychiatric disorders*

In a Phase 2 double-blind, placebo controlled cross-over clinical trial conducted in 19 patients at low doses completed in 2008 and conducted in Europe. The primary outcome measure was slow wave sleep as determined by polysomnography. ITI-007 demonstrated a dose-related statistically significant increase in slow wave sleep. Secondary measures were consistent with improvement of sleep maintenance in patients with primary insomnia, indicated by decreased waking after sleep onset, increased total sleep time, and no increase in latency to sleep onset. At these low doses ITI-007 did not induce sleep, but rather helped maintain sleep once sleep had been initiated. In addition, ITI-007 was not associated with next day cognitive impairment, or “hang-over” effects. We believe that ITI-007 may be particularly useful in the treatment of sleep disorders that accompany neuropsychiatric and neurologic disorders, including schizophrenia, autism spectrum disorder, or ASD, Parkinson’s disease and dementia. Previous work has suggested that selective 5-HT<sub>2A</sub> receptor antagonists increase deep, slow wave sleep in both humans and animals. We believe, however, that other neuropharmacological mechanisms, in addition to 5-HT<sub>2A</sub> receptor antagonism, such as engaging some dopamine modulation, may be

beneficial for the successful treatment of sleep maintenance insomnia, or SMI, in humans. We believe that ITI-007 represents a new approach to the treatment of sleep maintenance insomnia because of its unique pharmacology and neuropharmacological interactions beyond selective 5-HT<sub>2A</sub> receptor antagonism. We believe that ITI-007 offers a potentially new approach to the treatment of sleep maintenance disorders, particularly in those disorders that accompany neuropsychiatric and neurologic disorders. Many of these disorders are accompanied by profound sleep deficits, which impair daytime functioning including cognition, exacerbate disease symptoms and increase the cost of care. We are presently exploring clinical designs to incorporate the examination of sleep disturbances in one or more of these indications. There is no assurance that any such design would be sufficient for an FDA approval for this indication.

*ITI-007 for the treatment of behavioral disturbances associated with dementia, including Alzheimer's disease*

Behavioral disturbances are common in dementia and Alzheimer's disease. These disturbances are a major component of the burden to caregivers, and often lead to institutionalization. Although currently available treatments for patients with dementia mainly address cognitive disturbances, behavioral disturbances are considerably more problematic and likely more amenable to drug treatment. Several behavioral symptoms are quite prevalent in patients with dementia, including patients with Alzheimer's disease. Rates of depression in Alzheimer's disease are estimated to be up to 87%, although most estimates are between 30% and 50%. Agitation and aggression are present in approximately 60% of patients. Sleep disturbances, particularly as an increased likelihood of day-night reversal, are present in up to approximately 60% of patients. In view of the potential multiple effects of ITI-007 on aggression, agitation, sleep disorders and depression, and its safety profile to date, we believe that ITI-007 may provide a novel therapy for treating the behavioral disturbances accompanying dementia, including Alzheimer's disease. Clinical trials are planned to address the therapeutic utility of ITI-007 for the treatment of behavioral disturbances in dementia and Alzheimer's disease. We believe that our completed Phase 1 studies support advancing ITI-007 into Phase 2 trials in this patient population, although we may conduct additional Phase 1 studies to better define the dose range in elderly subjects and patients with dementia.

*ITI-007 for the treatment of sleep and behavioral disturbances associated with autism spectrum disorder*

Sleep problems are common in patients with autism spectrum disorder, or ASD, and are not adequately treated by currently available interventions. Approximately two thirds of children and adolescents with ASD experience sleep problems, higher than the rate of sleep problems in age-matched developmentally typical children. Moreover, individuals with ASD suffer from behavioral disturbances, including aggression, irritability, anxiety and depression. With its multiple pathway mechanism of action, we believe that ITI-007 could address the multi-faceted behavioral symptoms associated with ASD. 5-HT<sub>2A</sub> receptor antagonism is predicted to increase slow wave sleep, improve sleep maintenance and reduce aggression. D<sub>2</sub> receptor modulation is predicted to improve sleep maintenance and reduce irritability and aggression. Serotonin reuptake inhibition is predicted to reduce anxiety and depression. Accordingly, we believe that ITI-007 could improve sleep maintenance, reduce behavioral disturbances and enhance social interaction in patients with ASD. We believe that our completed Phase 1 studies support advancing ITI-007 into Phase 2 trials in this patient population, and we are presently exploring the feasibility of such trials.

*ITI-007 for the treatment of depression and other mood disorders*

As a potent 5-HT<sub>2A</sub> receptor antagonist and serotonin reuptake inhibitor, we believe that ITI-007 could improve symptoms of depression with fewer side effects than selective serotonin reuptake inhibitors, or SSRIs. Dopamine modulation by ITI-007 may reduce irritability and aggression that can accompany many mood disorders. As such, ITI-007 may be effective for the treatment of mood disorders including major depressive disorder, or MDD, posttraumatic stress disorder, or PTSD, and intermittent explosive disorder, or IED. We are presently exploring the feasibility of clinical studies in these indications.

**ITI-002 (PDE1) Program**

We have a second major program, called our ITI-002 program, that has generated a portfolio of compounds that have demonstrated the ability to modulate CNS pathways that are critical to controlling cognition and motor behavior through the inhibition of an important intracellular enzyme, PDE1. In March 2011, we entered into a license and collaboration agreement with Takeda to develop and commercialize selected PDE1 inhibitors in our ITI-002 program for the treatment of CIAS and other disorders, including Parkinson's disease, cognitive impairment in Alzheimer's disease, and Attention Deficit Hyperactivity Disorder. Cognitive deficits are believed to underlie much of the significant functional impairments observed in patients with schizophrenia. One of these portfolio compounds, ITI-214, has advanced into Phase 1 clinical studies. In the first quarter of 2013, we announced the completion by Takeda of a single ascending dose Phase 1 study in 70 healthy volunteers in the United States under an IND filed by Takeda in 2012. Takeda will be solely responsible for development, manufacturing and commercialization of PDE1 inhibitors. The results of this randomized, double-blind, placebo-controlled Phase 1 study indicated that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Moreover, the study demonstrated a favorable pharmacokinetic profile of ITI-214 consistent with once-a-day dosing. We believe that this study represents a significant milestone as the first use of a potent and highly specific PDE1 inhibitor in humans. We have worked closely with Takeda since 2011 to advance ITI-214 into clinical development and to optimize select backup/follow-on compounds for treating other CNS diseases, including Parkinson's disease, cognitive impairment in Alzheimer's disease and attention deficit and hyperactivity disorders. We believe that inhibition of PDE1 may also be beneficial in a number of therapeutic indications

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outside of CNS diseases, such as pulmonary arterial hypertension, heart failure, muscular dystrophy and inflammatory disease. We are pursuing additional ITI-002 PDE1 inhibitor compounds outside the scope of the Takeda collaboration for the treatment of cardiovascular and other disorders.

### ***Additional PDE Programs***

There are multiple forms and isoforms of PDE with distinct roles in intracellular signaling. We have developed strong internal expertise in the design and synthesis of inhibitors specific for individual PDE isoforms. Based on our understanding of the expression and functions of these isoforms in the CNS, we have identified PDE2 and PDE9 as compelling targets for drug discovery. We believe that inhibitors of these PDEs may be useful in treating neurodegeneration and bioenergetic failure in a variety of CNS diseases.

### ***Alzheimer's disease—ITI-012 (Casein Kinase 1 Inhibitors) and ITI-009 (gSAP Inhibitors)***

We are pursuing early stage drug discovery programs targeting two different pathways thought to be involved in the pathogenesis of Alzheimer's disease. The first program targets the enzyme casein kinase 1, or CK1, the misregulation of which in Alzheimer's disease may provoke misfolding of a neuronal protein, tau, which has been linked to cellular loss in the brains of patients with Alzheimer's disease. We are currently optimizing our CK1 inhibitors in anticipation of advancing them into preclinical development. We have a second program targeting the protein Gamma Secretase Activating Protein, or gSAP. We have demonstrated in preclinical models that inhibiting gSAP lowers the level of a toxic protein located in the brain called Abeta. Scientists in the field of dementia and Alzheimer's disease believe that inhibiting the accumulation of Abeta may slow the onset of Alzheimer's disease. The discovery of gSAP was made by ITI in collaboration with Dr. Paul Greengard, Nobel Laureate and ITI co-founder. The preclinical characterization of this class of molecules is ongoing. We believe that these compounds have the potential to provide novel, disease-modifying treatments for Alzheimer's disease and related disorders.

### **Intellectual Property**

#### ***Our Patent Portfolio***

As of September 30, 2013, we owned or controlled approximately 60 patent families filed in the United States and other major markets worldwide, including approximately 28 issued or allowed U.S. patents, 42 pending U.S. patent applications, 97 issued foreign patents, and 333 foreign patent applications, directed to novel compounds, formulations, methods of treatment, synthetic methods, and platform technologies.

Our ITI-007 program on novel compounds for neuropsychiatric and neurodegenerative diseases includes patents exclusively in-licensed from Bristol Myers Squibb on families of compounds, including the ITI-007 lead molecule. We have extensively characterized this lead and filed additional patent applications on polymorphs, formulations, additional indications, derivatives and additional compounds. The ITI-007 lead molecule has composition of matter protection through 2025 and additional Orange Book-listable protection to 2034. Additionally,

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we expect to have data exclusivity in the European Union for up to 11 years from launch. We also have a follow-on program, directed to compounds structurally related to the ITI-007 lead, but having composition of matter protection beyond 2031.

Our program on PDE1 inhibitors for cognition and dopamine-mediated disorders, such as Parkinson's disease, includes patent protection for the lead, ITI-214, as well as a wide range of filings on other proprietary compounds and indications. Certain PDE1 inhibitors are being developed under a joint development agreement with Takeda, under which we received an upfront cash payment and are eligible to receive payments for development and sales, as well as royalty payments. We also have an option to co-promote with Takeda in the U.S., and we retain certain rights to PDE1 inhibitor compounds and uses outside the scope of that collaboration. The ITI-214 lead molecule has composition of matter protection to 2029, with possible extensions and additional Orange Book-listable protection to 2034. Additionally, we expect to have data exclusivity in the European Union for up to 11 years from commercial launch. We are also evaluating potential follow-on compounds for ITI-214 which would have patent protection beyond 2030.

We have also filed patent applications on novel proprietary targets and lead compounds for Alzheimer's disease, which would provide compound protection beyond 2028 or beyond 2034, depending on which compound is ultimately selected for development.

### ***License Agreement***

#### ***The Bristol-Myers Squibb License Agreement***

On May 31, 2005 we entered into a world-wide, exclusive License Agreement with Bristol-Myers Squibb Company, or BMS, pursuant to which we hold a license to certain patents and know-how of BMS relating to ITI-007 and other specified compounds. The agreement was amended on November 3, 2010. The licensed rights are exclusive, except BMS retains rights in specified compounds in the fields of obesity, diabetes, metabolic syndrome and cardiovascular disease. However, BMS has no right to use, develop or commercialize ITI-007 and other specified compounds in any field of use. We have the right to grant sublicenses of the rights conveyed by BMS. We are obliged under the license to use commercially reasonable efforts to develop and commercialize the licensed technology. We are also prohibited from engaging in the clinical development or commercialization of specified competitive compounds.

Under the agreement, we made an upfront payment of \$1.0 million to BMS, and we may be obliged to make milestone payments for each licensed product of up to an aggregate of approximately \$14.8 million. We are also obliged to make tiered single digit percentage royalty payments on sales of licensed products. We are obliged to pay to BMS a percentage of non-royalty payments made in consideration of any sublicense.

The agreement extends, and royalties are payable, on a country-by-country and product-by-product basis, through the later of ten years after first commercial sale of a licensed product in such country, expiration of the last licensed patent covering a licensed product, its method of manufacture or use, or the expiration of other government grants providing market exclusivity, subject to certain rights of the parties to terminate the agreement on the occurrence of certain events. On termination of the agreement, we may be obliged to convey to BMS rights in developments relating to a licensed compound or licensed product, including regulatory filings, research results and other intellectual property rights.

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## ***Collaboration Agreement***

### ***The Takeda Pharmaceutical License and Collaboration Agreement***

On February 25, 2011, we entered into a license and collaboration agreement with Takeda Pharmaceutical Company Limited under which we agreed to collaborate to research, develop and commercialize our proprietary compound ITI-214 and other selected compounds that selectively inhibit PDE1 for use in the prevention and treatment of human diseases. As part of the agreement, we assigned to Takeda certain patents owned by us that claim ITI-214 and granted Takeda an exclusive license to develop and commercialize compounds identified in the conduct of the research program that satisfy specified criteria. However, we have retained rights to all compounds that do not meet the specified criteria and we continue to develop PDE1 inhibitors outside the scope of the agreement.

Under the terms of the agreement, we are conducting a research program with an initial term of three years to identify and characterize compounds that meet certain specified criteria sufficient for further development by Takeda. We were responsible for our expenses incurred in the conduct of certain research activities specified in the research plan. Takeda has agreed to reimburse us for expenses we incur in conducting additional research activities.

Takeda is obliged to use commercially reasonable efforts to develop and commercialize licensed compounds at its expense, and has agreed to reimburse us for the costs and expenses of development activities we may perform. We have formed a joint steering committee with Takeda to coordinate and oversee activities on which we collaborate under the agreement. We have the option to co-promote any licensed product in the United States by assuming responsibility for a certain percentage of the detailing activity with respect to that product.

We are responsible for supplying Takeda with ITI-214 for nonclinical activities and phase 1 clinical trials at our expense. Takeda is responsible, at its expense, for the manufacture and supply of compounds that it develops and commercializes under the agreement for all other activities.

Upon execution of the agreement, Takeda made a nonrefundable payment to us. We are eligible to receive payments of approximately \$500,000,000 in the aggregate upon achievement of certain development milestones and up to an additional \$250,000,000 in the aggregate upon achievement of certain sales-based milestones, along with tiered royalty payments ranging from the high single digits to the low teens in percent based on net sales by Takeda.

The agreement extends, on a country-by-country and product-by-product basis, through the later of expiration of the last licensed patent covering a licensed product, its method of manufacture or use, the expiration of other government grants providing market exclusivity or ten years after first commercial sale of a licensed product in such country, subject to rights of the parties to sooner terminate the agreement on certain events and the right of Takeda to unilaterally terminate the agreement upon a specified number of days' prior notice. Upon the termination of

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the agreement, Takeda is obliged to assign to us the patents covering ITI-214 assigned to Takeda upon the execution of the agreement, to grant us a license to develop and commercialize licensed compounds developed by Takeda and to transfer to us certain materials, information and regulatory materials reasonably necessary for us to continue the development and commercialization of those compounds.

### **Manufacturing**

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on one third-party contract manufacturer for all of our required raw materials, active pharmaceutical ingredient, or API, and finished product for our preclinical research and clinical trials, including the Phase 2 trial for ITI-007 for the treatment of schizophrenia. We believe that we would be able to contract with another third-party contract manufacturer to obtain API if our existing source of API was no longer available, but there is no assurance that API would be available from another third-party manufacturer on acceptable terms, on the timeframe that our business would require, or at all. We do not have long-term agreements with our existing third-party contract manufacturer. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved. As ITI-007 and any of our other product candidates continue to progress towards potential regulatory approval, we intend to enter into agreements with a third-party contract manufacturer and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors.

### **Sales and Marketing**

We currently have no marketing, sales or distribution capabilities. In order to commercialize any of our product candidates, we must develop these capabilities internally or through collaboration with third parties. In selected therapeutic areas where we feel that our product candidates can be commercialized by a specialty sales force that calls on a limited and focused group of physicians, we may plan to participate in the commercialization of our product candidates in the United States. In therapeutic areas that require a large sales force selling to a large and diverse prescribing population, we may elect to commercialize through, or in collaboration with, strategic partners. We may choose to commercialize our products in markets outside of the United States by establishing one or more strategic alliances in the future.

### **Competition**

We face, and will continue to face, intense competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. We compete, or will compete, with existing and new products being developed by our competitors. Some of these competitors are pursuing the development of pharmaceuticals that target the same diseases and conditions that our research and development programs target.

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Even if we are successful in developing our product candidates, the resulting products would compete with a variety of established drugs in the areas of our targeted CNS therapeutic indications. Our potential products for the treatment of schizophrenia and bipolar disorder would compete with, among other branded products, Abilify®, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical; Fanapt®, marketed by Novartis Pharmaceuticals; Seroquel XR®, marketed by AstraZeneca; Invega®, marketed by Janssen; and Latuda®, marketed by Sunovion. In addition, our product candidates, if approved, will compete with, among other generic antipsychotic products, haloperidol, risperidone, quetiapine, olanzapine and clozapine.

In addition, the companies described above and other competitors may have a variety of drugs in development or awaiting FDA approval that could reach the market and become established before we have a product to sell. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Many of our competitors are using technologies or methods different or similar to ours to identify and validate drug targets and to discover novel small molecule drugs. Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory clearances.

In addition, many of our competitors and their collaborators have substantially greater advantages in the following areas:

- capital resources;
- research and development resources;
- manufacturing capabilities; and
- sales and marketing.

Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved by the FDA or are in advanced development. We face competition from other companies, academic institutions, governmental agencies and other public and private research organizations for collaborative arrangements with pharmaceutical and biotechnology companies, in recruiting and retaining highly qualified scientific and management personnel and for licenses to additional technologies. Our competitors, either alone or with their collaborators, may succeed in developing technologies or drugs that are more effective, safer, and more affordable or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Developments by others may render our product candidates or our technologies obsolete. Our failure to compete effectively could have a material adverse effect on our business.

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## Government Regulation

### *United States—FDA Process*

The research, development, testing, manufacture, labeling, promotion, advertising, import and export, distribution and marketing, among other things, of drug products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications, or NDAs, warning letters, fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

*Drug Approval Process.* None of our drug product candidates may be marketed in the United States until the drug has received FDA approval. Such approval can take many years to obtain and may be rejected by the FDA at a number of steps. The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive pre-clinical laboratory tests, animal studies, and formulation studies in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA after completion of all clinical trials;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient, or API, and finished drug product are produced and tested to assess compliance with current Good Manufacturing Practices, or cGMPs;
- satisfactory completion of FDA inspections of clinical trial sites to assure that data supporting the safety and effectiveness of product candidates has been generated in compliance with Good Clinical Practices; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.



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Pre-clinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the conduct of the trial, such as whether human research subjects will be exposed to an unreasonable health risk. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be provided to the FDA as part of a separate submission to the IND. Further, an Institutional Review Board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the study protocol and informed consent information for study subjects for any clinical trial before it commences at that center, and the IRB must monitor the study until it is completed. There are also requirements governing reporting of on-going clinical trials and clinical trial results to public registries. Study subjects must sign an informed consent form before participating in a clinical trial.

Clinical trials necessary for product approval typically are conducted in three sequential phases, but the phases may overlap.

- Phase 1 usually involves the initial introduction of the investigational drug into a limited population, typically healthy humans, to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness.
- Phase 2 usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific targeted indications. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 trials, commonly referred to as pivotal studies, are undertaken in an expanded patient population at multiple, geographically dispersed clinical trial centers to further evaluate clinical efficacy and test further for safety by using the drug in its final form. There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the FDA or an IRB may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Moreover, the FDA may approve an NDA for a product candidate, but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. Post-approval trials are typically referred to as Phase 4 clinical trials.

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During the development of a new drug, sponsors are given an opportunity to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach an agreement on the next phase of development. Sponsors typically use the end of Phase 2 meeting to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trial that they believe will support approval of the new drug. A sponsor may request a Special Protocol Assessment, or SPA, to reach an agreement with the FDA that the protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the product candidate with respect to effectiveness in the indication studied. If such an agreement is reached, it will be documented and made part of the administrative record, and it will be binding on the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the product after clinical studies begin, or if the sponsor fails to follow the protocol that was agreed upon with the FDA. There is no guarantee that a study will ultimately be adequate to support an approval even if the study is subject to an SPA.

Concurrent with clinical trials, companies usually complete additional animal safety studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the final drugs. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Assuming successful completion of the required clinical testing, the results of pre-clinical studies and of clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. An NDA must be accompanied by a significant user fee, which is waived for the first NDA submitted by a qualifying small business. In July 2012, the Food and Drug Administration Safety and Innovation Act, or FDASIA, was signed into law. Among other things, FDASIA reauthorizes the FDA's authority to collect user fees from industry participants to fund reviews of innovator drugs.

The testing and approval process requires substantial time, effort and financial resources. The FDA will review the NDA and may deem it to be inadequate to support approval, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but it typically follows such recommendations.

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Before approving an NDA, the FDA inspects the facility or the facilities at which the drug and/or its active pharmaceutical ingredient is manufactured and will not approve the product unless the manufacturing is in compliance with cGMPs. If the FDA evaluates the NDA and the manufacturing facilities are deemed acceptable, the FDA may issue an approval letter, or in some cases a Complete Response Letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or additional clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials is not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Alternatively, the FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy to mitigate risks of the drug, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. Once the FDA approves a drug, the FDA may withdraw product approval if on-going regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety effects of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

*Post-Approval Requirements.* After a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. In addition, certain changes to an approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA, typically a new NDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any product candidate will be approved on a timely basis, or at all.

If post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA and maintain pharmacovigilance programs to proactively look for these adverse events; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) continue to have quality control and manufacturing procedures conform to cGMPs after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities, which includes assessment of on-going compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We intend to

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use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall of the product from the market or withdrawal of approval of the NDA for that drug.

*Patent Term Restoration and Marketing Exclusivity.* Depending upon the timing, duration and specifics of FDA approval of the use of our drugs, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the extension must be requested prior to expiration of the patent. The U.S. Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Data and market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to all of the pre-clinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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## **Foreign Regulation**

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials and approval of foreign countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the European Economic Area, or EEA, which is comprised of the 27 member states of the European Union, or Member States, plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MAs:

- **Community MAs** – These are issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA; for products that constitute a significant therapeutic, scientific or technical innovation; or for products that are in the interest of public health in the European Union.
- **National MAs** – These are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, and are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State. The competent authority of the Reference Member State prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling or packaging proposed by the Reference Member State, the product is subsequently granted a National MA in all the Member States (i.e., in the Reference Member State and the Member States Concerned).

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Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

As in the United States, it may be possible in foreign countries to obtain a period of market and/or data exclusivity that would have the effect of postponing the entry into the marketplace of a competitor's generic product. For example, if any of our products receive marketing approval in the EEA, we expect they will benefit from eight years of data exclusivity and ten years of marketing exclusivity. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), we obtain an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies. The data exclusivity period begins on the date of the product's first marketing authorization in the European Union and prevents generics from relying on the marketing authorization holder's pharmacological, toxicological and clinical data for a period of eight years. After eight years, a generic product application may be submitted and generic companies may rely on the marketing authorization holder's data. However, a generic cannot launch until two years later (or a total of 10 years after the first marketing authorization in the European Union of the innovator product), or three years later (or a total of 11 years after the first marketing authorization in the European Union of the innovator product) if the marketing authorization holder obtains marketing authorization for a new indication with significant clinical benefit within the eight-year data exclusivity period. In Japan, our products may be eligible for eight years of data exclusivity. There can be no assurance that we will qualify for such regulatory exclusivity, or that such exclusivity will prevent competitors from seeking approval solely on the basis of their own studies.

When conducting clinical trials in the European Union, we must adhere to the provisions of the European Union Clinical Trials Directive and the laws and regulations of the European Union Member States implementing them. These provisions require, among other things, that the prior authorization of an Ethics Committee and the competent Member State authority is obtained before commencing the clinical trial.

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### ***Pricing and Reimbursement***

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability of adequate coverage and reimbursement from third-party payors, such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations of member patients for such products. We may need to conduct pharmacoeconomic studies to demonstrate the cost-effectiveness of our products for formulary coverage and reimbursement. Even with such studies, our products may be considered less safe, less effective or less cost-effective than existing products, and third-party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

In addition, particularly in the United States and increasingly in other countries, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted to potentially impact reimbursement rates for the products we are developing and may develop in the future and could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

Political, economic and regulatory influences are subjecting the health care industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the health care system in ways that could significantly affect our future business. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the PPACA, enacted in March 2010, substantially changes the way health care is financed by both governmental and private insurers. Among other cost containment measures, PPACA establishes:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a new Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the donut hole; and
- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select

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Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

### ***Sales and Marketing***

The FDA regulates all advertising and promotion activities for products under its jurisdiction prior to and after approval, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to collect additional data or conduct additional pre-clinical studies and clinical trials. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patient. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

Outside the United States, our ability to market a product is contingent upon obtaining marketing authorization from the appropriate regulatory authorities. The requirements governing marketing authorization, pricing and reimbursement vary widely from country to country.

We may also be subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that



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our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal health care programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also may be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing. Given the penalties that may be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government was to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.

### **Employees**

As of September 30, 2013, we employed 21 employees, 20 of whom were full-time. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees for research and development, clinical and regulatory affairs and general and administrative activities over the next few years. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

### **Properties**

Our headquarters are located at 3960 Broadway, New York, New York 10032, where we occupy approximately 13,000 square feet of office and laboratory space. The term of the lease expires September 30, 2014, and we have the option to extend the term of the lease for one additional year, until September 30, 2015. We also lease office space in Towson, Maryland on a month to month basis.

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**Legal Proceedings**

We are not currently involved in any material legal proceedings.

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**CAUTIONARY STATEMENT REGARDING  
FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act that relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “targets,” “likely,” “will,” “would,” “could,” “should,” “continue,” and similar expressions or phrases, or the negative of those expressions or phrases, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on our projections of the future that are subject to known and unknown risks and uncertainties and other factors that may cause our actual results, level of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. The sections in this report entitled “Description of the Business of Intra-Cellular Therapies, Inc.,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as other sections in this report, discuss some of the factors that could contribute to these differences. These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that we may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates;
- our plans to research, develop and commercialize our future product candidates;
- our collaborators’ election to pursue research, development and commercialization activities;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to successfully commercialize our product candidates;
- the size and growth of the markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available;

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- regulatory developments in the United States and other countries;
  - the performance of our third-party suppliers and manufacturers and our ability to obtain alternative sources of raw materials;
  - our ability to obtain additional financing;
  - our use of the proceeds from our recently completed private placement;
  - the accuracy of our estimates regarding expenses, future revenues, capital requirements and the need for additional financing; and
  - our ability to attract and retain key scientific or management personnel.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important cautionary statements in this report, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this report and the documents that we reference in this report and have filed as exhibits to this report completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this report are made as of the date of this report, and we do not assume, and specifically disclaim, any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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## RISK FACTORS

*Investing in our common stock involves a high degree of risk. In addition to the other information set forth in this Current Report on Form 8-K, you should carefully consider the factors discussed below when considering an investment in our common stock. If any of the events contemplated by the following discussion of risks should occur, our business, results of operations and financial condition could suffer significantly. As a result, you could lose some or all of your investment in our common stock. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.*

### **Risks Related to Our Business**

***We currently do not have, and may never have, any products that generate significant revenues.***

We have a limited operating history on which to evaluate our business and prospects. To date, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products.

We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the European Union and elsewhere will approve them for commercialization. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. ITI-007, our most advanced drug candidate, is currently in Phase 2 clinical trials and ITI-214 is currently in Phase 1 clinical trials. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

***There is no guarantee that our currently ongoing Phase 2 or our other planned clinical trials for ITI-007 in acute schizophrenia or in other indications will be successful.***

In our Phase 1 and initial Phase 2 clinical trials, our lead product candidate, ITI-007, has demonstrated improved sleep maintenance, and clinical signals consistent with reduction in psychosis, depression and insomnia. We are currently evaluating ITI-007 in a randomized, placebo and active controlled Phase 2 clinical trial for the treatment of acute schizophrenia. We currently anticipate the results of this trial will be available in the fourth quarter of 2013. Our preclinical studies and initial clinical trials demonstrate that ITI-007 has shown evidence of addressing the symptoms of schizophrenia without causing cardiovascular and metabolic abnormalities, or motor impairments. Further, we believe ITI-007 may be effective at doses that

do not cause adverse effects displayed by existing antipsychotic drugs that tend to lead to high rates of noncompliance by the patients who most need these drugs. We are currently in the process of attempting to prove our hypotheses in later-stage clinical trials.

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we are currently conducting our Phase 2 clinical trial in patients with acute schizophrenia and plan to conduct further clinical studies in patients with acute schizophrenia and other indications, there is no guarantee that we will have the same level of success in these trials as we have had in our earlier clinical trials, or be successful at all. We may need to conduct additional clinical trials before we are able to advance ITI-007 into Phase 3 clinical trials in patients with acute schizophrenia.

In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than acute schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, intermittent explosive disorder, non-motor disorders associated with Parkinson's disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested ITI-007 in Phase 2 clinical trials in the patient population for these other indications.

If we do not successfully complete clinical development of ITI-007, we will be unable to market and sell products derived from it and to generate product revenues. Even if we do successfully complete clinical trials for ITI-007 in patients with acute schizophrenia, those results are not necessarily predictive of results of future pivotal trials that may be needed before we may submit an NDA to the FDA for the initial or other future indications. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even less result in the NDA ultimately being approved by the FDA for commercialization.

***Preliminary and interim data from our clinical studies that we may announce or publish from time to time may change as more patient data become available.***

From time to time, we may announce or publish preliminary or interim data from our clinical studies. For example, we have included in this filing a discussion of our analysis of the interim results of our Phase 2 clinical trial of ITI-007 in patients with schizophrenia. Preliminary and interim results of a clinical trial are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, preliminary and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

***If the FDA does not agree with our clinical development plans to advance ITI-007 for the treatment of schizophrenia and bipolar disorder with separate, but overlapping, well-controlled clinical trials in both indications, our development of ITI-007 may be delayed and the costs of our development of ITI-007 would increase.***

If our Phase 2 trial in acute exacerbated schizophrenia successfully meets its endpoints, we intend to initiate Phase 3 trials in schizophrenia in the second half of 2014 and plan to initiate separate additional trials in bipolar disorder in 2015. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. After the completion of the ITI-007-005 Phase 2 trial in schizophrenia, we plan to request a meeting with the FDA to discuss our clinical development plan for ITI-007, including our plan to conduct separate, but overlapping, well-controlled clinical efficacy trials in schizophrenia and bipolar disorder. The FDA may not agree with our clinical development plans to advance ITI-007 for the treatment of schizophrenia and bipolar disorder with separate, but overlapping, well-controlled clinical trials in both indications. Our clinical plans may change based on the outcome of the ITI-007-005 Phase 2 trial in schizophrenia and based on any discussions with the FDA. If the FDA does not agree with our clinical development plans for ITI-007, our development of ITI-007 may be delayed and the costs of our development of ITI-007 would increase, which may have an adverse effect on our business, financial condition and results of operations.

***Safety issues with our product candidates, or with product candidates or approved products of third parties that are similar to our product candidates, could give rise to delays in the regulatory approval process, restrictions on labeling or product withdrawal after approval.***

Problems with product candidates or approved products marketed by third parties that utilize the same therapeutic target or that belong to the same therapeutic class as our product candidates could adversely affect the development, regulatory approval and commercialization of our product candidates. In 2012, the FDA released draft guidance recommending that prospective suicidality assessments be performed in clinical trials of any drug being developed for a psychiatric indication. Our development programs are focused on psychiatric indications. Our PDE1 program is a novel target and may have unexpected safety effects that do not appear until late in clinical development or after commercial approval. To date, we have not experienced any treatment-related serious adverse effects, or SAEs, in clinical trials for any of our product candidates; however, some approved products marketed by third parties for psychiatric indications that utilize different therapeutic targets or are in a different therapeutic class have experienced SAEs. As we continue the development and clinical trials of our product candidates, there can be no assurance that our product candidates will not experience any SAEs.

Discovery of previously unknown class effect problems may prevent or delay clinical development and commercial approval of product candidates or result in restrictions on permissible uses after their approval, including withdrawal of the medicine from the market. Many drugs acting on the CNS include boxed warnings and precautions related to suicidal behavior or ideation, driving impairment, somnolence/sedation and dizziness, discontinuation, weight gain, non-insulin dependent (type II) diabetes, cardiovascular side effects, sleep disturbances, and motor disturbances. If we or others later identify undesirable side effects caused by the mechanisms of action or classes of our product candidates or specific product candidates:

- we may be required to conduct additional clinical trials or implement a Risk Evaluation and Mitigation Strategies program prior to approval;

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- regulatory authorities may not approve our product candidates or, as a condition of approval, require specific warnings and contraindications;
  - regulatory authorities may withdraw their approval of the product and require us to take our drug off the market;
  - we may have limitations on how we promote our drugs;
  - sales of products may decrease significantly;
  - we may be subject to litigation or product liability claims; and
  - our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which, in turn, could delay or prevent us from generating significant revenues from its sale.

Finally, if the FDA determines that a drug may present a risk of substance abuse, it can recommend to the Drug Enforcement Administration that the drug be scheduled under the Controlled Substances Act. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for our product candidates would delay commercialization of our product candidates, and severely harm our business and financial condition.

***If we seek to enter into strategic alliances for our drug candidates, but fail to enter into and maintain successful strategic alliances, we may have to reduce or delay our drug candidate development or increase our expenditures.***

An important element of a biotechnology company's strategy for developing, manufacturing and commercializing its drug candidates may be to enter into strategic alliances with pharmaceutical companies or other industry participants to advance its programs and enable it to maintain its financial and operational capacity. We may face significant competition in seeking appropriate alliances. If we seek such alliances, we may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we seek such alliances and then fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

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***To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.***

We are currently party to a license and collaboration agreement with Takeda Pharmaceutical Company Limited. Biotechnology companies at our stage of development sometimes become dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of drug candidates, particularly after the Phase 2 stage of clinical testing. If we elect to enter into collaborative arrangements or strategic alliances, these arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances would subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

***We expect our net losses to continue for at least several years and are unable to predict the extent of future losses or when we will become profitable, if ever.***

We have experienced significant net losses since our inception. As of June 30, 2013, we had an accumulated deficit of approximately \$44.6 million. We expect to incur net losses over the next several years as we advance our programs and incur significant clinical development costs. We have not received, and do not expect to receive for at least the next several years, any revenues from the commercialization of our product candidates. Substantially all of our revenues for the year ended December 31, 2012 were from our license and collaboration agreement with Takeda and our agreements with various U.S. governmental agencies and other parties, including our research and development grants. We anticipate that our collaborations, which provide us with research funding and potential milestone payments will continue to be our primary sources of revenues for the next several years. We cannot be certain that the milestones required to trigger payments under our existing collaborations will be achieved or that we will enter into additional collaboration agreements. To obtain revenues from our product candidates, we must succeed, either alone or with others, in developing, obtaining regulatory approval for, and manufacturing and marketing drugs with significant market potential. We may never succeed in these activities, and may never generate revenues that are significant enough to achieve profitability.



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*If we fail to obtain the capital necessary to fund our operations, we will be unable to successfully develop our products.*

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled \$10.3 million at June 30, 2013. On August 29, 2013, immediately prior to the Merger, ITI received proceeds of approximately \$60.0 million from the closing of its private placement of ITI common stock, which included approximately \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes, and which resulted in net proceeds, after expenses, of approximately \$40.0 million. While we believe that our existing cash resources and anticipated payments from our existing collaborations will be sufficient to fund our cash requirements for the next 12 months, we will require significant additional financing in the future to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the progress in, and the costs of, our preclinical studies and clinical trials and other research and development programs;
- the scope, prioritization and number of our research and development programs;
- the ability of our collaborators and us to reach the milestones, and other events or developments, triggering payments under our collaboration agreements or to otherwise make payments under these agreements;
- our ability to enter into new, and to maintain existing, collaboration and license agreements;
- the extent to which our collaborators are obligated to reimburse us for clinical trial costs under our collaboration agreements;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for clinical or commercial production;
- the costs of preparing applications for regulatory approvals for our product candidates;
- the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory clearances to market our product candidates; and
- the costs associated with litigation.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through our existing cash, cash equivalents and investment securities, strategic

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collaborations, private or public sales of our securities, debt financings, grant funding, or by licensing all or a portion of our product candidates or technology. Turmoil and volatility in the financial markets have adversely affected the market capitalizations of many biotechnology companies, and generally made equity and debt financing more difficult to obtain. This, coupled with other factors, may limit our access to additional financing over the near-term future. This could have a material adverse effect on our ability to access sufficient funding. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts.

***Our management has broad discretion over the use of our cash and we may not use our cash effectively, which could adversely affect our results of operations.***

Our management has significant flexibility in applying our cash resources and could use these resources for corporate purposes that do not increase our market value, or in ways with which our stockholders may not agree. We may use our cash resources for corporate purposes that do not yield a significant return or any return at all for our stockholders, which could adversely affect our future growth prospects.

***Our lead product candidate, ITI-007, is only part way through the clinical trials we anticipate needing to complete before we may be able to submit an NDA to the FDA. Clinical trials are long, expensive and unpredictable, and there is a high risk of failure.***

Preclinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to delays. It may take several years to complete the preclinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

In connection with clinical trials, we face risks that a product candidate may not prove to be efficacious; patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested; the results may not confirm the positive results of our earlier preclinical studies and clinical trials; and the results may not meet the level of statistical significance required by the FDA or other regulatory agencies. If we do not successfully complete preclinical and clinical development, we will be unable to market and sell products derived from our product candidates and to generate product revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA or the FDA may approve the NDA.

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***Delays, suspensions and terminations in our clinical trials could result in increased costs to us, delay our ability to generate product revenues and therefore may have a material adverse effect on our business, results of operations and future growth prospects.***

The commencement of clinical trials can be delayed for a variety of reasons, including: delays in demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial; reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites; manufacturing sufficient quantities of a product candidate; obtaining clearance from the FDA to commence clinical trials pursuant to an IND; obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

Once a clinical trial has begun, it may be delayed, suspended or terminated due to a number of factors, including: ongoing discussions with regulatory authorities regarding the scope or design of our clinical trials or requests by them for supplemental information with respect to our clinical trial results; failure to conduct clinical trials in accordance with regulatory requirements; lower than anticipated screening or retention rates of patients in clinical trials; serious adverse events or side effects experienced by participants; and insufficient supply or deficient quality of product candidates or other materials necessary for the conduct of our clinical trials.

Many of these factors may also ultimately lead to denial of regulatory approval of a current or potential product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

***We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing our product candidates.***

Although we design and manage our current preclinical studies and clinical trials, we do not now have the ability to conduct clinical trials for our product candidates on our own. In addition to our collaborators, we rely on contract research organizations, medical institutions, clinical investigators, and contract laboratories to perform data collection and analysis and other aspects of our clinical trials. In addition, we also rely on third parties to assist with our preclinical studies, including studies regarding biological activity, safety, absorption, metabolism, and excretion of product candidates.

Our preclinical activities or clinical trials may be delayed, suspended, or terminated if the quality or accuracy of the data obtained by the third parties on whom we rely is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or if for other reasons, these third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines, or these third parties need to be replaced.

If the third parties on whom we rely fail to perform, our development costs may increase, our ability to obtain regulatory approval, and consequently, to commercialize our product candidates may be delayed or prevented altogether. We currently use several contract research

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organizations to perform services for our preclinical studies and clinical trials. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or incurring additional expenses.

***Even if we successfully complete the clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.***

Even if we successfully complete the clinical trials for one or more of our product candidates, the product candidates may fail for other reasons, including the possibility that the product candidates will:

- fail to receive the regulatory approvals required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable; or
- fail to compete with product candidates or other treatments commercialized by our competitors.

If we are unable to receive the required regulatory approvals, secure our intellectual property rights, minimize the incidence of any adverse side effects or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected.

***Following regulatory approval of any of our drug candidates, we will be subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.***

With regard to our drug candidates, if any, approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood,

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nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

***Our product candidates may not gain acceptance among physicians, patients, or the medical community, thereby limiting our potential to generate revenues, which will undermine our future growth prospects.***

Even if our product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product candidate by physicians, health care professionals and third-party payors, and our profitability and growth will depend on a number of factors, including:

- the ability to provide acceptable evidence of safety and efficacy;
- pricing and cost effectiveness, which may be subject to regulatory control;
- our ability to obtain sufficient third-party insurance coverage or reimbursement;
- effectiveness of our or our collaborators' sales and marketing strategy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is at least as beneficial as the current standard of care or otherwise does not provide some additional patient benefit over the current standard of care, that product will not achieve market acceptance and we will not generate sufficient revenues to achieve profitability.

***The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.***

We are highly dependent on our senior management and key clinical development, scientific and technical personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, clinical development, scientific or technical staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. We intend to expand and develop new drug candidates, and will need additional funding to grow our business. We will need to hire additional employees in order to continue our research and

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clinical trials and to market our drugs when approved. This strategy will require us to recruit additional executive management and clinical development, regulatory, scientific, technical and sales and marketing personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific, technical and sales and marketing expertise, and this competition is likely to continue. The inability to attract and retain sufficient clinical development, scientific, technical and managerial personnel, due to intense competition and our limited resources, would limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

***We may not be able to continue or fully exploit our partnerships with outside scientific and clinical advisors, which could impair the progress of our clinical trials and our research and development efforts.***

We work with scientific and clinical advisors at academic and other institutions who are experts in the field of CNS disorders. They advise us with respect to our clinical trials. These advisors are not our employees and may have other commitments that would limit their future availability to us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services, which may impair our reputation in the industry and delay the development or commercialization of our product candidates.

***Relying on third-party manufacturers may result in delays in our clinical trials, regulatory approvals and product introductions.***

We have no manufacturing facilities and do not have extensive experience in the manufacturing of drugs or in designing drug-manufacturing processes. We have contracted with third-party manufacturers to produce, in collaboration with us, our product candidates, including ITI-007, for clinical trials. If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we may need to amend our contract with our current manufacturer or contract with another third party to manufacture them in larger quantities. While we believe that there are alternative sources available to manufacture our product candidates, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without delays or additional expenditures. We cannot estimate these delays or costs with certainty but, if they were to occur, they could cause a delay in our development and commercialization efforts. We have not entered into long-term agreements with our current third-party manufacturers or with any alternate suppliers. Although we intend to do so prior to any commercial launch of a product that is approved by the FDA in order to ensure that we maintain adequate supplies of commercial drug product, we may be unable to enter into such agreements or do so on commercially reasonable terms, which could delay a product launch or subject our commercialization efforts to significant supply risk.

The manufacturers of our product candidates are obliged to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. In addition, the facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we request regulatory approval from the FDA. A failure of any of our current or future contract

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manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in clinical trials or in obtaining regulatory approval of product candidates or the ultimate launch of products based on our product candidates into the market. Failure by our current or future third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

***We will need to continue to manage our organization and we may encounter difficulties with our staffing and any future transitions, which could adversely affect our results of operations.***

We will need to effectively manage our operations and facilities in order to advance our drug development programs (including ITI-007, ITI-214 and those compounds covered by our collaboration with Takeda), achieve milestones under our license and collaboration agreement with Takeda, facilitate additional collaborations, and pursue other development activities. It is possible that our infrastructure may be inadequate to support our future efforts and growth. In particular, we may have to develop internal sales, marketing, and distribution capabilities if we decide to market any drug that we may successfully develop. We may not successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals.

***Our ability to generate product revenues will be diminished if our products do not receive coverage from payors or sell for inadequate prices, or if patients are unable to obtain adequate levels of reimbursement.***

Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for any approved products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use any products we may market unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products.

In addition, the market for any products for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

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Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products candidates to each payor separately, with no assurance that coverage will be obtained. If we are unable to obtain coverage of, and adequate payment levels for, our products from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize any approved products and thereby adversely impact our profitability, results of operations, financial condition, and future success.

***In the future, if we have products that are approved, health care legislation may make it more difficult to receive revenues from those products.***

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory proposals in recent years to change the health care system in ways that could impact our ability to sell our products profitably. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, became law in the United States. PPACA substantially changed the way health care is financed by both governmental and private insurers and significantly affects the health care industry. Among the provisions of PPACA of importance to our potential product candidates are the following:

- imposition of an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government health care programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in



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2014 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any "payments or transfers of value" made or distributed to prescribers, teaching hospitals and other health care providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Many of the details regarding the implementation of PPACA are yet to be determined and, at this time, it remains unclear what the full effect that PPACA would have on our business. On June 28, 2012, the U.S. Supreme Court upheld the constitutionality of PPACA, excepting certain provisions that would have required each state to expand its Medicaid programs or risk losing all of the state's Medicaid funding. At this time, it remains unclear whether there will be any further changes made to PPACA, whether in part or in its entirety. Some states have indicated that they intend not to implement certain sections of PPACA, and some members of the U.S. Congress are still working to repeal PPACA. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with any products we may market, which could negatively impact our profitability.

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We expect that PPACA, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other health care reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any products for which we receive regulatory approval.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any products we may develop, we may not be able to generate product revenue.***

We do not currently have an organization for the sales, marketing or distribution of pharmaceutical products. In order to market any products that may be approved by the FDA, we must build our sales, marketing, managerial, and related capabilities or make arrangements with third parties to perform these critical commercial services. If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

#### **Risks Related to Our Intellectual Property**

***Our ability to compete may be undermined if we do not adequately protect our proprietary rights.***

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates and technologies and their uses, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, proprietary technologies, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. We have patent rights under issued patents in many cases covering our ITI-007 and ITI-002 development programs. Nonetheless, the issued patents and patent applications covering our primary technology programs remain subject to uncertainty and continuous monitoring and action by us due to a number of factors, including:

- we may not have been the first to make the inventions covered by our pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the technologies we rely upon;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;

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- any or all of our pending patent applications may not result in issued patents;
  - we may not seek or obtain patent protection in all countries that will eventually provide a significant business opportunity;
  - any patents issued to us or our collaborators may not provide a basis for commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
  - our proprietary technologies may not be patentable;
  - others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
  - others may identify prior art which could invalidate our patents; or
  - changes to patent laws that limit the exclusivity rights of patent holders.

Even if we have or obtain patents covering our product candidates or technologies, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others have or may have filed, and in the future are likely to file, patent applications covering compounds, assays, genes, gene products or therapeutic products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to genes, nucleic acids, polypeptides, chemical compounds or therapeutic products, and some of these may encompass reagents utilized in the identification of candidate drug compounds or compounds that we desire to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the area of central nervous system disorders and the other fields in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, that may later result in issued patents that our product candidates or technologies may infringe. These patent applications may have priority over patent applications filed by us.

We regularly conduct searches to identify patents or patent applications that may prevent us from obtaining patent protection for our proprietary compounds or that could limit the rights we have claimed in our patents and patent applications. Disputes may arise regarding the ownership or inventorship of our inventions. It is difficult to determine how such disputes would be resolved. Others may challenge the validity of our patents. If our patents are found to be invalid, we will lose the ability to exclude others from making, using or selling the inventions claimed therein.

Some of our academic institutional licensors, research collaborators and scientific advisors have rights to publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information will be impaired. Additionally, any employee whose employment with us terminates, whether voluntarily by the employee or by us in connection with restructurings or

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otherwise, may seek future employment with our competitors. Although each of our employees is required to sign a confidentiality agreement with us at the time of hire, we cannot guarantee that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, technology that we may license-in may become important to some aspects of our business. We generally will not control the patent prosecution, maintenance or enforcement of in-licensed technology.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of drug discovery and development of small molecule drugs, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.***

There is significant litigation in our industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our drug development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. We may need to resort to litigation to enforce a patent issued to us, protect our trade secrets or determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We also may not be able to afford the costs of litigation.

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***The patent applications of pharmaceutical and biotechnology companies involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.***

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. The USPTO's standards are uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings in the USPTO (and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office), which proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Similarly, opposition or invalidity proceedings could result in loss of rights or reduction in the scope of one or more claims of a patent in foreign jurisdictions. In addition, such interference, reexamination and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us or may limit the number of patents or claims we can obtain. In particular, there have been proposals to shorten the exclusivity periods available under U.S. patent law that, if adopted, could substantially harm our business. The product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. If any of our product candidates becomes a marketable product, we will rely on our exclusivity under patents to sell the compound and recoup our investments in the research and development of the compound. If the exclusivity period for patents is shortened, then our ability to generate revenues without competition will be reduced and our business could be materially adversely impacted. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans and, in these countries, patent protection may not be available at all to protect our product candidates. In addition, U.S. patent laws may change, which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was recently signed into law and includes a number of significant changes to U.S. patent law. These include changes to transition from a "first-to-invent" system to a "first-to-file" system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The USPTO has been in the process of implementing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act may affect our ability to obtain, enforce or defend our patents. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

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If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, proprietary technologies and their uses, we could lose our competitive advantage and competition we face would increase, reducing our potential revenues and adversely affecting our ability to attain or maintain profitability.

### **Risks Related to Our Industry**

***We will be subject to stringent regulation in connection with the marketing of any products derived from our product candidates, which could delay the development and commercialization of our products.***

The pharmaceutical industry is subject to stringent regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Neither we nor our collaborators can market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and an extensive regulatory clearance process implemented by the FDA. Satisfaction of regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product, and requires substantial resources. Even if regulatory approval is obtained, it may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, and/or marketing of such products, and requirements for post-approval studies, including additional research and development and clinical trials. These limitations may limit the size of the market for the product or result in the incurrence of additional costs. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues and continue our business.

Outside the United States, the ability to market a product is contingent upon receiving approval from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing, and reimbursement vary widely from country to country. Only after the appropriate regulatory authority is satisfied that adequate evidence of safety, quality, and efficacy has been presented will it grant a marketing authorization. Approval by the FDA does not automatically lead to the approval by regulatory authorities outside the United States and, similarly, approval by regulatory authorities outside the United States will not automatically lead to FDA approval.

***Many of our competitors have greater resources and capital than us, putting us at a competitive disadvantage. If our competitors develop and market products that are more effective than our product candidates, they may reduce or eliminate our commercial opportunity.***

Competition in the pharmaceutical and biotechnology industries is intense and increasing. We face competition from pharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies, both in the United States and abroad. Some of these competitors have products or are pursuing the development of drugs that target the same diseases and conditions that are the focus of our drug development programs.

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For example, our potential products for the treatment of acute schizophrenia would compete with, among other branded products, Abilify®, marketed jointly by Bristol-Myers Squibb and Otsuka Pharmaceutical, Fanapt®, marketed by Novartis Pharmaceuticals, Seroquel XR®, marketed by AstraZeneca, Invega®, marketed by Janssen, and Latuda®, marketed by Sunovion. In addition, our products will compete with, among other generic antipsychotic drugs, haloperidol, risperidone, quetiapine, olanzapine and clozapine.

Many of our competitors and their collaborators have significantly greater experience than we do in the following:

- identifying and validating targets;
- screening compounds against targets;
- preclinical studies and clinical trials of potential pharmaceutical products; and
- obtaining FDA and other regulatory approvals.

In addition, many of our competitors and their collaborators have substantially greater capital and research and development resources, manufacturing, sales and marketing capabilities, and production facilities. Smaller companies also may prove to be significant competitors, particularly through proprietary research discoveries and collaboration arrangements with large pharmaceutical and established biotechnology companies. Many of our competitors have products that have been approved or are in advanced development and may develop superior technologies or methods to identify and validate drug targets and to discover novel small molecule drugs. Our competitors, either alone or with their collaborators, may succeed in developing drugs that are more effective, safer, more affordable, or more easily administered than ours and may achieve patent protection or commercialize drugs sooner than us. Our competitors may also develop alternative therapies that could further limit the market for any drugs that we may develop. Our failure to compete effectively could have a material adverse effect on our business.

***Any claims relating to improper handling, storage, or disposal of biological, hazardous, and radioactive materials used in our business could be costly and delay our research and development efforts.***

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents, biological materials such as blood from patients that have the potential to transmit disease, chemicals that cause cancer, and various radioactive compounds. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws

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and regulations could be significant, and current or future environmental regulations may impair our research, development, or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, or we could be required to suspend or modify our operations and our research and development efforts.

***Consumers may sue us for product liability, which could result in substantial liabilities that exceed our available resources and damage our reputation.***

Researching, developing, and commercializing drug products entail significant product liability risks. Liability claims may arise from our and our collaborators' use of products in clinical trials and the commercial sale of those products. Consumers may make these claims directly and our collaborators or others selling these products may seek contribution from us if they receive claims from consumers. We have obtained limited product liability insurance coverage for our clinical trials. Our product liability insurance coverage for clinical trials is currently limited to an aggregate of \$10 million. As such, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Although we currently have product liability insurance that covers our clinical trials, we will need to increase and expand this coverage as we commence larger scale trials and if our product candidates are approved for commercial sale. This insurance may be prohibitively expensive or may not fully cover our potential liabilities. Inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of products that we or our collaborators develop. Product liability claims could have a material adverse effect on our business and results of operations. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products.

#### **Risks Relating to Owning Our Common Stock**

***There is currently no market for our common stock and there can be no assurance that any market will ever develop. You may therefore be unable to re-sell shares of our common stock at times and prices that you believe are appropriate.***

Our common stock is not listed on a national securities exchange, an over-the-counter market or any other exchange. Therefore, there is no trading market, active or otherwise, for our common stock and our common stock may never be included for trading on any stock exchange, automated quotation system or any over-the-counter market. Accordingly, our common stock is highly illiquid and you will likely experience difficulty in re-selling such shares at times and prices that you may desire.

***Our common stock may not be eligible for listing or quotation on any securities exchange.***

We do not currently meet the initial listing standards of any national securities exchange and our common stock is not quoted for sale on any over-the-counter trading system. We cannot assure you that we will be able to meet the initial listing standards of any national securities exchange, or, if we do meet



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such initial listing standards, that we will be able to maintain any such listing. Further, the national securities exchanges have adopted so-called “seasoning” rules that require that we meet certain requirements, including prescribed periods of time trading over-the-counter and minimum filings of periodic reports with the SEC, before we are eligible to apply for listing on such national securities exchanges. We intend to contact an authorized market maker for an over-the-counter quotation system for sponsorship of our common stock, but we cannot guarantee that such sponsorship will be approved and our common stock listed and quoted for sale. Even if our common stock is quoted for sale on an over-the-counter quotation system, buyers may be insufficient in numbers to allow for a robust market and it may prove impossible to sell your shares. In addition, an investor may find it difficult to obtain accurate quotations as to the market value of our common stock. In addition, if we fail to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity. This would also make it more difficult for us to raise additional capital.

***The price of our common stock could be subject to volatility related or unrelated to our operations.***

If a market for our common stock develops, its market price could fluctuate substantially due to a variety of factors, including market perception of our ability to meet our growth projections and expectations, quarterly operating results of other companies in the same industry, trading volume in our common stock, changes in general conditions in the economy and the financial markets or other developments affecting our business and the business of others in our industry. In addition, the stock market itself is subject to extreme price and volume fluctuations. This volatility has had a significant effect on the market price of securities issued by many companies for reasons related and unrelated to their operating performance and could have the same effect on our common stock.

***The designation of our common stock as a “penny stock” would limit the liquidity of our common stock.***

Our common stock may be deemed a “penny stock” (as that term is defined under Rule 3a51-1 of the Exchange Act) in any market that may develop in the future. Generally, a “penny stock” is a common stock that is not listed on a securities exchange and trades for less than \$5.00 per share. Prices often are not available to buyers and sellers and the market may be very limited. Penny stocks in start-up companies are among the riskiest equity investments. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. The document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also provide purchasers with bid and offer quotations and information regarding broker and salesperson compensation and make a written determination that the penny stock is a suitable investment for the purchaser and obtain the purchaser’s written agreement to the purchase. Many brokers choose not to participate in penny stock transactions. Because of the penny stock rules, there may be less trading activity in penny stocks in any market that develops for our common stock in the future and stockholders are likely to have difficulty selling their shares.

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***Management and certain members of our board of directors beneficially own a substantial amount of our outstanding equity securities and will be able to exert substantial control over us.***

Our executive officers and directors beneficially own a substantial percentage of the outstanding equity securities of the Company. Accordingly, if they act as a group, the executive officers and directors of the Company will be able to make all business decisions, including with respect to such matters as amendments to the Company's charter, other fundamental corporate transactions, such as mergers, asset sales and the sale of the Company, and otherwise will be able to direct the Company's business and affairs.

***We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.***

As a public company, we will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will also incur substantial expenses in connection with the preparation and filing of the registration statement for resale of our common stock that we initially filed on September 18, 2013, and responding to SEC comments in connection with its review of such registration statement. We will also incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC or any stock exchange or inter-dealer quotations system on which our common stock may be listed in the future. The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable currently to estimate these costs with any degree of certainty. We also expect that these new rules and regulations may make it difficult and expensive for us to retain our director and officer liability insurance, and if we are able to retain such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as our executive officers.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.***

We will be required to comply with Section 404 of the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is

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a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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***If we are unable to register in a timely manner the shares of common stock that we issued to stockholders in the Merger, then the ability to re-sell shares of our common stock will be delayed.***

We filed a registration statement with the SEC, which has not yet been declared effective, to register the resale of the shares of our common stock issued in connection with the Merger. There are many reasons, including some over which we have little or no control, which could keep the registration statement from being declared effective by the SEC, including delays resulting from the SEC review process and comments raised by the SEC during that process. Accordingly, in the event that the registration statement is not declared effective within these timeframes, the shares of common stock proposed to be covered by such registration statement will not be eligible for resale until the registration statement is effective or an exemption from registration, such as Rule 144, becomes available. In addition, we have agreed to pay damages to the investors in the Private Placement if we do not satisfy certain deadlines and requirements in connection with the registration statement, as specified in the Registration Rights Agreement.

***We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, which may include, but are not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, and exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of \$1 billion or more during such fiscal year, (3) the date on which we issue more than \$1 billion in non-convertible debt in a three-year period or (4) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” may make it harder for investors to analyze our results of operations and financial prospects.

***Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.***

Because we did not become a reporting company by conducting an underwritten initial public offering, or IPO, of our common stock, and because we will not be listed on a national securities exchange, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we became a public reporting company by means of an IPO because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

***The resale of shares covered by a registration statement could adversely affect the market price of our common stock in the public market, should one develop, which result would in turn negatively affect our ability to raise additional equity capital.***

The sale, or availability for sale, of our common stock in the public market may adversely affect the prevailing market price of our common stock and may impair our ability to

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raise additional capital by selling equity or equity-linked securities. We filed a registration statement with the SEC to register the resale of substantially all of the shares of our common stock issued in connection with the Merger. Once effective, the registration statement will permit the resale of these shares at any time, subject to applicable lock-up restrictions described in the “Certain Relationships and Related Person Transactions—Agreements with Stockholders—Lock-Up Provisions in Registration Rights Agreement” section. The resale of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate. Furthermore, we expect that, because there will be a large number of shares registered pursuant to the registration statement, selling stockholders will continue to offer shares covered by such registration statement for a significant period of time, the precise duration of which cannot be predicted. Accordingly, the adverse market and price pressures resulting from an offering pursuant to the registration statement may continue for an extended period of time and continued negative pressure on the market price of our common stock could have a material adverse effect on our ability to raise additional equity capital.

***If securities or industry analysts do not publish, or cease publishing, research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.***

If a trading market for our common stock develops, the trading market for our common stock will be influenced by whether industry or securities analysts publish research and reports about us, our business, our market or our competitors and, if any analysts do publish such reports, what they publish in those reports. We may not obtain analyst coverage in the future. Any analysts that do cover us may make adverse recommendations regarding our stock, adversely change their recommendations from time to time, and/or provide more favorable relative recommendations about our competitors. If any analyst who may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, or if analysts fail to cover us or publish reports about us at all, we could lose, or never gain, visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We do not anticipate paying cash dividends in the foreseeable future.***

We currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our securities if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future. Moreover, you may not be able to re-sell your shares at or above the price you paid for them.

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**MANAGEMENT'S DISCUSSION AND ANALYSIS  
OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion of the financial condition and results of operations of Intra-Cellular Therapies, Inc. and its wholly-owned subsidiary should be read in conjunction with the financial statements and the notes to those statements filed as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**Overview**

Effective as of August 29, 2013, we consummated the Merger and changed our name from "Oneida Resources Corp." to "Intra-Cellular Therapies, Inc."

We are a biopharmaceutical company focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system. Our lead product candidate, ITI-007, is in Phase 2 clinical trials as a first-in-class treatment for schizophrenia. We believe that ITI-007 and follow-on compounds have utility to treat additional indications, which we may investigate, either on our own or with a partner. We hold exclusive, worldwide commercialization rights to ITI-007 and a family of related compounds from Bristol-Myers Squibb Company.

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme PDE1. We have licensed the lead compound in the ITI-002 portfolio, ITI-214, and other compounds in that portfolio, to Takeda. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials and is being developed for the treatment of cognitive impairment associated with schizophrenia and other disorders.

Our pipeline also includes preclinical programs that are focused on advancing drugs for the treatment of cognitive dysfunction, in both schizophrenia and Alzheimer's disease, and for disease modification and the treatment of neurodegenerative disorders, including Alzheimer's disease.

Since inception, we have devoted all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of June 30, 2013, our accumulated deficit was \$44.6 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and pre-clinical drug candidates and programs. Our operating expenses are comprised of research and development expenses and general and administrative expenses.

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for the fiscal years ended December 31, 2012 and 2011 have been primarily from a license and collaboration agreement with Takeda, and, to a much lesser extent, from grants from U.S. government agencies and foundations. Prior to 2011, our revenue was entirely from grants from these agencies and foundations.

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Our corporate headquarters and research facility are located in New York, New York.

## **Recent Developments**

### ***Private Placement***

Prior to the Merger, ITI sold to accredited investors approximately \$60.0 million of its shares of common stock, or 18,889,307 shares, at a price of \$3.1764 per share, which included approximately \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes, or Notes, and which resulted in net proceeds, after expenses, of approximately \$40.0 million. We refer to this transaction as the Private Placement. Also, ITI granted the investors in the Private Placement registration rights requiring ITI or any successor to register those shares of ITI common stock (which were exchanged for shares of our common stock, along with the rest of the outstanding shares of ITI capital stock, except for dissenting shares, at the Effective Time) for public resale, as described in more detail below. The then existing stockholders of ITI who agreed to become parties to the registration rights agreement also became entitled to such registration rights, subject to specified differences in the agreement between the rights of new investors and existing stockholders. The existing Second Amended and Restated Investor Rights Agreement, by and among ITI and the investors listed therein, dated as of October 25, 2007, as amended, was terminated at the Effective Time. The Private Placement closed immediately prior to the filing of a Certificate of Merger with the Secretary of State of the State of Delaware, on August 29, 2013.

### ***Reverse Merger***

On August 29, 2013, pursuant to the Merger Agreement, Merger Sub merged with and into ITI, with ITI remaining as the surviving entity and a wholly-owned operating subsidiary of the Company. The Merger was effective on August 29, 2013, upon the filing of a Certificate of Merger with the Secretary of State of the State of Delaware. As part of the Merger, ITI changed its name to ITI, Inc.

At the Effective Time, the legal existence of Merger Sub ceased and each share of ITI common stock and each share of ITI preferred stock that was issued and outstanding immediately prior to the Effective Time was automatically exchanged for 0.5 shares of our common stock. We issued an aggregate of 22,134,647 shares of our common stock upon such exchange of the outstanding shares of ITI common stock and preferred stock. In addition, at the Effective Time, we assumed ITI's 2003 Equity Incentive Plan, as amended, or the 2003 Equity Incentive Plan, and all options to purchase ITI common stock then outstanding under the 2003 Equity Incentive Plan, and such options became exercisable for an aggregate of 1,462,380 shares of our common stock, subject to the vesting and other terms of such options. The vesting of such options was not accelerated as a result of the Merger. At the Effective Time, we also assumed the outstanding warrant to purchase ITI common stock, and such warrant became exercisable for 1,822 shares of our common stock.

Immediately following the Effective Time, pursuant to the terms of the Redemption Agreement, we completed the closing of a redemption of 5,000,000 shares of our

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common stock from our then-current sole stockholder in consideration of \$60,000, plus professional costs related to the transaction, not to exceed \$20,000. The 5,000,000 shares constituted all of the issued and outstanding shares of our capital stock, on a fully-diluted basis, immediately prior to the Merger.

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, section 805 entitled, “*Business Combinations*,” ITI is considered the accounting acquirer in the Merger. ITI is considered the acquirer for accounting purposes, and will account for the transaction as a capital transaction, because ITI’s former stockholders received 100% of the voting rights in the combined entity and ITI’s senior management represents all of the senior management of the combined entity. Consequently, the assets and liabilities and the historical operations that will be reflected in our consolidated financial statements will be those of ITI and will be recorded at the historical cost basis of the Company.

## **Results of Operations**

### ***Revenues***

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales for at least the next several years. Our revenues for the last two years have been primarily from the license and collaboration agreement with Takeda, and, to a much lesser extent, grants from U.S. government agencies and foundations. Prior to 2011, our revenue was entirely from grants from these agencies and foundations.

The revenue from Takeda has been comprised primarily of an upfront payment, a milestone payment and reimbursements for costs incurred in the development of and patent prosecutions for compounds subject to the collaboration. The upfront payment was evaluated and it was determined that there were separate units of accounting for the deliverables that are provided for in the license and collaboration agreement. A larger portion of the upfront payment was considered a license fee, and the remaining portion was deemed to be related to the performance of agreed upon activities under the collaboration component of the license and collaboration agreement. We determined this amount in accordance with ASC Topic 605-25, using best estimate of selling price, for the work that we would be required to perform. We considered multiple factors in estimating this amount, including, but not limited to, direct external expenses and internal costs for salary and related fringes, among others. The straight line method of amortization with a three-year schedule was used and revenue was and will be recognized equally for the years 2011 through 2013. Revenue from the license payment was recognized as earned when received. Revenue from milestone payments is recognized when all of the following conditions are met: (1) the milestone payments are non-refundable, (2) the achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement, (3) substantive effort on our part is involved in achieving the milestone, (4) the amount of the milestone payment is reasonable in relation to the effort



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expended or the risk associated with achievement of the milestone, and (5) a reasonable amount of time passes between the up-front license payment and the first milestone payment. Reimbursement revenue is recognized when the costs are incurred and the services have been performed.

We expect our revenues for the next several years to consist of limited reimbursable costs incurred for patent prosecutions, amortized revenue in 2013 related to the upfront payment made by Takeda, and reimbursements related to our collaboration with Takeda under the license and collaboration agreement. In addition, we expect to receive possible milestone payments under the license and collaboration agreement, but these are not assured at this time and would not be significant enough to fund operations for a meaningful period of time.

### *Expenses*

The process of researching and developing drugs for human use is lengthy, unpredictable and subject to many risks. We are unable with any certainty to estimate either the costs or the timelines in which those costs will be incurred. We have one project, ITI-007 for the treatment of schizophrenia, which consumes a large proportion of our current, as well as projected, resources. We intend to pursue other disease indications that ITI-007 may address, but there are large costs associated with pursuing FDA approval for those indications, which would include the cost of additional clinical trials. Our other projects, exclusive of the Takeda collaboration, are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to enter into and complete clinical trials. Expenditures that we incur on these projects will be subject to availability of funding in addition to the funding required for the advancement of ITI-007. Any failure or delay in the advancement of ITI-007 could require us to re-allocate resources from our other projects to the advancement of ITI-007, which could have a significant material adverse impact on the advancement of these other projects and on our operations.

Our operating expenses are comprised of (i) research and development expenses and (ii) general and administrative expenses. Our research and development costs are comprised of:

- internal recurring costs, such as labor and fringe benefits, materials and supplies, facilities and maintenance costs; and
- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing and related testing, and clinical trial activities.

General and administrative expenses are incurred in three major categories:

- salaries and related benefit costs;
- patent, legal and professional costs; and
- office and facilities overhead.

The following table sets forth our revenues and operating expenses for the fiscal years ended December 31, 2012 and 2011, and for the three and six month periods ended June 30, 2013 and 2012:

	For the Year Ended December 31		Three Months Ended June 30		Six Months Ended June 30	
	2012	2011	2013	2012	2013	2012
	<i>(Audited)</i>		<i>(Unaudited)</i>		<i>(Unaudited)</i>	
			<i>(in thousands)</i>			
<b>Revenues</b>	\$ 3,118	\$ 23,362	\$ 643	\$ 1,495	\$ 1,242	\$ 2,071
<b>Expenses</b>						
Research and Development	15,486	7,655	7,788	9,439	12,740	13,133
General and Administrative	4,035	4,612	903	1,115	1,950	2,112
	<u>19,521</u>	<u>12,267</u>	<u>8,691</u>	<u>10,554</u>	<u>14,690</u>	<u>15,245</u>
<b>Net Income (Loss)</b>	\$ <u>(16,591)</u>	\$ <u>11,092</u>	\$ <u>(8,277)</u>	\$ <u>(9,056)</u>	\$ <u>(13,916)</u>	\$ <u>(13,167)</u>

#### **Comparison of Years Ended December 31, 2012 and December 31, 2011**

##### *Research and Development Expenses*

Total research and development expenses were approximately \$15.5 million for the fiscal year ended December 31, 2012, as compared to \$7.7 million for the fiscal year ended December 31, 2011. This increase of \$7.8 million in total research and development expenses is due primarily to an increase of \$9.1 million in direct costs for clinical trials. Clinical trial costs for the fiscal year ended December 31, 2011 were \$1.5 million. This increase in clinical trial costs was offset in part by lower costs during the fiscal year ended December 31, 2012 to manufacture drug product required for clinical trials and testing, and by lower costs associated with non-clinical drug testing.

The research and development expenses incurred for amounts payable to external parties started to become a larger component of our research and development costs during the fiscal year ended December 31, 2011, and comprise a significant portion of our research and development spending during the fiscal year ended December 31, 2012, due primarily to the preparation for and commencement of our Phase 2 clinical trial for ITI-007. We incurred expenses of approximately \$12.2 million and \$4.2 million during the years ended December 31, 2012 and 2011, respectively, for amounts payable to external parties who manufactured, tested and performed clinical trial activities for all of our projects. During the same periods, our internal research and development expenses were approximately \$3.3 million and \$3.5 million during the years ended December 31, 2012 and 2011, respectively. As of September 30, 2013, we employed 14 full time personnel in our research and development group.

The clinical development work related to ITI-007 requires the largest portion of our resources and, consequently, comprises the majority of our spending. We spent approximately \$11.3 million and \$2.9 million on direct external costs for the development of ITI-007, exclusive of internal labor and fringes, during the periods ended December 31, 2012 and 2011, respectively. As development of ITI-007 progresses, we anticipate costs for ITI-007 to increase considerably in the next several years as we complete the ongoing Phase 2 clinical trial for ITI-007 and begin other clinical trials. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product and the creation of an inventory of drug product in anticipation of possible FDA approval.

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We currently have several projects in addition to ITI-007 that are in the research and development stages. These are in the areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including Alzheimer's disease, among others. We have used internal resources and incurred expenses not only in relation to the development of ITI-007 but on these additional projects as well. We have not, however, reported these costs on a project by project basis, as they are broadly spread among these projects. The external costs for these projects have been minimal and are reflected in the amounts discussed in this section " – Research and Development Expenses." During the years ended December 31, 2012 and 2011, we also incurred costs that were both reimbursable and non-reimbursable under the license and collaboration agreement with Takeda. We incurred approximately \$700,000 and \$320,000 on direct costs that were billable to Takeda for the years ended December 31, 2012 and 2011, respectively. We anticipate that these costs will be reduced significantly as the research portion of the license and collaboration agreement concludes in February 2014.

#### *General and Administrative Expenses*

Salaries and related benefit costs for our executive, finance and administrative functions for 2012 and 2011 constituted slightly less than half of the total general and administrative costs. The next major categories of expenses are patent costs, some of which are reimbursed by Takeda, legal, accounting and other professional fees and, to a lesser extent, facilities and general office-related overhead. We expect all of these costs to increase significantly as we expand our operations and become subject to the reporting requirements of a public company. General and administrative expenses were \$4.0 million for the fiscal year ended December 31, 2012 compared to \$4.6 million for the fiscal year ended December 31, 2011. The decrease is the result of higher legal, patent and personnel costs in 2011 related to consummating the license and collaboration agreement, offset in part by a decrease in patent costs for other non-Takeda related products.

#### ***Comparison of Three and Six Month Periods Ended June 30, 2013 and June 30, 2012***

##### *Research and Development Expenses*

Research and development expenses decreased for both the three and six month periods ended June 30, 2013 as compared to the three and six month periods ended June 30, 2012 by approximately \$1.7 million and \$393,000, respectively. The decrease in the three month period ended June 30, 2013 as compared to the three month period ended June 30, 2012 is due almost exclusively to lower costs of manufacturing of compounds, outside clinical testing and non-clinical testing. The decrease in the six month period ended June 30, 2013 as compared to the six month period ended June 30, 2012 is due to approximately \$1.1 million of lower manufacturing costs of compounds and approximately \$100,000 of lower non-clinical testing offset in part by approximately \$900,000 of higher clinical testing costs. The variations in the above costs are primarily related to the timing of these expenses from period to period. We were conducting comparable levels of clinical testing for our ITI-007 compound in the periods under comparison.

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The increase in clinical testing costs for the six month period ended June 30, 2013 as compared to the six month period ended June 30, 2012 is also the result of a slight increase in the number of clinical trial subjects being tested in 2013.

#### *General and Administrative Expenses*

General and administrative expenses decreased slightly for both the three and six month periods ended June 30, 2013 as compared to the three and six month periods ended June 30, 2012 by approximately \$212,000 and \$162,000, respectively. The decrease of \$212,000 for the three month period ended June 30, 2013 as compared to the three month period ended June 30, 2012 is primarily the result of approximately \$97,000 of lower patent filing costs, with the remainder comprised primarily of lower professional fees. The \$162,000 decrease for the six month period ended June 30, 2013 as compared to the six month period ended June 30, 2012 is due to lower professional fees of approximately \$36,000, and the rest is due to minor increases and decreases in other expense category items.

#### **Liquidity and Capital Resources**

Through June 30, 2013, we have funded our operations with approximately \$109.0 million of cash that has been obtained from the following main sources: \$25.4 million from sales of equity; \$0.2 million from the exercise of stock options; \$15.3 million in sales of convertible promissory notes; \$40.6 million from grants from government agencies and foundations; and \$27.5 million in total payments received under the license and collaboration agreement with Takeda, including approximately \$1.7 million for reimbursement of development costs incurred in 2011 and 2012 and \$1.4 million for patent costs incurred during the same time period. During the fiscal year ended December 31, 2012, we did not receive any funding through grants. We do not believe that grant revenue will be a significant source of funding in the near future. We expect that reimbursements of our development costs by Takeda will decline going forward, and we do not expect such reimbursements to be a significant source of funding in the future. We also expect the reimbursements for patent filing costs will remain at the same level, but because reimbursements will be offset by the actual expenditures incurred, reimbursements do not represent a net source of funding for us.

In October and November 2012, we issued convertible promissory notes, or Notes, having an aggregate principal amount of approximately \$15.2 million. We issued additional Notes having an aggregate principal amount of \$0.1 million in March 2013. The Notes were unsecured and accrued interest at a rate of 6% per year, were originally scheduled to mature on April 25, 2013, but were extended until October 25, 2013. The principal amount of the Notes, together with the accrued interest thereon, converted into shares of ITI common stock at the closing of the private placement described above under "Recent Developments – Private Placement."

As of December 31, 2012, we had a total of \$19.1 million in cash, cash equivalents and certificates of deposit, or CDs, and approximately \$18.2 million of short term liabilities consisting of \$3.0 million of short term liabilities from operations and \$15.2 million in principal amount of Notes. As of June 30, 2013, we had a total of \$10.3 million in cash, cash equivalents

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and CDs, and approximately \$22.7 million of short term liabilities consisting of \$7.4 million of short term liabilities from operations and \$15.3 million in principal amount of Notes. This reduction in working capital of \$12.4 million for the six month period ended June 30, 2013 is primarily due to the funding of the Phase 2 clinical trial for ITI-007, our lead drug candidate. Working capital used to fund recurring operations during this period was approximately \$4.5 million. We expect to consume working capital of approximately \$11.0 to \$12.0 million for the second half of 2013. This will be due primarily to expenses incurred for the completion of the Phase 2 clinical trial and, to a lesser extent, the preparations for additional trials and non-clinical testing related to the development of ITI-007.

Prior to the Merger, on August 29, 2013, ITI closed the Private Placement in which it sold to accredited investors approximately \$60.0 million of its shares of common stock, which included approximately \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of the Notes. All of the shares issued in the Private Placement, along with the other shares of ITI that were outstanding immediately prior to the Merger, were exchanged for shares of our common stock at the Effective Time. For a more detailed discussion of the Private Placement and the Merger, see “Recent Developments – Reverse Merger” above.

Our cash, cash equivalents and investment securities totaled \$10.3 million at June 30, 2013. On August 29, 2013, immediately prior to the Merger, ITI sold approximately \$60.0 million of its common stock, which included approximately \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI’s then outstanding convertible promissory notes, and which resulted in net proceeds, after expenses, of approximately \$40.0 million. While we believe that our existing cash resources and anticipated payments from our existing collaborations will be sufficient to fund our cash requirements for the next 12 months, we will require significant additional financing in the future to continue to fund our operations.

We have incurred losses in every year since inception with the exception of the fiscal year ended December 31, 2011. These losses have resulted in significant cash used in operations. During the fiscal year ended December 31, 2012, our cash used in operations was approximately \$18.9 million. During the fiscal year ended December 31, 2011, if we exclude the upfront fee and milestone payments from Takeda, our cash used in operations would have been \$7.8 million. This increase of cash used during calendar 2012 is primarily due to the clinical development and clinical trial activities for ITI-007. While we have several research and development programs underway, the ITI-007 program has advanced the furthest and will continue to consume increasing amounts of cash for conducting clinical trials and the testing and manufacturing of product material. As we continue to conduct these activities necessary to pursue FDA approval of ITI-007 and our other product candidates, we expect the cash needed to fund operations to increase significantly over the next several years.

Until we can generate significant revenues from operations, we will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to the recent volatile nature of the financial markets and, in particular, the adverse impact on market capitalization and valuation of biotechnology companies, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress for our ITI-007 program could have a material adverse impact on our ability to raise additional capital.

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If we cannot raise adequate capital in the future, we will be required to delay and possibly eliminate the research and development work not only of our lead drug candidate ITI-007, but also our other preclinical stage product candidates. In this case, we could be required to relinquish greater or all rights to our product candidates at an earlier stage of development and on less favorable terms than we would otherwise agree.

Our cash is maintained in money market accounts and, to a lesser extent, in CDs at major financial institutions. Due to the current low interest rates available for these instruments, we are earning limited interest income. Our investment portfolio has not been adversely impacted by the problems in the credit markets that have existed over the last several years, but there can be no assurance that our investment portfolio will not be adversely affected in the future.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

#### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Judgments must also be made about the disclosure of contingent liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management makes estimates and exercises judgment in revenue recognition and stock-based compensation. Actual results may differ from those estimates and under different assumptions or conditions.

We believe that the following critical accounting policies affect management's more significant judgments and estimates used in the preparation of our financial statements:

#### ***Revenue Recognition***

Revenue is recognized when all terms and conditions of the agreements have been met, including persuasive evidence of an arrangement, delivery has occurred or services have been rendered, price is fixed or determinable and collectability is reasonably assured. We are reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. We record the amount of reimbursement as revenues on a gross basis in accordance with ASC 605-45, "*Revenue Recognition/Principal Agent Considerations.*" We are the primary obligor with respect to

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purchasing goods and services from third-party suppliers, are obligated to compensate the service provider for the work performed, and have discretion in selecting the supplier. Provisions for estimated losses on research grant projects and any other contracts are made in the period such losses are determined.

Effective January 1, 2011, we adopted a new accounting standard that amends the guidance on the accounting for arrangements involving the delivery of more than one element. Pursuant to the new standard, each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For us, this determination is generally based on whether the deliverable has “stand-alone value” to the customer. We adopted this new accounting standard on a prospective basis for all Multiple-Deliverable Revenue Arrangements, or MDRAs, entered into on or after January 1, 2011, and for any MDRAs that were entered into prior to January 1, 2011, but materially modified on or after that date.

For MDRAs entered into prior to January 1, 2011 (pre-2011 arrangements) and not materially modified thereafter, we continue to apply our prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, up-front fees related to intellectual property rights/licenses, where we have continuing involvement and where standalone value could not be determined under the previous guidance, is recognized ratably over the estimated period of ongoing involvement. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

The adoption of this accounting standard did not have a material impact on our results of operations for the years ended December 31, 2012 and 2011, or on our financial positions as of December 31, 2012 and 2011.

In January 2011, we adopted ASC Topic 605-28, “*Milestone Method*.” Under this guidance, we recognize revenue contingent upon the achievement of a substantive milestone in its entirety in the period the milestone is achieved. Substantive milestone payments are recognized upon achievement of the milestone only if all of the following conditions are met:

- the milestone payments are non-refundable;
- achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- substantive effort on our part is involved in achieving the milestone;
- the amount of the milestone payment is reasonable in relation to the effort expended or the risk associated with achievement of the milestone; and
- a reasonable amount of time passes between the up-front license payment and the first milestone payment, as well as between each subsequent milestone payment.

Determination as to whether a payment meets the aforementioned conditions involves management’s judgment. If any of these conditions are not met, the resulting payment would not

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be considered a substantive milestone, and therefore, the resulting payment would be considered part of the consideration for the single unit of accounting and be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable. In addition, the determination that one such payment was not a substantive milestone could prevent us from concluding that subsequent milestone payments were substantive milestones and, as a result, any additional milestone payments could also be considered part of the consideration for the single unit of accounting and would be recognized as revenue as such performance obligations are performed under either the proportional performance or straight-line methods, as applicable.

### ***Stock-Based Compensation***

Stock-based payments are accounted for in accordance with the provisions of ASC 718, "*Compensation – Stock Compensation.*" The fair value of share-based payments is estimated, on the date of grant, using the Black-Scholes-Merton option-pricing model, or the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. As stock-based compensation expense recognized in the statements of operations for the fiscal years ended December 31, 2012 and 2011 is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures are based on our historical experience for the fiscal years ended December 31, 2012 and 2011, and have not been material.

We utilize the Black-Scholes model for estimating fair value of our stock options granted. Option valuation models, including Black-Scholes model, require the input of subjective assumptions, and changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

Expected volatility rates are based on historical volatility of the common stock of comparable publicly traded entities and other factors due to the lack of historic information of our common stock. The expected life of stock-based options is the period of time for which the stock-based options are expected to be outstanding. Given the lack of historic exercise data, the expected life is determined using the "simplified method" which is defined as the midpoint between the vesting date and the end of the contractual term.

The risk-free interest rates are based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have not paid dividends to its stockholders since its inception and do not plan to pay cash dividends in the foreseeable future. Therefore, we have assumed an expected dividend rate of zero.



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Given the absence of an active market for our common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of our convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of our common stock, we considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, "*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*."

Under ASC 718, the cumulative amount of compensation cost recognized for instruments classified as equity that ordinarily would result in a future tax deduction under existing tax law shall be considered to be a deductible difference in applying ASC 740, "*Income Taxes*." The deductible temporary difference is based on the compensation cost recognized for financial reporting purposes; however, these provisions currently do not impact us, as all the deferred tax assets have a full valuation allowance.

Since we had net operating loss carry-forwards as of December 31, 2012 and 2011, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to non-employees are accounted for under the provisions of ASC 718 and ASC 505-50, "*Equity/Equity-Based Payments to Non-Employees*." Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed and are marked to market during the service period.

#### **Recently Issued Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our financial statements, see Exhibit 99.1, "Notes to Financial Statements – Note 2 – Summary of Significant Accounting Policies."

**SECURITY OWNERSHIP OF  
CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth the number of shares of our common stock beneficially owned as of September 30, 2013, by (i) each of our current directors and named executive officers, (ii) all executive officers and directors as a group, and (iii) each person known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders, subject to community property laws, where applicable. Percentage of ownership is based on 22,134,647 shares of common stock outstanding on September 30, 2013, after giving effect to the Private Placement and Merger on August 29, 2013. Unless otherwise noted below, the address of each stockholder below is c/o Intra-Cellular Therapies, Inc., 3960 Broadway, New York, New York 10032.

Beneficial Owner	Title	Shares of Common Stock Beneficially Owned (#)(1)	Percentage of Common Stock Beneficially Owned (%)(1)
<b>Directors and Named Executive Officers</b>			
Sharon Mates, Ph.D.(2)	Chairman, President and Chief Executive Officer	1,341,433	6.0%
Lawrence J. Himeline(3)	Vice President of Finance, Chief Financial Officer and Secretary	154,999	*
Allen A. Fienberg, Ph.D.(4)	Vice President of Business Development	342,499	1.5%
Christopher Alafi, Ph.D.(5)	Director	4,046,638	18.3%
Richard Lerner, M.D.(6)	Director	116,250	*
Joel S. Marcus(7)	Director	1,383,348	6.2%
Sir Michael Rawlins, M.D., FRCP, FMedSci	Director	—	*
<i>All current executive officers and directors as a group (9 persons)(8)</i>		7,631,583	33.3%
<b>Other 5% or More Stockholders</b>			
Alafi Capital Company, LLC and Moshe Alafi(9)		3,558,627	16.1%
Alexandria Real Estate Equities, Inc.(10)		1,283,856	5.8%
Entities affiliated with Fidelity Investments(11)		1,999,120	9.0%
Paul Greengard, Ph.D.(12)		1,131,250	5.1%
Morton I. Sosland(13)		3,388,389	15.3%

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- \* Represents beneficial ownership of less than 1% of the shares of common stock.
- (1) Beneficial ownership is determined in accordance with SEC rules, and includes any shares as to which the stockholder has sole or shared voting power or investment power, and also any shares which the stockholder has the right to acquire within 60 days of September 30, 2013, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the stockholder that he, she or it is a direct or indirect beneficial owner of those shares.
  - (2) Consists of 1,053,935 shares of common stock and options to purchase 287,498 shares of common stock which are exercisable within 60 days of September 30, 2013.
  - (3) Consists of 50,000 shares of common stock and options to purchase 104,999 shares of common stock which are exercisable within 60 days of September 30, 2013.
  - (4) Consists of 237,500 shares of common stock and options to purchase 104,999 shares of common stock which are exercisable within 60 days of September 30, 2013. Does not include: (i) 208,023 shares of common stock held by J.D.F. Holdings Ltd., in which Dr. Fienberg holds a 20% ownership interest; and (ii) 50,000 shares of common stock held by two trusts for the benefit of members of Dr. Fienberg's family. Dr. Fienberg has no voting or investment control with respect to any of the shares owned by J.D.F. Holdings Ltd. or held in the trusts.
  - (5) Consists of 3,542,885 shares of common stock held by Alafi Capital Company, LLC, or Alafi Capital, and 503,753 shares of common stock held by a trust for the benefit of members of the Alafi family. Dr. Alafi is a managing partner of Alafi Capital and has shared voting and investment power with respect to the shares owned by Alafi Capital and full voting and investment power with respect to shares owned by the trust. Does not include 503,776 shares held by two other trusts for the benefit of members of the Alafi family for which Dr. Alafi does not have voting or investment control. The address for Dr. Alafi is c/o Alafi Capital Company, LLC, 8 Admiral Drive, Suite 324, Emeryville, CA 94608.
  - (6) Consists of options to purchase 78,750 shares of common stock held by Dr. Lerner which are exercisable within 60 days of September 30, 2013, and 37,500 shares of common stock held by the Lerner Family Trust UAD 11/14/94, or the Lerner Family Trust. Dr. Lerner shares voting and investment control with respect to the shares held by the Lerner Family Trust.
  - (7) Consists of (i) 1,283,856 shares of common stock held by Alexandria Equities, LLC, (ii) 15,742 shares of common stock held by the Joel S. Marcus and Barbara A. Marcus Family Trust, and (iii) options to purchase 83,750 shares of common stock held by Mr. Marcus, which are exercisable within 60 days of September 30, 2013. Mr. Marcus is the Chairman, CEO and Founder of Alexandria Real Estate Equities, Inc., which is the managing member of Alexandria Equities, LLC, which has full voting and investment power with respect to the shares owned by Alexandria Equities, LLC. As an officer of Alexandria Real Estate Equities, Inc., Mr. Marcus may be deemed to have voting and investment power with respect to the shares owned by Alexandria Equities, LLC. Mr. Marcus disclaims beneficial ownership of the shares held by Alexandria Equities, LLC, except to the extent of his underlying pecuniary interest therein. The address for Mr. Marcus is c/o Alexandria Real Estate Equities, Inc., 385 East Colorado Boulevard, Suite 299, Pasadena, CA 91101.
  - (8) See footnotes 2 through 7. Also includes 100,000 shares of common stock and options to purchase 115,833 shares of common stock held by Lawrence P. Wennogle, Ph.D., Vice President, Drug Discovery, which are exercisable within 60 days of September 30, 2013, and options to purchase 30,583 shares of common stock, which are exercisable within 60 days of September 30, 2013, held by Kimberly E. Vanover, Ph.D., Vice President, Clinical Development.

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- (9) Consists of 3,542,885 shares of common stock held by Alafi Capital and 15,742 shares of common stock held by Moshe Alafi. Christopher Alafi, Ph.D., one of our directors, and Moshe Alafi are each managing partners of Alafi Capital and share voting and investment power with respect to the shares owned by Alafi Capital. The address for Moshe Alafi and Alafi Capital is 8 Admiral Drive, Suite 324, Emeryville, CA 94608.
- (10) Consists of 1,283,856 shares of common stock held by Alexandria Equities, LLC. Joel S. Marcus, one of our directors, is the Chairman, CEO and Founder of Alexandria Real Estate Equities, Inc., which is the managing member of Alexandria Equities, LLC, which has full voting and investment power with respect to the shares owned by Alexandria Equities, LLC. As an officer of Alexandria Real Estate Equities, Inc., Mr. Marcus may be deemed to have voting and investment power with respect to the shares owned by Alexandria Equities, LLC. Mr. Marcus disclaims beneficial ownership of the shares held by Alexandria Equities, LLC, except to the extent of his underlying pecuniary interest therein. The address for Alexandria Equities, LLC is c/o Alexandria Real Estate Equities, Inc., 385 East Colorado Boulevard, Suite 299, Pasadena, CA 91101.
- (11) Fidelity Management & Research Company, or Fidelity, 82 Devonshire Street, Boston, Massachusetts 02109, a wholly-owned subsidiary of FMR LLC and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of 1,999,120 shares of common stock as a result of acting as investment adviser to various investment companies registered under Section 8 of the Investment Company Act of 1940. Edward C. Johnson 3d and FMR LLC, through its control of Fidelity, and the funds each has sole power to dispose of the 1,999,120 shares of common stock owned by the Funds. Members of the family of Edward C. Johnson 3d, Chairman of FMR LLC, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Edward C. Johnson 3d, Chairman of FMR LLC, has the sole power to vote or direct the voting of the shares owned directly by the Fidelity Funds, which power resides with the Funds' Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established by the Funds' Boards of Trustees.
- (12) Consists of 1,131,250 shares of common stock held by Dr. Greengard. Does not include 1,500,000 shares of common stock held by six trusts for the benefit of members of Dr. Greengard's family, as the trustee of these trusts, Ursula von Rydingsvard, Dr. Greengard's spouse, has sole voting and investment control over the shares held by the trusts. The address for Dr. Greengard and the trusts is Dr. Paul Greengard, c/o TAG Associates, 75 Rockefeller Plaza, 9th Floor, New York, NY 10019.
- (13) Consists of 707,287 shares of common stock held by David N. Sosland Trust A; 1,948,554 shares of common stock held by The Sosland Family Trust B Partnership; and 732,548 shares of common stock held by The Sosland Foundation. Morton I. Sosland is Trustee of the David N. Sosland Trust A, Managing Partner of The Sosland Family Trust B Partnership and Vice Chairman of The Sosland Foundation, which we refer to collectively as the Sosland Holders. As such, Mr. Sosland has sole voting and investment power with respect to the shares held by the Sosland Holders. The address for Mr. Sosland and the Sosland Holders is 4800 Main Street, Suite 100, Kansas City, MO 64112.

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## MANAGEMENT AND DIRECTORS

Effective immediately following the Merger, Sharon Mates, Ph.D. was appointed to our board of directors, and together with the sole director of the Shell Company, Samir N. Masri, constituted our board of directors immediately following the Merger. Effective on September 9, 2013, the eleventh day after we filed with the SEC and transmitted to our sole stockholder prior to the Merger a Schedule 14f-1 reporting a change in the majority of our directors, the board of directors was reconstituted by the appointment of Christopher Alafi, Ph.D., Richard Lerner, M.D., Joel S. Marcus and Sir Michael Rawlins, M.D., FRCP, FMedSci, to serve with Dr. Mates as directors, and the resignation of Mr. Masri as a director. Our executive management team was also reconstituted upon the closing of the Merger by the appointment of Dr. Mates as our President and Chief Executive Officer, Allen A. Fienberg, Ph.D. as our Vice President of Business Development, Lawrence J. Hineline as our Vice President of Finance, Chief Financial Officer and Secretary, Lawrence P. Wennogle, Ph.D. as our Vice President, Drug Discovery and Kimberly E. Vanover, Ph.D. as our Vice President, Clinical Development, and the resignation of Samir N. Masri as our Chief Executive Officer, Chief Financial Officer, President and Secretary.

### Executive Officers and Directors

The following table sets forth certain information concerning our executive officers and directors as of September 30, 2013:

<u>Name</u>	<u>Age</u>	<u>Position</u>
<i>Executive Officers</i>		
Sharon Mates, Ph.D.	60	Chairman, President and Chief Executive Officer
Lawrence J. Hineline	57	Vice President of Finance, Chief Financial Officer and Secretary
Allen A. Fienberg, Ph.D.	53	Vice President of Business Development
Lawrence P. Wennogle, Ph.D.	63	Vice President, Drug Discovery
Kimberly E. Vanover, Ph.D.	47	Vice President, Clinical Development
<i>Non-Employee Directors</i>		
Christopher Alafi, Ph.D.	50	Director
Richard Lerner, M.D.	75	Director
Joel S. Marcus	66	Director
Sir Michael Rawlins, M.D., FRCP, FMedSci	72	Director

### Executive Officers

*Sharon Mates, Ph.D.* Dr. Mates has been the Chairman of the board of directors, President and Chief Executive Officer of ITI since June 2002. Dr. Mates co-founded ITI in May 2002. Prior to co-founding ITI, Dr. Mates was a co-founder of Functional Genetics, and served as its Chairman and Chief Executive Officer from December 2000 until August 2003. From 1989-1998 Dr. Mates was the President and a board member of

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North American Vaccine Inc. and its predecessor companies. She has served on several boards, and recently completed a board membership and a two-year chairmanship of the Board of the New York Biotechnology Association. Dr. Mates has also served on the Advisory Council of the Center for Society and Health at the Harvard School of Public Health, the Board of Visitors of the Biotechnology Institute of the University of Maryland and the board of directors of Gilda's Club of New York. Earlier in her career, Dr. Mates spent several years as a research analyst and investment banker, and as an advisor to the life sciences industry. Dr. Mates received her B.S. from the Ohio State University and her Ph.D. from the University of Washington, and completed her postdoctoral fellowships at The Massachusetts General Hospital and Harvard Medical School.

We believe that Dr. Mates possesses specific attributes that qualify her to serve as chairman of our board of directors, including the perspective and experience she brings as the co-founder, President and Chief Executive of ITI, which brings historic knowledge, operational expertise and continuity to our board of directors, and her industry expertise, including over 24 years of experience leading both private and public companies.

*Lawrence J. Hinline, CPA.* Mr. Hinline has served as Vice President of Finance, Chief Financial Officer and Secretary of ITI since June 2002. From December 2000 to November 2003, Mr. Hinline was the Vice-President of Finance and Chief Financial Officer of Functional Genetics, Inc. Prior to that, Mr. Hinline served as the Vice President of Finance of North American Vaccine, Inc. and its predecessor companies from 1993 to 2000, and he served as Corporate Controller from 1989 to 1993. During this time, Mr. Hinline oversaw the growth of the accounting function and its systems for the company that emerged as a start-up and was later acquired by Baxter Health Care. Mr. Hinline is a licensed CPA in the State of Maryland and received his Bachelor's Degree from the University of Maryland Baltimore County.

*Allen A. Fienberg, Ph.D.* Dr. Fienberg has served as Vice President of Business Development of ITI since June 2002. He co-founded ITI in May 2002. Dr. Fienberg received his A.B. degree in Genetics from the University of California, Berkeley and his Ph.D. in Human Genetics from Yale University. He completed post-doctoral studies at The Rockefeller University under the direction of Dr. Paul Greengard from 1991-1999. From 1999-2001, Dr. Fienberg was a staff scientist at the Genomics Institute of the Novartis Research Foundation and was appointed a Research Assistant Professor at The Rockefeller University from 2001-2002.

*Lawrence P. Wennogle, Ph.D.* Dr. Wennogle has served as Vice President, Drug Discovery of ITI since January 2003. For the past 33 years, Dr. Wennogle has been involved in research and development in the pharmaceutical industry aimed at the discovery of novel pharmaceutical entities for human diseases. He was a Staff Scientist and Principal Research Fellow at Ciba-Geigy and Novartis Pharmaceutical Corporation for 19 years, where he led drug discovery programs for CNS disorders, cardiovascular diseases, diabetes and inflammation. Dr. Wennogle received his B.A. from Ithaca College and his Ph.D. in Biochemistry from the University of Colorado, Boulder. He then completed two post-doctoral positions, one at the University of Colorado and the second at the Pasteur Institute in Paris, France, working under Jean-Pierre Changeux on the structure-function of the nicotinic acetylcholine receptor.

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*Kimberly E. Vanover, Ph.D.* Dr. Vanover joined ITI in March 2007 and has been Vice President, Clinical Development of ITI since January 2011. Previously, she was Executive Director, Clinical Development of ITI from January 2008 to December 2010 and Senior Director, Clinical Development of ITI from March 2007 to December 2007. She has spent over 20 years on the discovery and development of small molecule drugs for the treatment of neuropsychiatric and neurodegenerative diseases. Dr. Vanover was Postdoctoral Research Scientist at Lederle Laboratories from 1992 to 1994, Postdoctoral Research Trainee in the Department of Psychiatry at the University of California San Diego from 1994 to 1995, Senior Scientist and Group Leader at CoCensys from 1995 to 2000 and held positions as Group Leader and Director at ACADIA Pharmaceuticals from 2000 to 2007. In these positions, Dr. Vanover participated in the discovery and development of a broad range of new CNS therapeutics, including drugs to treat psychosis, insomnia, cognitive impairment, movement disorders, acute and neuropathic pain, anxiety, epilepsy, and drug abuse. Dr. Vanover received her B.A. in Psychology from the University of Missouri and her Ph.D. in Biopsychology from the University of Chicago.

#### **Non-Employee Directors**

*Christopher Alafi, Ph.D.* Dr. Alafi has served on the board of directors of ITI since January 2013. Dr. Alafi has been a General Partner of Alafi Capital Company, LLC, a venture capital firm, since 1995. He was previously a Physiology and Anatomy teacher at Santa Monica College, a visiting scholar in the Department of Chemistry at Stanford University and a researcher at DNAX. Dr. Alafi currently serves as a director of ISTO Technologies, Inc. and has previously served as a director of Coley Pharmaceutical Group, Inc., CyberGold, Inc. and Stereotaxis, Inc. Dr. Alafi received a B.A. in Biology from Pomona College and a D.Phil. in Biochemistry from the University of Oxford.

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We believe that Dr. Alafi possesses specific attributes that qualify him to serve as a member of our board of directors, including the perspective and experience he brings as a General Partner of Alafi Capital Company, LLC.

*Richard Lerner, M.D.* Dr. Lerner has served on the board of directors of ITI since 2002. Dr. Lerner served as President of the Scripps Research Institute, a private, non-profit biomedical research organization from 1986 to January 2012, and since then has served and continues to serve as Institute Professor. Dr. Lerner received the Wolf Prize in Chemistry in 1994, the California Scientist of the Year Award in 1996, the Paul Ehrlich and Ludwig Darmstaedter Prize in 2003, and the Prince of Asturias Award in 2012 for his achievements in the development of catalytic antibodies and combinatorial antibody libraries. Dr. Lerner is a member of the National Academy of Sciences and the Royal Swedish Academy of Sciences. Dr. Lerner served as a director of Kraft Foods, Inc. from 2005 to March 2012 and currently serves as a director of Opko Health, Inc., Teva Pharmaceutical Industries Ltd., and Sequenom, Inc. Dr. Lerner received his M.D. from Stanford Medical School.

We believe that Dr. Lerner possesses specific attributes that qualify him to serve as a member of our board of directors, including his service as a director of other public companies, combined with his business acumen and judgment provide our board of directors with valuable scientific and operational expertise and leadership skills.

*Joel S. Marcus J.D., CPA.* Mr. Marcus has served on the board of directors of ITI since April 2006. Mr. Marcus co-founded Alexandria Real Estate Equities, Inc. in 1994, Alexandria Venture Investments in 1996, and the annual Alexandria Summit in 2011. He has served as Chairman of the Board of Directors of Alexandria Real Estate Equities, Inc. since May 2007, Chief Executive Officer since March 1997, President since February 2009, and a director since the company's inception in 1994. From 1986 to 1994, Mr. Marcus was a partner at the law firm of Brobeck, Phleger & Harrison LLP, specializing in corporate finance and capital markets, venture capital, and mergers and acquisitions. From 1984 to 1994, he also served as General Counsel and Secretary of Kirin-Amgen, Inc., a joint venture that financed the development of, and owned patents to, two multi-billion dollar genetically engineered biopharmaceutical products. Mr. Marcus was formerly a practicing certified public accountant and tax manager with Arthur Young & Co. specializing in the financing and taxation of REITs. He received his undergraduate and Juris Doctor degrees from the University of California, Los Angeles. In addition to ITI, Mr. Marcus serves on the boards of the Accelerator Corporation, of which he was one of the original architects and co-founders, Foundation for the National Institutes of Health (FNIH), Multiple Myeloma Research Foundation (MMRF), and the Partnership for New York City. Mr. Marcus also served on the Board of Trustees of PennyMac Mortgage Investment Trust, a publicly traded mortgage REIT, from August 2009 to August 2012. Mr. Marcus received the Ernst & Young 1999 Entrepreneur of the Year Award (Los Angeles – Real Estate).

We believe that Mr. Marcus possesses specific attributes that qualify him to serve as a member of our board of directors, including his many years of experience in the life sciences industry and his extensive experience serving as a director and an executive officer of other public companies.



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*Sir Michael Rawlins, M.D., FRCP, FMedSci.* Sir Michael has served on the board of directors of ITI since May 2013. Sir Michael is known for his long standing leadership of the United Kingdom's National Institute for Clinical Excellence, or NICE, which he led from its inception in 1999 through March 2013. Recently in July 2012, Sir Michael was appointed as the President of the United Kingdom's Royal Society of Medicine, a center for education and scholarship both in the UK and globally. Sir Michael was a professor of clinical pharmacology and a general physician at the University of Newcastle upon Tyne from 1973 to 2006. He received the Prince Mahidol Award for Medicine in 2012, the Galen Medal in 2010, and the Hutchinson Medal in 2003. Sir Michael was appointed Knight Bachelor in 1999.

We believe that Sir Michael possesses specific attributes that qualify him to serve as a member of our board of directors, including his extensive experience in areas of health policy and economics.

#### **Scientific Advisory Board**

We have a Scientific Advisory Board which is chaired by Paul Greengard, Ph.D., one of our founders. Dr. Greengard received his Ph.D. in biophysics from Johns Hopkins University in 1953. After postgraduate work in England, he served for nine years as director of biochemical research at the Geigy Research Laboratories. In 1968, he was appointed Professor of Pharmacology at Yale University. In 1983, he was appointed the Vincent Astor Professor at The Rockefeller University, where he founded the Laboratory of Molecular and Cellular Neuroscience.

Dr. Greengard is a pioneer in the field of neuronal signal transduction and his seminal discoveries over the years have provided a framework by which to understand the complexity of how neurotransmitters function in the brain. Dr. Greengard's many awards and honors include the CIBA-Geigy Drew Award in Biomedical Research (1979), the New York Academy of Sciences Award in Biological and Medical Sciences (1980), the Andrew D. White Professorship-at-Large of Cornell University (1981-87), the Pfizer Biomedical Research Award (1987), the Ralph W. Gerard Prize in Neuroscience, Society for Neuroscience (1994), the Charles A. Dana Award for Pioneering Achievements in Health (1997), and the Nobel Prize in Physiology or Medicine (2000). Dr. Greengard has also been a consultant to major pharmaceutical companies and a Chairman and member of the scientific advisory boards of numerous biotechnology companies.

We have additional members of our Scientific Advisory Board who change from time to time, with whom we consult on an as-needed basis.

#### **Medical Advisory Board**

Carol A. Tamminga, M.D. is the Chair of our Medical Advisory Board. Dr. Tamminga is the Chair of the Psychiatry Department at the University of Texas Southwestern School of Medicine. She holds the McKenzie Foundation Chair in Psychiatry, the Communities Foundation of Texas, Inc. Chair in Brain Science and is the Chief of Translational Neuroscience Research in Schizophrenia.

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Jeffrey Lieberman, M.D. is the Lawrence C. Kolb Professor and Chairman of Psychiatry, at the Columbia University College of Physicians and Surgeons; and Director, of the New York State Psychiatric Institute; Psychiatrist-in-Chief, New York Presbyterian Hospital-Columbia University Medical Center.

John M. Kane, M.D. is Professor and Chairman of Psychiatry at The Hofstra North Shore-LIJ School of Medicine and Vice President for Behavioral Health Services at The North Shore-LIJ Health System.

Christoph U. Correll, M.D. is Professor of Psychiatry and Molecular Medicine, Hofstra North Shore LIJ School of Medicine; Medical Director, Recognition and Prevention (RAP) Program, The Zucker Hillside Hospital, North Shore Long Island Jewish Health System.

Donald Goff, M.D. is Professor and Vice Chair for Research in the Department of Psychiatry at New York University Langone Medical Center (NYULMC) and Director of the Nathan S. Kline Institute for Psychiatric Research.

#### **Compensation Committee Interlocks and Insider Participation**

We currently do not have a compensation committee. While ITI had a compensation committee comprised of all directors serving on the ITI board of directors, no member of ITI's compensation committee has at any time been an employee of ours or ITI other than Dr. Mates, who did not vote on her own compensation. None of our executive officers serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

#### **Board Composition and Election of Directors**

##### ***Terms of Office***

Our restated certificate of incorporation, which we expect to file on or about November 7, 2013, the date that is 20 calendar days from the date we filed with the SEC and mailed to our sole stockholder prior to the Merger a definitive Schedule 14C reporting the adoption of the restated certificate of incorporation by our sole stockholder prior to the Merger, and our restated bylaws, which became effective upon the Merger, provide that, subject to any applicable rights of holders of any preferred stock then outstanding, the authorized number of directors may be changed only by resolution of our board of directors. We currently have authorized five directors. In accordance with our restated certificate of incorporation and restated bylaws, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders commencing with the meeting in 2014, the successors to the directors whose terms then expire will be elected to serve until the third annual meeting following the election. Our directors are divided among the three classes as follows:

- the Class I directors are Richard Lerner, M.D. and Sir Michael Rawlins, M.D., FRCP, FMedSci, and their terms will expire at the annual meeting of stockholders to be held in 2014;

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- the Class II directors are Christopher Alafi, Ph.D. and Joel S. Marcus, and their terms will expire at the annual meeting of stockholders to be held in 2015; and
  - the Class III director is Sharon Mates, Ph.D. and her term will expire at the annual meeting of stockholders to be held in 2016.

Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that each class will consist of approximately one-third of the directors.

#### ***Director Independence***

Our securities are not listed on a national securities exchange or on any inter-dealer quotation system which has a requirement that a majority of directors be independent. We evaluate independence, however, by the standards for director independence set forth in the NASDAQ Marketplace Rules. Under Rules 5605 and 5615 of the NASDAQ Marketplace Rules, a majority of a listed company's board of directors must be comprised of independent directors, subject to certain phase-in exceptions. In addition, NASDAQ Marketplace Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and governance and nominating committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2) of the NASDAQ Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our board of directors has determined that none of Dr. Alafi, Dr. Lerner, Mr. Marcus or Sir Michael, representing four out of our five directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the NASDAQ Marketplace Rules. Dr. Mates is employed by the Company and is therefore not independent under NASDAQ Marketplace Rules.

#### ***Board of Directors' Meetings***

During the fiscal year ended December 31, 2012, there were five meetings of ITI's board of directors, and the compensation committee, which was the only standing

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committee of ITI's board of directors, met one time. No director of ITI attended fewer than 75% of the total number of meetings of ITI's board of directors and of committees of its board of directors on which he or she served during fiscal 2012, except for David Kipnis, M.D., a former director of ITI, who attended three of the six meetings of ITI's board of directors and committees of its board of directors during fiscal 2012. In addition, Christopher Alafi, Ph.D. and Sir Michael Rawlins, M.D., FRCP, FMedSci were not elected as directors of ITI until 2013. Our board of directors intends to adopt a policy under which each member of our board of directors is strongly encouraged but not required to attend each annual meeting of our stockholders. Neither we nor ITI held an annual meeting of stockholders in 2012.

#### ***Committees of the Board of Directors***

Our board of directors does not currently have an audit committee, a compensation committee or a nominating and governance committee. Our board of directors intends to establish an audit committee, a compensation committee and a nominating and corporate governance committee. Each committee will operate under a charter to be approved by our board of directors.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations regarding the filing of required reports, we believe that all Section 16(a) filing requirements applicable to our directors, executive officers and greater-than-ten-percent beneficial owners with respect to fiscal 2012 were met, as our directors, executive officers and greater-than-ten percent beneficial owners were not required to file reports under Section 16(a) before the Company became an Exchange Act reporting company in fiscal 2013.

#### **Code of Ethics**

Prior to the Merger, the Company had adopted a code of conduct and ethics. We intend to adopt an amended and restated code of conduct and ethics that will apply to all of our employees, including our principal executive officer and our principal financial and accounting officer, and plan to post a copy of such code of conduct and ethics on our website at [www.intracellulartherapies.com](http://www.intracellulartherapies.com). Once we adopt the amended and restated code of conduct and ethics, disclosure regarding any amendments to, or waivers from, provisions of the amended and restated code of conduct and ethics that we intend to adopt that apply to our directors, principal executive and financial officers will be included in a Current Report on Form 8-K within four business days following the date of the amendment or waiver, unless website posting or the issuance of a press release of such amendments or waivers is then permitted by any applicable stock exchange.

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**Board Leadership Structure and Role on Risk Oversight**

Our board of directors does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the board of directors, as our board of directors believes it is in the best interest of the Company to make that determination based on the position and direction of the Company and the membership of the board of directors. Our board of directors has determined that having an employee director serve as Chairman is in the best interest of the Company's stockholders at this time because of the efficiencies achieved in having the role of Chief Executive Officer and Chairman combined, and because the detailed knowledge of our day-to-day operations and business that the Chief Executive Officer possesses greatly enhances the decision-making processes of our board of directors as a whole. We have a strong governance structure in place, including independent directors, to ensure the powers and duties of the dual role are handled responsibly. We do not have a lead independent director.

The Chairman of the board of directors and the other members of the board of directors work in concert to provide oversight of our management and affairs. Our board of directors encourages communication among its members and between management and the board of directors to facilitate productive working relationships. Working with the other members of the board of directors, Dr. Mates also strives to ensure that there is an appropriate balance and focus among key board responsibilities such as strategic development, review of operations and risk oversight.

**Indemnification of Directors and Officers**

Our pending restated certificate of incorporation and our restated bylaws effective upon consummation of the Merger provide that each person who was or is made a party to or is threatened to be made a party to or is otherwise involved (including, without limitation, as a witness) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director, officer, or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action in an official capacity as a director, officer or trustee or in any other capacity while serving as a director, officer or trustee, shall be indemnified and held harmless by us to the fullest extent authorized by the Delaware General Corporation Law against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such.

Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reasonable cause to believe his or her conduct was unlawful. In a derivative action (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be

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in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the Delaware Chancery Court or the court in which the action or suit was brought shall determine that such person is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, Article Eighth of our pending restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

- from any breach of the director's duty of loyalty to us or our stockholders;
- from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law; and
- from any transaction from which the director derived an improper personal benefit.

We have entered into indemnification agreements with our directors and certain officers, in addition to the indemnification to be provided in our pending restated certificate of incorporation and provided for in our restated bylaws, and intend to enter into indemnification agreements with any new directors and executive officers in the future. We have purchased and intend to maintain insurance on behalf of any person who is or was a director or officer against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

In addition, as a condition to the Merger, we also entered into an indemnity agreement with the former officer and director of the Public Shell pursuant to which we agreed to indemnify such former officer and director for actions taken by him in his official capacity relating to the consideration, approval and consummation of the Merger and certain related transactions.

The foregoing discussion of our pending restated certificate of incorporation, restated bylaws, indemnification agreements, indemnity agreement, and Delaware law is not intended to be exhaustive and is qualified in its entirety by such restated certificate of incorporation, restated bylaws, indemnification agreements, indemnity agreement, or law.

#### **Provisions of Delaware Law Governing Business Combinations**

We are subject to the "business combination" provisions of Section 203 of the Delaware General Corporation Law. In general, such provisions prohibit a publicly held Delaware corporation from engaging in any "business combination" transactions with any "interested stockholder" for a period of three years after the date on which the person became an "interested stockholder," unless:

- prior to such date, the board of directors approved either the "business combination" or the transaction which resulted in the "interested stockholder" obtaining such status; or

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- upon consummation of the transaction which resulted in the stockholder becoming an “interested stockholder,” the “interested stockholder” owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the “interested stockholder”) those shares owned by (a) persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
  - at or subsequent to such time the “business combination” is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the “interested stockholder.”

A “business combination” is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an “interested stockholder” is a person who, together with affiliates and associates, owns 15% or more of a corporation’s voting stock or within three years did own 15% or more of a corporation’s voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

## EXECUTIVE OFFICER AND DIRECTOR COMPENSATION

Unless we specifically indicate otherwise, all share and per share numbers included in this “Executive Officer and Director Compensation” section have been adjusted as necessary to reflect the exchange of shares in the Merger.

### Summary Compensation Table

The following table shows the total compensation paid or accrued during the last two fiscal years ended December 31, 2012 and 2011 to (1) our President and Chief Executive Officer and (2) our two next most highly compensated executive officers who earned more than \$100,000 during the fiscal year ended December 31, 2012 and were serving as executive officers as of such date.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$) <sup>(1)</sup>	All Other Compensation (\$) <sup>(2)</sup>	Total (\$)
Sharon Mates, Ph.D.	2012	588,400	117,700	100,000	7,750	813,850
<i>Chairman, President and Chief Executive Officer</i>	2011	565,800	313,200 <sup>(3)</sup>	—	7,600	886,600
Lawrence J. Hineline	2012	250,000	17,500	20,000	7,750	295,250
<i>Vice President of Finance, Chief Financial Officer and Secretary</i>	2011	237,600	30,900	—	7,378	275,878
Allen A. Fienberg, Ph.D.	2012	250,400	8,800	20,000	7,750	286,950
<i>Vice President of Business Development</i>	2011	243,100	17,000	—	7,543	267,643

- (1) These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 5 to our audited financial statements for the fiscal years ended December 31, 2012 and 2011 attached as Exhibit 99.1 to this Current Report on Form 8-K for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates.”
- (2) Consists of \$250 in life insurance premiums we paid for a term life insurance policy to benefit the executive officer with a face value of \$150,000, and the balance in matching contributions under our 401(k) plan.
- (3) Dr. Mates received a bonus of \$113,200 for her performance during the fiscal year ended December 31, 2011 plus an additional bonus of \$200,000 for her performance in connection with our entering into the license and collaboration agreement with Takeda Pharmaceutical Company Limited.



## 2012 Fiscal Year Grants of Plan-Based Awards

The following table shows information regarding grants of equity awards that we made during the fiscal year ended December 31, 2012 to each of our executive officers named in the Summary Compensation Table. We did not grant any non-equity incentive plan awards during the fiscal year ended December 31, 2012.

Name	Compensation Committee Approval <sup>(1)</sup>	Grant Date <sup>(1)</sup>	All Other Option Awards: Number of Securities Underlying Options <sup>(#)</sup> <sup>(2)</sup>	Exercise or Base Price of Option Awards <sup>(\$/Sh)</sup> <sup>(3)</sup>	Grant Date Fair Value of Stock and Option Awards <sup>(\$)</sup> <sup>(4)</sup>
Sharon Mates, Ph.D.	12/20/2011	5/1/2012	50,000	2.84	100,000
Lawrence J. Hineine	12/20/2011	5/1/2012	10,000	2.84	20,000
Allen A. Fienberg, Ph.D.	12/20/2011	5/1/2012	10,000	2.84	20,000

- (1) On December 20, 2011, the compensation committee of ITI approved these option grants to be granted following the completion of a valuation of ITI's common stock. Following the completion of the valuation of ITI's common stock, on May 1, 2012 the board of directors of ITI approved these grants at an exercise price of \$2.84 per share. In addition, on December 20, 2012, the compensation committee approved grants of 50,000 options to Dr. Mates, 10,000 options to Mr. Hineine and 7,500 options to Dr. Fienberg (the "Additional Grants") to be granted following the completion of a valuation of ITI's common stock and an increase in the number of shares reserved under ITI's 2003 Equity Incentive Plan. Following the completion of the valuation of ITI's common stock and the increase in the number of shares reserved under ITI's 2003 Equity Incentive Plan, on May 31, 2013 the board of directors of ITI approved the Additional Grants at an exercise price of \$3.26 per share.
- (2) These awards are subject to vesting, as described in detail under "– Outstanding Equity Awards at 2012 Fiscal Year-End" below.
- (3) The 2003 Equity Incentive Plan provides that the exercise price shall be determined by using the fair market value of our common stock, which is defined under the 2003 Equity Incentive Plan as the value of our common stock determined in good faith by our board of directors.
- (4) These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 5 to our audited financial statements for the fiscal years ended December 31, 2012 and 2011 attached as Exhibit 99.1 to this Current Report on Form 8-K for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates."

## Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table

*Sharon Mates, Ph.D.* We entered into an employment agreement with Dr. Mates in February 2008, who has been our President and Chief Executive Officer since 2003. The agreement provides for a salary of \$503,000 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Dr. Mates is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2013, increased Dr. Mates' salary to \$611,900. In 2012, she was awarded a bonus of \$117,700, which represented a bonus of 20% of her then current base salary of \$588,400. In addition, her employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times her base salary; however, we paid a premium in the amount of \$250 on a life insurance policy with a face value of \$150,000, to which she assented. For 2012, we also paid \$7,500 in matching contributions under our 401(k) plan. The employment agreement also provides that Dr. Mates is entitled to participate in

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our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Dr. Mates provides notice that we or she, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

If Dr. Mates' employment is terminated for any reason, she will be entitled to compensation and benefits through the last day of her employment, including accrued but untaken vacation. If her employment is terminated due to her death or disability, we will also pay her or her estate the compensation which would otherwise have been payable to her through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If her employment is terminated without cause by us or she terminates her employment for good reason, she will receive the following severance benefits following her employment termination, on condition that she executes a general release in our favor: (a) payment of 12 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release she executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to her termination; and (c) all of her unvested stock options will become fully vested and exercisable. Dr. Mates will also be entitled to such severance benefits if we elect not to renew her employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Dr. Mates executing a general release in favor of us, returning all our property, and complying with her employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Dr. Mates will not be eligible for such severance benefits if she or we wish to renew the agreement on different terms than those contained in her employment agreement. In the event of a change of control, all of her unvested stock options and restricted stock will immediately vest. If her employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, she terminates her employment for good reason during such period, or she terminates her employment for any reason within one month following a change of control, she will be eligible for the following severance benefits following her employment termination: (a) payment of 18 months of her then current base salary and the pro rata portion of an amount equal to the bonus she was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release, and (b) payment for 18 months of the portion of the COBRA premiums that we paid prior to her termination. Such severance benefits following a change of control are payable on condition that she executes a general release in favor of us, returns all our property and complies with her post-termination obligations under her employment agreement, her proprietary information, inventions, and non-competition agreement, and her general release.

Pursuant to her proprietary information, inventions, and non-competition agreement, Dr. Mates has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of her employment or (ii) compete with us for a period of one year after the later of the termination of her employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

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*Lawrence J. Hinline.* We entered into an employment agreement with Mr. Hinline in February 2008, who has been our Vice President of Finance, Chief Financial Officer and Secretary since 2002. The agreement provides for a salary of \$216,400 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Mr. Hinline is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2013, increased Mr. Hinline's salary to \$257,500. In 2012, he was awarded a bonus of \$17,500, which represented a bonus of 7% of his then current base salary of \$250,000. In addition, his employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times his base salary; however, we paid a premium in the amount of \$250 on a life insurance policy with a face value of \$150,000, to which he assented. For 2012, we also paid \$7,500 in matching contributions under our 401(k) plan. The employment agreement also provides that Mr. Hinline is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Mr. Hinline provides notice that we or he, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

If Mr. Hinline's employment is terminated for any reason, he will be entitled to compensation and benefits through the last day of his employment, including accrued but untaken vacation. If his employment is terminated due to his death or disability, we will also pay him or his estate the compensation which would otherwise have been payable to him through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If his employment is terminated without cause by us or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination, on condition that he executes a general release in our favor: (a) payment of 12 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release he executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to his termination; and (c) all of his unvested stock options will become fully vested and exercisable. Mr. Hinline will also be entitled to such severance benefits if we elect not to renew his employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Mr. Hinline executing a general release in our favor, returning all our property, and complying with his employment agreement, proprietary information, inventions, and non-competition agreement, and the general release and (ii) Mr. Hinline will not be eligible for such severance benefits if he or we wish to renew the agreement on different terms than those contained in his employment agreement. In the event of a change of control, all of his unvested stock options and restricted stock will immediately vest. If his employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, he terminates his employment for good reason during such period, or he terminates his employment for any reason within one month following a change of control, he will be eligible for the following severance benefits following his employment termination: (a) payment of 18 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, which severance payments will be paid in one lump sum on the eighth day following the effective date of the general release, and (b) payment for 18 months of

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the portion of the COBRA premiums that we paid prior to his termination. Such severance benefits following a change of control are payable on condition that he executes a general release in favor of us, returns all our property and complies with his post-termination obligations under his employment agreement, his proprietary information, inventions, and non-competition agreement, and his general release.

Pursuant to his proprietary information, inventions, and non-competition agreement, Mr. Hineline has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of his employment or (ii) compete with us for a period of one year after the later of the termination of his employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

*Allen A. Fienberg, Ph.D.* We entered into an employment agreement with Dr. Fienberg in February 2008, who has been our Vice President of Business Development since 2002. The agreement provides for a salary of \$221,400 effective in February 2008, subject to our annual review and adjustment in the discretion of our board of directors, and that Dr. Fienberg is eligible for bonus payments and stock options as may be awarded by our board of directors. The most recent adjustment, effective on January 1, 2013, increased Dr. Fienberg's salary to \$257,900. In 2012, he was awarded a bonus of \$8,800, which represented a bonus of 3.5% of his then current base salary of \$250,400. In addition, his employment agreement provides that we will pay the premium on a life insurance policy in an amount equal to one and one half times his base salary; however, we paid a premium in the amount of \$250 on a life insurance policy with a face value of \$150,000, to which he assented. For 2012, we also paid \$7,500 in matching contributions under our 401(k) plan. The employment agreement also provides that Dr. Fienberg is entitled to participate in our benefit plans on the same basis as other executive level employees as well as long-term disability insurance and reimbursement for reasonable business expenses. The initial term of the agreement was three years and will be renewed for successive one year terms, unless we or Dr. Fienberg provides notice that we or he, as the case may be, does not wish to renew the agreement or wishes to renew the agreement on different terms than those contained in the agreement.

If Dr. Fienberg's employment is terminated for any reason, he will be entitled to compensation and benefits through the last day of his employment, including accrued but untaken vacation. If his employment is terminated due to his death or disability, we will also pay him or his estate the compensation which would otherwise have been payable to him through the end of the month in which such termination occurs as well as payment for any accrued but untaken vacation. If his employment is terminated without cause by us or he terminates his employment for good reason, he will receive the following severance benefits following his employment termination, on condition that he executes a general release in our favor: (a) payment of 12 months of his then current base salary and the pro rata portion of an amount equal to the bonus he was awarded for the previous year, if any, which severance payments will be paid in one lump sum on the date the general release he executes becomes effective; (b) payment for 12 months of the portion of the COBRA premiums that we paid prior to his termination; and (c) all of his unvested stock options will become fully vested and exercisable. Dr. Fienberg will also be entitled to such severance benefits if we elect not to renew his employment agreement for reasons other than death, disability or cause, but (i) such severance benefits are conditioned on Dr. Fienberg executing a general release in our favor, returning all our property, and complying with his employment agreement, proprietary information, inventions, and non-competition

agreement, and the general release and (ii) Dr. Fienberg will not be eligible for such severance benefits if he or we wish to renew the agreement on different terms than those contained in his employment agreement. In the event of a change of control, 75% of his unvested stock options and restricted stock will immediately vest.

Pursuant to his proprietary information, inventions, and non-competition agreement, Dr. Fienberg has agreed to not (i) solicit customers, consultants, contractors or employees of ours for a period of one year after the termination of his employment or (ii) compete with us for a period of one year after the later of the termination of his employment or the date a court of competent jurisdiction enters an order enforcing the non-competition provision.

The meanings of the terms “cause,” “good reason,” “disability” and “change of control” for purposes of these employment agreements are described below under “Potential Payments upon Termination or Change in Control.”

#### Outstanding Equity Awards at 2012 Fiscal Year-End

The following table shows grants of stock options and grants of unvested stock awards outstanding on the last day of the fiscal year ended December 31, 2012, including both awards subject to performance conditions and non-performance-based awards, to each of the executive officers named in the Summary Compensation Table.

Name(1)	Number of Securities Underlying Unexercised Options (#)(2)		Option Exercise Price (\$)	Option Expiration Date
	Exercisable	Unexercisable		
Sharon Mates, Ph.D.	50,000	0	\$ 0.30	12/16/2013
	50,000	0	\$ 0.50	12/19/2014
	25,000	0	\$ 0.60	12/14/2015
	25,000	0	\$ 1.36	12/5/2016
	37,500	0	\$ 1.50	12/12/2017
	50,000	0	\$ 1.50	12/18/2018
	50,000	0	\$ 2.74	6/10/2020
	33,333	16,667	\$ 2.74	12/21/2020
	16,666	33,334	\$ 2.84	4/30/2022
Lawrence J. Hinline	50,000	0	\$ 0.30	12/16/2013
	37,500	0	\$ 0.50	12/19/2014
	12,500	0	\$ 0.60	12/14/2015
	12,500	0	\$ 1.36	12/5/2016
	12,500	0	\$ 1.50	12/12/2017
	10,000	0	\$ 1.50	12/18/2018
	10,000	0	\$ 2.74	6/10/2020
	6,666	3,334	\$ 2.74	12/21/2020
	3,333	6,667	\$ 2.84	4/30/2022
Allen A. Fienberg, Ph.D.	37,500	0	\$ 0.30	12/16/2013
	37,500	0	\$ 0.50	12/19/2014
	12,500	0	\$ 0.60	12/14/2015
	12,500	0	\$ 1.36	12/5/2016
	12,500	0	\$ 1.50	12/12/2017
	10,000	0	\$ 1.50	12/18/2018
	10,000	0	\$ 2.74	6/10/2020
	6,666	3,334	\$ 2.74	12/21/2020
	3,333	6,667	\$ 2.84	4/30/2022

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- (1) On December 20, 2012, the compensation committee of ITI approved grants of 50,000 options to Dr. Mates, 10,000 options to Mr. Hineline and 7,500 options to Dr. Fienberg (the "Additional Grants") to be granted following the completion of a valuation of ITI's common stock and an increase in the number of shares reserved under ITI's 2003 Equity Incentive Plan. Following the completion of the valuation of ITI's common stock and the increase in the number of shares reserved under ITI's 2003 Equity Incentive Plan, on May 31, 2013 the board of directors of ITI approved the Additional Grants at an exercise price of \$3.26 per share, which are not reflected in this table.
  - (2) Unless otherwise indicated, each option to purchase our common stock vests as to 1/3 of the shares on the first anniversary of the grant date, 1/3 of the shares on the second anniversary of the grant date, and 1/3 of the shares on the third anniversary of the grant date. Each option to purchase our common stock that expires on April 30, 2022 vests as to 1/3 of the shares on December 20, 2012, 1/3 of the shares on December 20, 2013 and 1/3 of the shares on December 20, 2014. Each of these options has a ten year term from the date of grant.

#### **Option Exercises and Stock Vested in 2012**

During the fiscal year ended December 31, 2012, none of our named executive officers exercised any options.

#### **Pension Benefits**

We do not have any qualified or non-qualified defined benefit plans.

#### **Nonqualified Deferred Compensation**

We do not have any nonqualified defined contribution plans or other deferred compensation plans.

#### **Potential Payments upon Termination or Change in Control**

Upon termination of employment without cause or a resignation for good reason, each as defined below, our named executive officers are entitled to receive severance payments. Severance for termination without cause or termination for good reason, each as defined below, for named executive officers is 12 months of base salary plus the pro rata portion of an amount equal to the bonus awarded to such named executive officer for the previous year, if any. In addition, each named executive officer is entitled to payment of 12 months of the portion of the premiums for medical insurance coverage under COBRA that we paid prior to such named executive officer's termination. Payment of these severance benefits is conditioned on the named executive officer signing a general release in our favor.

The table below summarizes the potential payments and benefits to each of our named executive officers assuming a termination without cause or resignation for good reason had occurred as of December 31, 2012.

<b>Name</b>	<b>Severance Payments(1)</b>	<b>Bonus Payments(2)</b>	<b>Post-Termination Benefits(3)</b>	<b>Total Benefits</b>
Sharon Mates, Ph.D.	\$ 588,400	\$ 113,200	\$ 14,976	\$716,576
Lawrence J. Himeline	\$ 250,000	\$ 30,900	\$ 14,976	\$295,876
Allen A. Fienberg, Ph.D.	\$ 250,400	\$ 17,000	\$ 14,976	\$282,376

- (1) The severance agreements for our named executive officers are set forth in their respective employment agreements.
- (2) Reflects a pro rata portion of the named executive officer's 2011 bonus based on the period from January 1, 2012 through December 31, 2012, which equals the full amount of the named executive officer's 2011 bonus. However, the 2012 bonus had already been paid to such named executive officers prior to December 31, 2012 in the amounts set forth in the "Summary Compensation Table" above, so we would not have paid the amounts set forth in this column at December 31, 2012 in addition to the 2012 bonus payments already made.
- (3) Represents premiums that would be payable by us for continuation of the executive's medical and dental insurance coverage, assuming a termination without cause or resignation for good reason had occurred as of December 31, 2012.

The table below summarizes the potential payments and benefits to each of our named executive officers assuming a termination following a change in control had occurred at December 31, 2012. Each of our named executive officers has agreed in writing that the Merger does not constitute a change in control under their respective employment agreements.

<b>Name</b>	<b>Severance Payments(1)</b>	<b>Bonus Payments(1)(2)</b>	<b>Value of Additional Vested Option Awards(1)(3)</b>	<b>Post- Termination Benefits(1)(4)</b>	<b>Total Benefits</b>
Sharon Mates, Ph.D.	\$ 882,600	\$ 113,200	\$ 22,668	\$ 22,464	\$1,040,932
Lawrence J. Himeline	\$ 375,000	\$ 30,900	\$ 4,533	\$ 22,464	\$ 432,897
Allen A. Fienberg, Ph.D.	N/A	N/A	\$ 3,400	N/A	\$ 3,400

- (1) Each of our named executive officers, except for Dr. Fienberg, shall, if the executive's employment is terminated for reasons other than death or disability within three months before or 12 months following a change of control, the executive terminates his or her employment for good reason during such period, or the executive terminates his or her employment for any reason within one month following a change of control, be entitled to (a) payment of 18 months of the executive's then current base salary and the pro rata portion of an amount equal to the bonus the executive was awarded for the previous year, if any, and (b) payment by us of 18 months of the portion of the premiums for medical insurance coverage under COBRA that we paid prior to such executive's termination. Such severance benefits following a change of control are payable on condition that the executive executes a general release in favor of us, returns all our property and complies with his or her post-termination obligations under his or her employment agreement, proprietary information, inventions, and non-competition agreement, and general release. In addition, in the event of a change of control, any unvested stock options or restricted stock awarded to Dr. Mates or Mr. Himeline will immediately vest and become exercisable and 75% of any unvested stock options or restricted stock awarded to Dr. Fienberg will immediately vest and become exercisable.

- (2) Reflects a pro rata portion of the named executive officer's 2011 bonus based on the period from January 1, 2012 through December 31, 2012, which equals the full amount of the named executive officer's 2011 bonus. However, the 2012 bonus had already been paid to such named executive officers prior to December 31, 2012 in the amounts set forth in the "Summary Compensation Table" above, so we would not have paid the amounts set forth in this column at December 31, 2012 in addition to the 2012 bonus payments already made.
- (3) This represents the intrinsic value of the number of option shares that would vest, assuming a change of control termination had occurred at December 31, 2012.
- (4) Represents premiums that would be payable by us for continuation of the executive's medical and dental insurance coverage, assuming a change of control termination had occurred at December 31, 2012.

The table below summarizes the potential payments and benefits to each of our named executive officers assuming a change in control without termination had occurred at December 31, 2012.

<u>Name</u>	<u>Severance Payments</u>	<u>Bonus Payments</u>	<u>Value of Additional Vested Option Awards(1)(2)</u>	<u>Post- Termination Benefits</u>	<u>Total Benefits</u>
Sharon Mates, Ph.D.	N/A	N/A	\$ 22,668	N/A	\$22,668
Lawrence J. Hineline	N/A	N/A	\$ 4,533	N/A	\$ 4,533
Allen A. Fienberg, Ph.D.	N/A	N/A	\$ 3,400	N/A	\$ 3,400

- (1) In the event of a change of control, any unvested stock options or restricted stock awarded to Dr. Mates or Mr. Hineline will immediately vest and become exercisable and 75% of any unvested stock options or restricted stock awarded to Dr. Fienberg will immediately vest and become exercisable.
- (2) This represents the intrinsic value of the number of option shares that would vest, assuming a change of control without termination had occurred at December 31, 2012.

For purposes of severance payments, "good reason" is defined as an executive resigning after the occurrence of one of the following events without the executive's written consent:

- The assignment to the executive of any duties or responsibilities which result in the material diminution of the executive's position;
- a reduction by the Company in the executive's annual base salary of 5% or greater with respect to Dr. Mates and Mr. Hineline, and of greater than 5% with respect to Dr. Fienberg;
- a material change in the geographic location at which the executive is required to perform services; or
- material breach by the Company of any material provision of the executive's employment agreement.

The executive must provide us with written notice within 60 days after the occurrence of a good reason event, and we have 30 days to correct the event after receipt of the notice.



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For purposes of severance payments, “cause” is defined as a termination by us after the occurrence of one of the following events:

- a good faith finding by the Company that the executive has engaged in gross negligence or gross misconduct that is materially injurious to the Company;
- the executive’s conviction of a felony or crime involving fraud or embezzlement of Company property;
- the executive’s material breach of the executive’s employment agreement which, if curable, has not been cured by the executive within 60 days after he or she receives written notice from the Company stating with reasonable specificity the nature of the breach;
- material breach of fiduciary duty; or
- refusal to follow or implement a clear and reasonable directive of our board of directors as a whole (or an officer of the Company, in the case of Mr. Hine and Dr. Fienberg), provided that such directive is ethical and legal and which, if curable, has not been cured by the executive within 60 days after he or she receives written notice from the Company stating with reasonable specificity the nature of such refusal.

For purposes of severance payments, the determination of “disability” will occur when the executive is unable due to a physical or mental condition to perform the essential functions of his or her position with or without reasonable accommodation for 90 consecutive days, or 180 days in the aggregate whether or not consecutive, during any 360-day period, or based on the written certification by a licensed physician of the likely continuation of such condition for such period.

For purposes of severance payments, a “change in control” means:

- a sale, lease or other disposition of all or substantially all of the assets of the Company;
- a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, own less than 50% of the outstanding voting power of the surviving entity (and its parent) following the consolidation, merger or reorganization; or
- any transaction (or series of related transactions involving a person or entity, or a group of affiliated persons or entities) in which in excess of 50% of the Company’s outstanding voting power is transferred.

Notwithstanding the foregoing, a “change in control” will not be deemed to occur on account of the sale or acquisition of the Company’s capital stock by institutional investors or venture capital firms for the primary purpose of obtaining financing for the Company.

### Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2012 to each of our directors, other than Dr. Mates who does not receive compensation for her service as a director.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards <sup>(1)</sup> (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation (\$)	Total (\$)
David Kipnis, M.D. <sup>(2)(3)</sup>	N/A	N/A	24,500	N/A	N/A	N/A	24,500
Richard Lerner, M.D. <sup>(4)</sup>	N/A	N/A	24,500	N/A	N/A	N/A	24,500
Joel S. Marcus <sup>(5)</sup>	N/A	N/A	24,500	N/A	N/A	N/A	24,500

- (1) These amounts represent the aggregate grant date fair value for option awards granted to our named executive officers, computed in accordance with FASB ASC Topic 718. See Note 5 to our audited financial statements for the fiscal years ended December 31, 2012 and 2011 attached as Exhibit 99.1 to this Current Report on Form 8-K for details as to the assumptions used to calculate the fair value of the option awards. See also our discussion of stock-based compensation under “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates.”
- (2) Dr. Kipnis resigned from the board of directors effective December 31, 2012. Effective January 1, 2013, the board of directors appointed Christopher Alafi, Ph.D. as a director, and effective May 10, 2013, the board of directors appointed Sir Michael Rawlins as a director.
- (3) As of December 31, 2012, Dr. Kipnis held 102,500 options to purchase shares of our common stock, of which 96,250 options were vested.
- (4) As of December 31, 2012, Dr. Lerner held 110,000 options to purchase shares of our common stock, of which 103,750 options were vested.
- (5) As of December 31, 2012, Mr. Marcus held 77,500 options to purchase shares of our common stock, of which 71,250 options were vested.

### Director Compensation Policy

As compensation to our non-employee directors for the year ending December 31, 2013 and the years ended December 31, 2012 and 2011, we granted options to purchase 20,000 shares, 12,500 shares and 12,500 shares of our common stock, respectively, to each of our non-employee directors serving during such years. We granted any non-employee director who resigned from or joined the ITI board of directors during such years the pro rata portion of the annual option grant representing the portion of such year during which such non-employee director served. We intend to adopt a non-employee director compensation policy designed to ensure that the compensation aligns the directors’ interests with the long-term interests of the stockholders, that the structure of the compensation is simple, transparent and easy for stockholders to understand and that our directors are fairly compensated.

## EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2012.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders <sup>(1) (2)</sup>	1,707,113	\$ 1.38	44,867 <sup>(1)</sup>
Equity compensation plans not approved by security holders	—	—	—
<b>Total</b>	<b>1,707,113<sup>(2)</sup></b>	<b>\$ 1.38<sup>(2)</sup></b>	<b>44,867<sup>(2)</sup></b>

- (1) This plan consists of the 2003 Equity Incentive Plan. The 2003 Equity Incentive Plan terminated by its terms in July 2013. As a result of such termination, no additional awards may be granted under the 2003 Equity Incentive Plan, but equity awards previously granted under the 2003 Equity Incentive Plan will remain outstanding and continue to be governed by the terms of the 2003 Equity Incentive Plan.
- (2) The table above does not include shares that are reserved for issuance under the 2013 Equity Incentive Plan, which was adopted in connection with the Merger, which consists of 799,934 shares reserved plus up to an additional 1,462,380 shares reserved solely after the cancellation or expiration of any unexercised stock options that we assumed in the Merger, subject to adjustment as provided in the plan.

### 2003 Equity Incentive Plan

The ITI 2003 Equity Incentive Plan, as amended, was adopted by the board of directors of ITI in July 2003 and by the stockholders of ITI in September 2003. The 2003 Equity Incentive Plan was subsequently amended in January 2006, February 2010 and December 2012, and expired by its terms in July 2013. As a result of such expiration, no additional awards may be granted under the 2003 Equity Incentive Plan, but equity awards previously granted under the 2003 Equity Incentive Plan will remain outstanding and continue to be governed by the terms of the 2003 Equity Incentive Plan. In connection with the Merger, we assumed the options then outstanding under the 2003 Equity Incentive Plan, and immediately following the Merger on August 29, 2013, the only outstanding awards under the 2003 Equity Incentive Plan were options to purchase 1,462,380 shares of our common stock. The 2003 Equity Incentive Plan is administered by our board of directors.

If we are acquired, the surviving or acquiring company may assume or continue the outstanding options by substituting either (a) the consideration payable with respect to the outstanding shares of common stock in connection with the acquisition or (b) shares of stock of the successor or acquiring company. If the surviving or acquiring company does not assume or continue the outstanding options, the outstanding options will be accelerated in full prior to the effective time of the acquisition and will terminate if not exercised at or prior to such effective time.

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## 2013 Equity Incentive Plan

In August 2013, our board of directors approved the 2013 Equity Incentive Plan. The 2013 Equity Incentive Plan will be effective on November 7, 2013, the date that is 20 days after we mailed the definitive information statement on Schedule 14C to our sole stockholder prior to the Merger or such later date as required by the Exchange Act or other applicable law. Unless sooner terminated by our board of directors or our stockholders, the 2013 Equity Incentive Plan will expire 10 years from its date of effectiveness. Under our 2013 Equity Incentive Plan, we may grant incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights and other stock awards to our employees, directors and consultants.

The maximum number of shares of our common stock that may be delivered in satisfaction of awards under the 2013 Equity Incentive Plan is 799,934 shares, plus up to an additional maximum of 1,462,380 shares which may be issued solely after the cancellation or expiration of any unexercised stock options that we assumed in the Merger. These numbers are subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

In addition, the 2013 Equity Incentive Plan contains an “evergreen” provision, which allows for an annual increase in the number of shares of our common stock available for issuance under the 2013 Equity Incentive Plan on January 1 of each year commencing on January 1, 2014 and ending upon expiration of the 2013 Equity Incentive Plan. The annual increase in the number of shares shall be equal to the lesser of:

- 800,000 shares of our common stock;
- 4% of the number of shares of our common stock outstanding as of such date; and
- such lesser number of shares as determined by our board of directors prior to the applicable January 1<sup>st</sup> date.

Shares of our common stock to be issued under the 2013 Equity Incentive Plan may be authorized but unissued shares of our common stock or previously issued shares acquired by us. Any shares of our common stock underlying awards that otherwise expire, terminate, or are forfeited or reacquired by us will again be available for issuance under the 2013 Equity Incentive Plan.

The 2013 Equity Incentive Plan will be administered by our board of directors until we establish a compensation committee. Our board of directors, or compensation committee once established, will have full power and authority to determine the terms of awards granted pursuant to this plan, including:

- which employees, directors and consultants shall be granted awards;

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- the type of award to be granted;
  - the terms and conditions of each award, including the schedule upon which the participant may exercise or otherwise receive common stock under the award; and
  - all other terms and conditions upon which each award may be granted in accordance with the 2013 Equity Incentive Plan.

However, at such time as the Company may be subject to Section 162(m) of the Internal Revenue Code of 1986, as amended, or the Code, a maximum of 200,000 shares of our common stock subject to options, stock appreciation rights and other awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the award is granted may be granted to any one participant during any one calendar year.

Our board of directors may amend or discontinue the 2013 Equity Incentive Plan at any time and may amend any outstanding award. No such amendment may materially impair the rights under any outstanding award without the holder's consent. Stockholder approval will be required for any amendment to the 2013 Equity Incentive Plan to the extent such approval is required by law, including the Code or applicable stock exchange requirements.

If we are acquired, our board of directors (or compensation committee, once established) will (i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the award or to substitute a similar award for the award; (ii) cancel or arrange for the cancellation of the award, to the extent not vested or not exercised prior to the effective time of the transaction, in exchange for such cash consideration, if any, as our board of directors in its sole discretion, may consider appropriate; and (iii) make a payment, in such form as may be determined by our board of directors equal to the excess, if any, of (A) the value of the property the holder would have received upon the exercise of the award immediately prior to the effective time of the transaction, over (B) any exercise price payable by such holder in connection with such exercise. In addition in connection with such transaction, our board of directors may accelerate the vesting, in whole or in part, of the award (and, if applicable, the time at which the award may be exercised) to a date prior to the effective time of such transaction and may arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to an award.

#### **CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS**

Since January 1, 2011, ITI has engaged in the following transactions with its directors, executive officers and holders of more than 5% of its voting securities, which we refer to as our principal stockholders, and affiliates or immediate family members of

our directors, executive officers and principal stockholders. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

As described above, the following executive officers and directors held the following positions at ITI prior to the Merger:

- Sharon Mates, Ph.D., our President, Chief Executive Officer and Chairman of our board of directors, was the President, Chief Executive Officer and Chairman of the board of directors of ITI prior to the Merger.
- Lawrence J. Hineine, our Vice President of Finance, Chief Financial Officer and Secretary, was the Vice President of Finance, Chief Financial Officer and Secretary of ITI prior to the Merger.
- Allen A. Fienberg, Ph.D., our Vice President of Business Development, was the Vice President of Business Development of ITI prior to the Merger.
- Lawrence P. Wennogle, Ph.D., our Vice President, Drug Discovery, was the Vice President, Drug Discovery of ITI prior to the Merger.
- Kimberly E. Vanover, Ph.D., our Vice President, Clinical Development, was the Vice President, Clinical Development of ITI prior to the Merger.
- Our directors Christopher Alafi, Ph.D., Richard Lerner, M.D., Joel S. Marcus and Sir Michael Rawlins, M.D., FRCP, FMedSci were each directors of ITI prior to the Merger.

Some of our directors are affiliated with our principal stockholders as indicated in the table below:

<u>Director</u>	<u>Affiliation with Principal Stockholder</u>
Christopher Alafi, Ph.D.	Dr. Alafi is a General Partner of Alafi Capital Company, LLC.
Joel S. Marcus	Mr. Marcus is co-founder, Chairman of the board of directors, Chief Executive Officer, President and a director of Alexandria Real Estate Equities, Inc., which is the managing member of Alexandria Equities, LLC.

The directors of ITI were previously selected as directors of ITI in accordance with the terms of ITI's then existing restated certificate of incorporation, which is no longer effective following the Merger, and ITI's Second Amended and Restated Voting Agreement effective as of October 25, 2007, as amended, which was terminated immediately prior to the Effective Time of the Merger.

### Convertible Promissory Notes Issued in 2012 and 2013

In October 2012, ITI entered into a convertible note purchase agreement with certain investors pursuant to which ITI issued convertible promissory notes having an aggregate principal amount of approximately \$15.3 million, which were issued on October 25, 2012, November 14, 2012 and March 20, 2013. Certain of these convertible promissory notes were purchased by our principal stockholders in the following amounts and on the following dates:

Name of Beneficial Owner <sup>(1)</sup>	Original Principal Amount of Convertible Notes	Issuance Date
Alafi Capital Company, LLC	\$ 6,423,419	October 25, 2012
Alexandria Equities, LLC	\$ 1,812,307	October 25, 2012
Sosland Family Trust B Partnership	\$ 4,783,094	October 25, 2012

- (1) Does not include the convertible promissory note having a principal amount of \$124,975 held by J.D.F. Holdings Ltd., in which Allen A. Fienberg, Ph.D., our Vice President of Business Development, holds a 20% ownership interest. Dr. Fienberg has no voting or investment control with respect to any of the securities owned by J.D.F. Holdings Ltd.

The convertible promissory notes were unsecured, accrued interest at the rate of 6% per year and had a maturity date of October 25, 2013. The convertible promissory notes converted into shares of ITI common stock in connection with the Private Placement discussed in “ – Common Stock Issued in Private Placement in 2013” below. In addition, ITI paid \$7,200 to the purchasers’ legal counsel for fees and expenses of purchasers’ legal counsel incurred in connection with the convertible promissory note financing.

### Common Stock Issued in Private Placement in 2013

The following table summarizes ITI’s sales of its common stock on August 29, 2013 in the Private Placement to our officers, directors and beneficial owners of more than five percent of any class of our voting securities. The purchase price of \$3.1764 per share (as adjusted to \$6.3528 after giving effect to the Merger) was the fair market value as determined by arms-length negotiations between sophisticated investors and ITI’s management and board of directors. In addition, the holders of the convertible promissory notes elected to convert the aggregate principal amount plus accrued interest on all of ITI’s outstanding convertible promissory notes into shares of ITI common stock at the purchase price of \$3.1764 per share (as adjusted to \$6.3528 after giving effect to the Merger). ITI received no additional consideration from the conversion of the convertible promissory notes.

Name of Beneficial Owner <sup>(1)</sup>	Purchase Price of ITI Common Stock	Principal Plus Accrued Interest of Convertible Notes Through Date of Conversion	Shares of ITI Common Stock Issued <sup>(5)</sup>
Sharon Mates, Ph.D. <sup>(2)</sup>	\$ 24,998	—	7,870
Joel S. Marcus and Barbara A. Marcus Family Trust <sup>(3)</sup>	\$ 100,006	—	31,484
Alafi Capital Company, LLC	\$ 4,747,498	\$ 6,748,637	3,619,234
Moshe Alafi <sup>(4)</sup>	\$ 100,006	—	31,484
Alexandria Equities, LLC	\$ 1,339,462	\$ 1,904,064	1,021,133
Entities affiliated with Fidelity Investments	\$ 12,700,003	—	3,998,238
David N. Sosland Trust A	\$ 900,004	—	283,341
Sosland Family Trust B Partnership	\$ 400,006	\$ 5,025,263	1,707,993
The Sosland Foundation	\$ 2,235,128	—	703,667

- (1) Does not include 104,301 shares of ITI common stock issued to J.D.F Holdings Ltd., in which Allen A. Fienberg, Ph.D., our Vice President of Business Development, holds a 20% ownership interest. Dr. Fienberg has no voting or investment control with respect to any of the shares owned by J.D.F. Holdings Ltd.
- (2) Dr. Mates is our Chairman, President and Chief Executive Officer.
- (3) Mr. Marcus is one of our directors. Mr. Marcus may also be deemed to beneficially own the shares held by Alexandria Equities, LLC set forth in the table.
- (4) Moshe Alafi may also be deemed to beneficially own the shares held by Alafi Capital Company, LLC set forth in the table.
- (5) Does not reflect the adjustment in the number of shares as a result of the Merger.

At the Effective Time of the Merger, on August 29, 2013, each share of ITI preferred stock and ITI common stock outstanding immediately prior to the Effective Time was exchanged for 0.5 shares of the Company's common stock. The following table summarizes the exchange of the outstanding shares of ITI preferred stock and common stock at the Effective Time by our officers, directors and beneficial owners of more than five percent of any class of our voting securities.

<b>Name of Beneficial Owner</b>	<b>Number of Shares of ITI Preferred Stock Held Immediately Prior to Exchange</b>	<b>Number of Shares of ITI Common Stock Held Immediately Prior to Exchange</b>	<b>Number of Shares of Company Common Stock Held Immediately Following Exchange</b>
Sharon Mates, Ph.D.(1)	—	2,107,870	1,053,935
Lawrence J. Himeline(2)	—	100,000	50,000
Allen A. Fienberg, Ph.D.(3)	—	475,000	237,500
Lawrence P. Wennogle(4)	—	200,000	100,000
Christopher Alafi, Ph.D.(5)	1,007,505	0	503,753
Richard Lerner, M.D.(6)	—	75,000	37,500
Joel S. Marcus and Barbara A. Marcus Family Trust(7)	—	31,484	15,742
Alafi Capital Company, LLC	3,466,535	3,619,234	3,542,885
Moshe Alafi(8)	—	31,484	15,742
Alexandria Equities, LLC	1,546,579	1,021,133	1,283,856
Entities affiliated with Fidelity Investments	—	3,998,238	1,999,120
Paul Greengard, Ph.D.(9)	—	2,262,500	1,131,250
David N. Sosland Trust A	1,131,233	283,341	707,287
The Sosland Family Trust B Partnership	2,189,115	1,707,993	1,948,554
The Sosland Foundation	761,429	703,667	732,548

- (1) Dr. Mates is our Chairman, President and Chief Executive Officer.
- (2) Mr. Himeline is our Vice President of Finance, Chief Financial Officer and Secretary.
- (3) Dr. Fienberg is our Vice President of Business Development. Does not include: (i) 311,745 shares of ITI preferred stock and 104,301 shares of ITI common stock held by J.D.F. Holdings Ltd., in which Dr. Fienberg holds a 20% ownership interest; or (ii) 100,000 shares of ITI common stock held by two trusts for the benefit of members of Dr. Fienberg's family, which were exchanged for an aggregate of 258,023 shares of our common stock at the Effective Time. Dr. Fienberg has no voting or investment control with respect to any of the shares owned by J.D.F. Holdings Ltd. or held in the trusts.



- (4) Dr. Wennogle is our Vice President, Drug Discovery.
- (5) Dr. Alafi is one of our directors. Consists of shares held by a trust for the benefit of members of Dr. Alafi's family. Dr. Alafi may also be deemed to beneficially own the shares held by Alafi Capital Company, LLC set forth in the table. Does not include 1,007,550 shares of ITI preferred stock, which were exchanged for 503,776 shares of our common stock at the Effective Time, held by two other trusts for the benefit of members of Dr. Alafi's family, as Dr. Alafi does not have voting or investment control over the shares held by those trusts.
- (6) Dr. Lerner is one of our directors. Consists of shares held by the Lerner Family Trust UAD 11/14/94, or the Lerner Family Trust. Dr. Lerner shares voting and investment control with respect to the shares held by the Lerner Family Trust.
- (7) Mr. Marcus is one of our directors. Mr. Marcus may also be deemed to beneficially own the shares held by Alexandria Equities, LLC set forth in the table.
- (8) Moshe Alafi may also be deemed to beneficially own the shares held by Alafi Capital Company, LLC set forth in the table.
- (9) Does not include 3,000,000 shares of ITI common stock, which were exchanged for 1,500,000 shares of our common stock at the Effective Time, held by six trusts for the benefit of members of Dr. Greengard's family, as the trustee of these trusts, Ursula von Rydingsvard, who is Dr. Greengard's spouse, has sole voting and investment control over the shares held by the trusts.

#### Assumption of Outstanding Stock Options in Merger

At the Effective Time, on August 29, 2013, the Company assumed all options to purchase ITI common stock then outstanding under the ITI 2003 Equity Incentive Plan, and such options became exercisable for an aggregate of 1,462,380 shares of Company common stock, subject to the vesting and other terms of such options. The vesting of such options was not accelerated as a result of the Merger. The following table provides the number of outstanding options and the weighted average exercise price of such options under the 2003 Equity Incentive Plan held by our officers, directors and beneficial owners of more than five percent of any class of our voting securities that the Company assumed from ITI in connection with the Merger, as adjusted for the exchange ratio in the Merger:

<b>Name of Beneficial Owner</b>	<b>Number of Shares of the Company's Common Stock Underlying Outstanding Options</b>	<b>Weighted Average Exercise Price Per Share</b>
Sharon Mates, Ph.D.	387,500	\$ 2.02
Lawrence J. Hineline	125,000	\$ 1.54
Allen A. Fienberg, Ph.D.	122,500	\$ 1.51
Lawrence P. Wennogle, Ph.D.	130,000	\$ 1.34
Kimberly E. Vanover, Ph.D.	49,750	\$ 2.38
Christopher Alafi, Ph.D.	29,375	\$ 3.26
Richard Lerner, M.D.	105,000	\$ 2.49
Joel S. Marcus	110,000	\$ 2.42
Sir Michael Rawlins, M.D., FRCP, FMedSci	27,000	\$ 3.26

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## **The Redemption**

Immediately following the Effective Time, pursuant to the terms of a Redemption Agreement dated August 29, 2013 by and among the Company and its then-current sole stockholder, we completed the closing of a redemption of 5,000,000 shares of Company common stock from our then-current sole stockholder in consideration of \$60,000, plus professional costs related to the transaction not to exceed \$20,000. The 5,000,000 shares constituted all of the issued and outstanding shares of the Company's capital stock, on a fully-diluted basis, immediately prior to the Merger.

## **Agreements with Stockholders**

### ***Termination of Existing Stockholder Agreements***

In connection with ITI's Series C preferred stock financing in 2007 and 2010, ITI entered into various stockholder agreements with the holders of its common stock and preferred stock relating to voting rights, information rights and registration rights, among other things. The stockholder agreements terminated immediately prior to the Effective Time of the Merger. Parties to the existing registration rights agreement, however, as well as our directors and executive officers and all of our other stockholders, were provided with an opportunity to become parties to the registration rights agreement that ITI entered into in connection with the Private Placement, as discussed below under "– Registration Rights Agreement."

### ***Registration Rights Agreement***

At the closing of the Private Placement, ITI entered into a registration rights agreement with the investors in the Private Placement and also the existing stockholders of ITI who agreed to become parties to certain provisions of the agreement or who choose to become parties in the future, which covers substantially all of our outstanding shares of common stock as of September 30, 2013. We assumed the registration rights agreement in connection with the Merger. Pursuant to the registration rights agreement and subject to the rules and regulations of the SEC, we have agreed to file a shelf registration statement covering the resale of the shares of our common stock held by the investors in the Private Placement and the shares of our common stock held by the former stockholders of ITI who are parties to the agreement. We are required to file the shelf registration statement within 45 days of the date of the registration rights agreement (October 13, 2013). We filed the registration statement that we are required to file under the registration rights agreement on September 18, 2013, but such registration statement has not yet been declared effective by the SEC. In the event fewer than all of our outstanding shares of common stock can be registered pursuant to the so-called Rule 415 doctrine, priority will be given to the shares issued in the Private Placement, but in such event at least 25% of the shares registered shall be those held by ITI's existing stockholders prior to the Private Placement.

We will be liable to each investor in the Private Placement (but not to the former stockholders of ITI who are parties to the agreement) for liquidated damages, on a 30-day basis, equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor, subject to an overall cap of 5%, (i) if we fail to file the registration statement on time, (ii) if the registration statement is not declared effective within 150 days from the date of the registration rights agreement (January 26, 2014), (iii) if we suspend (subject to limited blackout periods described below) or terminate the registration statement prior to the date which is the earlier of (x) the third anniversary of its effectiveness (or the third

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anniversary of the date on which all registrable shares are included therein, if later) and (y) the date on which all of the registrable shares cease to be registrable shares, or (iv) in the event one or more suspensions of the effectiveness of the registration statement exceeds 60 days in the aggregate during any 12-month period. We will be permitted to suspend the registration statement one or more times during any 12-month period provided such suspensions do not exceed 30 consecutive days or 60 days in the aggregate in any 12-month period. Any suspension associated with our filing of an annual, periodic or current report, as required by the Exchange Act, will be permitted and will not be counted against the 60 day limitation. Any shares not registered due to the Rule 415 doctrine will not be subject to liquidated damages. Expenses with respect to the filing and effectiveness of such registration statement (but not selling expenses, or underwriter or agent compensation) will be paid by us, including expenses of one counsel for the selling stockholders.

#### ***Lock-Up Provisions in Registration Rights Agreement***

One of the provisions of the registration rights agreement that is applicable to the former stockholders of ITI who are parties to the agreement, other than the investors in the Private Placement, who hold an aggregate of approximately 12,603,527 shares of common stock, is a lock-up provision pursuant to which these stockholders agreed, subject to specified exceptions, not to sell, transfer, dispose of, contract to sell, sell any option or contract to purchase, or otherwise transfer or dispose of, directly or indirectly, without the written consent of Leerink Swann LLC or, in certain circumstances, the two lead institutional investors in the Private Placement, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock until the earlier of (a) up to 180 days (as requested by the lead underwriter) after the date on which our shares of common stock are listed for trading on a national securities exchange in connection with a firm commitment underwritten public offering by us with gross proceeds to us of at least \$40 million, or (b) the date that is 18 months following the date of the Merger (February 28, 2015). These lock-up provisions will not apply to, among other things, shares of common stock acquired in connection with any follow-on securities offerings by us or in open market transactions, or upon the exercise of stock options granted pursuant to our equity incentive plans, so long as the shares acquired upon exercise remain subject to the lock-up provisions in the agreement, or certain gifts and other transfers for estate-planning purposes or by stockholders who are entities to their limited partners, members or stockholders, as specified in the agreement. In the event that a former stockholder of ITI was also an investor in the Private Placement, then these lock-up provisions in the agreement will only apply with respect to the shares held by such stockholder that were not purchased in the Private Placement. Under the registration rights agreement, we did not enter into any lock-up agreement or other restriction on the transfer or registration of the shares of our common stock acquired by the investors in the Private Placement (other than those imposed by non-disclosure agreements and the requirement that each investor continue to hold 200 shares of ITI common stock (which were exchanged for 100 shares of our common stock in the Merger) until the earlier of (y) the date on which our shares are listed on a national securities exchange or (z) the date 18 months after the closing of the Private Placement (February 28, 2015)).

#### **Indemnification Agreements**

We have entered into indemnification agreements with each of our directors and certain of our officers. The indemnification agreements, our

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pending restated certificate of incorporation and our restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, as a condition to the Merger, we also entered into an indemnity agreement with the former sole officer and director of the Company pursuant to which we agreed to indemnify him for actions taken by him in his official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions. See “Indemnification of Directors and Officers.”

#### **Indemnity Agreement**

As a condition to the Merger, we entered into an Indemnity Agreement with our former sole officer and director pursuant to which we agreed to indemnify such former officer and director for actions taken by him in his official capacities relating to the consideration, approval and consummation of the Merger and certain related transactions.

#### **Policy for Approval of Related Person Transactions**

We do not currently have a policy for the review and approval of related person transactions. We intend to adopt such a policy when we adopt an audit committee charter and establish an audit committee, which we expect will be responsible for reviewing and approving all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our board of directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest.

#### **Legal Proceedings**

We are not aware of any material proceedings in which any of our directors, executive officers or affiliates, any owner of record or beneficially of more than 5% of our common stock, or any associate of any such director, officer, affiliate or security holder is a party adverse to us or any of our subsidiaries or has a material interest adverse to us.

#### **Stockholder Communication with the Board of Directors**

Stockholders may send communications to our Board of Directors by writing to Intra-Cellular Therapies, Inc., 3960 Broadway New York, New York 10032, Attention: Board of Directors.

#### **Other Information**

We are required to file periodic reports, proxy statements and other information with the SEC. You may read and copy this information at the Public Reference Room of the SEC, 100 F. Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You may also obtain a copy of these reports by accessing the SEC’s website at <http://www.sec.gov>. You may also send communications to our Board of Directors at: Intra-Cellular Therapies, Inc., 3960 Broadway, New York, New York 10032, Attention: Board of Directors.

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## MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

There is not currently, and there has never been, any market for any of our securities. Our securities are not eligible for trading on any national securities exchange and are not quoted for sale on any over-the-counter markets, including the Over-the-Counter Bulletin Board.

As of September 30, 2013, we had 22,134,647 outstanding shares of common stock and no outstanding shares of preferred stock. As of September 30, 2013, there were 258 holders of record of our common stock.

## DESCRIPTION OF SECURITIES

The following statements are qualified in their entirety by reference to the detailed provisions of our certificate of incorporation, pending restated certificate of incorporation and restated bylaws.

### *Capital Structure*

We currently have authorized capital stock of 110,000,000 shares, of which 100,000,000 are designated as common stock, par value \$0.0001 per share, and 10,000,000 shares are designated as preferred stock, par value \$0.0001 per share. Under our restated certificate of incorporation approved by our sole director and sole stockholder prior to the Merger, which we expect to file on or about November 7, 2013, the date that is 20 days after we filed with the SEC and mailed to such stockholder a definitive Schedule 14C reporting the adoption of the restated certificate of incorporation, we will have authorized capital stock consisting of 105,000,000 shares, of which 100,000,000 will be designated as common stock, par value \$0.0001 per share, and 5,000,000 shares will be designated as preferred stock, par value \$0.0001 per share.

As of September 30, 2013, 22,134,647 shares of our common stock and no shares of our preferred stock were issued and outstanding.

### *Common Stock*

The holders of our common stock are entitled to one vote per share on matters on which our stockholders vote. There are no cumulative voting rights. Subject to any preferential dividend rights of any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if declared by our board of directors, out of funds that we may legally use to pay dividends. If we liquidate or dissolve, holders of our common stock are entitled to share ratably in our assets once our debts and any liquidation preference owed to any then-outstanding preferred stockholders are paid. Our restated certificate of incorporation does not provide our common stock with any redemption, conversion or preemptive rights.

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### **Preferred Stock**

If we issue preferred stock in the future, such preferred stock would have priority over common stock with respect to dividends and other distributions, including the distribution of assets upon liquidation. Our board of directors has the authority, without further stockholder authorization, to issue from time to time up to 10,000,000 shares of preferred stock in one or more series and to fix the terms, limitations, voting rights, relative rights and preferences and variations of each series. This amount will be set at 5,000,000 shares upon the effectiveness of our restated certificate of incorporation. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change of control of us or an unsolicited acquisition proposal.

### **Dividend Policy**

We have never paid cash dividends on any of our capital stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

### **Warrant**

As of September 30, 2013, we had one warrant outstanding to purchase 1,822 shares of our common stock at an exercise price of \$6.0264 per share.

### **Registration Rights**

On August 29, 2013, ITI entered into a registration rights agreement with the investors in the Private Placement and also the existing stockholders of ITI who agreed to become parties to certain provisions of the agreement or who choose to become parties in the future, which covers substantially all of our outstanding shares of common stock as of September 30, 2013. We assumed the registration rights agreement in connection with the Merger.

#### **Resale Registration Rights**

Pursuant to the registration rights agreement and subject to the rules and regulations of the SEC, we have agreed to file a shelf registration statement covering the resale of the shares of our common stock held by the investors in the Private Placement and the shares of our common stock held by the former stockholders of ITI who are parties to the agreement. We are required to file the shelf registration statement within 45 days of the date of the registration rights agreement (October 13, 2013). We filed the registration statement that we are required to file under the registration rights agreement, which we refer to as the initial registration statement, on September 18, 2013, but such registration statement has not yet been declared effective. In the event fewer than all of our outstanding shares of common stock can be registered pursuant to the so-called Rule 415 doctrine, priority will be given to the shares issued in the Private Placement, but in such event at least 25% of the shares registered shall be those held by ITI's existing stockholders prior to the Private Placement.

Registration of these shares under the Securities Act would result in the shares becoming saleable under the Securities Act immediately upon the effectiveness of such registration. Any sales of securities by holders of these shares could adversely affect the trading prices, if any, of our common stock.

We will be liable to each investor in the Private Placement (but not to the former stockholders of ITI who are parties to the agreement) for liquidated damages, on a 30-day basis, equal to 1.0% of the aggregate purchase price paid by the investor for the registrable shares of our common stock then held by the investor, subject to an overall cap of 5%, (i) if we fail to file the registration statement on time, (ii) if the registration statement is not declared effective within 150 days from the date of the registration rights agreement (January 26, 2014), (iii) if we suspend (subject to limited blackout periods described below) or terminate the registration statement prior to the date which is the earlier of (x) the third anniversary of its effectiveness (or the third anniversary of the date on which all registrable shares are included therein, if later) and (y) the date on which all of the registrable shares cease to be registrable shares, or (iv) in the event one or more suspensions of the effectiveness of the registration statement exceeds 60 days in the aggregate during any 12-month period. We will be permitted to suspend the registration statement one or more times during any 12-month period provided such suspensions do not exceed 30 consecutive days or 60 days in the aggregate in any 12-month period. Any suspension associated with our filing of an annual, periodic or current report, as required by the Exchange Act, will be permitted and will not be counted against the 60 day limitation. Any shares not registered due to the Rule 415 doctrine will not be subject to liquidated damages. Expenses with respect to the filing and effectiveness of such registration statement (but not selling expenses, or underwriter or agent compensation) will be paid by us, including expenses of one counsel for the selling stockholders.

#### **Form S-3 Demand Registration Rights**

Pursuant to the registration rights agreement, at any time after we become eligible to file a registration statement on Form S-3, subject to specified limitations set forth in the registration rights agreement, the holders of at least 12% of the registrable shares of common stock then outstanding may request that we register on Form S-3 all or a portion of the registrable shares so long as the total amount of the shares being registered have an anticipated aggregate offering price, net of selling expenses, of at least \$7,500,000.

#### **“Piggyback” Registration Rights**

Pursuant to the registration rights agreement, if we propose to register any of our common stock in a firm commitment underwritten offering, the holders of registrable shares of our common stock will be entitled to notice of the registration and have the right to require us to register all or a portion of the registrable shares then held by them, subject to our right and the right of our underwriters to reduce the number of shares proposed to be registered in view of market conditions.

#### **Expenses of Registration**

We have agreed to pay all fees and expenses relating to the initial registration statement, as well as all Form S-3 demand registrations and piggyback registrations, including up to \$25,000 in fees of one special counsel of the investors in connection with the filing of the initial registration statement.

#### **Expiration of Registration Rights**

The resale registration rights described above shall terminate upon the earlier of (1) the date on which all registrable shares have been effectively

registered under the Securities Act and disposed of in accordance with such registration statement, and (2) the later of the third anniversary of the date (A) the initial registration statement is declared effective and (B) all registrable shares have been registered in the initial registration statement.

#### **Lock-Up Provisions in Registration Rights Agreement**

The registration rights agreement contains lock-up provisions applicable to holders of our common stock. See “Certain Relationships and Related Person Transactions—Agreements with Stockholders—Lock-Up Provisions in Registration Rights Agreement.”

#### ***Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated Bylaws***

The provisions of Delaware law and our pending restated certificate of incorporation and restated bylaws could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. Such provisions also may have the effect of preventing changes in our management.

#### **Delaware Statutory Business Combinations Provision**

We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Section 203 prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a “business combination” is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an “interested stockholder” is a person who, together with his or her affiliates and associates, owns, or within three years prior, did own, 15% or more of the corporation’s voting stock.

#### **Classified Board of Directors; Removal of Directors for Cause**

Pursuant to our pending restated certificate of incorporation and restated bylaws, our board of directors is divided into three classes, with the term of office of the first class to expire at the first annual meeting of stockholders following the initial classification of directors, the term of office of the second class to expire at the second annual meeting of stockholders following the initial classification of directors, and the term of office of the third class to expire at the third annual meeting of stockholders following the initial classification of directors. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire, other than directors elected by the holders of any series of preferred stock under specified circumstances, will be elected for a three-year term of office. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. Members of the board of directors may only be removed for cause and only by the affirmative vote of 80% of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the board of directors. For example, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

#### **Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors**

Our restated bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder’s notice generally must be delivered not less than 90 days nor more than 120 days prior to the first anniversary of the previous year’s annual meeting date. For a special meeting, the notice must generally be delivered not earlier than the 90th day prior to the meeting and not later than the later of (1) the 60th day prior to the meeting or (2) the 10th day following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in the restated bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, such business will not be conducted at the meeting.

#### **Special Meetings of Stockholders**

Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

#### **No Stockholder Action by Written Consent**

Any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders.

#### **Super Majority Stockholder Vote Required for Certain Actions**

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation’s certificate of incorporation or bylaws, unless the corporation’s certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our restated certificate of incorporation requires the affirmative vote of the holders of at least 80% of our outstanding voting stock to amend or repeal any of the provisions discussed in this section of this report entitled “Anti-Takeover Effects of Delaware Law and Our Restated Certificate of Incorporation and Restated Bylaws.” This 80% stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any preferred stock that might then be outstanding. An 80% vote is also required for any amendment to, or repeal of, our restated bylaws by the stockholders. Our restated bylaws may be amended or repealed by a simple majority vote of the board of directors.

#### ***Transfer Agent and Registrar***

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A., with offices at 250 Royall Street, Canton, Massachusetts 02021.

***Recent Sales of Unregistered Securities***

Set forth below is information regarding shares of common stock, convertible preferred stock, convertible notes and warrants issued, and options granted, by us and by ITI within the past three years that were not registered under the Securities Act. Also included is the consideration, if any, received by us or ITI for such shares, notes, warrants and options and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed. The number of shares and the warrant issued prior to the Merger described below in paragraphs C and D below do not reflect the exchange of shares in the Merger, which is further described in paragraph E below.



*Original Issuances of Stock, Convertible Notes and Warrants*

A. On October 15, 2012, the Company issued an aggregate of 5,000,000 shares of its common stock to its then sole stockholder in exchange for \$10,000, which represented all of the Company's outstanding common stock immediately prior to the Merger.

B. On October 25, 2012, ITI issued convertible promissory notes having an aggregate principal amount of \$14,343,795 to seven accredited investors. On November 14, 2012, ITI issued additional convertible promissory notes having an aggregate principal amount of \$846,098 to two additional accredited investors. On March 20, 2013, ITI issued additional convertible promissory notes having an aggregate principal amount of \$100,000 to two additional accredited investors. In connection with the private placement described in paragraph D below, the principal amount of all outstanding convertible promissory notes, plus accrued interest, converted into ITI common stock on August 29, 2013.

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C. On April 19, 2013, ITI issued 36,450 shares of ITI common stock and a warrant to purchase 3,645 shares of ITI common stock to one accredited investor in exchange for biotechnology grant funding received from the investor.

D. On August 29, 2013, immediately prior to the Effective Time, ITI issued 18,889,307 shares of its common stock at a price of \$3.1764 per share, or an aggregate purchase price of approximately \$60.0 million, which included approximately \$15.3 million in principal and \$0.8 million in accrued interest from the conversion of ITI's then outstanding convertible promissory notes (such that ITI received approximately \$40.0 million in net proceeds, after expenses), to 206 accredited investors in a private placement. As part of the private placement, all outstanding convertible promissory notes, plus accrued interest thereon, described in paragraph B above, were converted into shares of ITI common stock at a price of \$3.1764 per share. Leerink Swann LLC acted as sole lead placement agent and National Securities Corporation and Livingston Securities LLC acted as co-agents for purposes of the sale of ITI common stock in the private placement. Entities and individuals affiliated with Leerink Swann LLC purchased an aggregate of 346,302 shares of ITI common stock in the private placement on the same terms as the other investors.

E. On August 29, 2013, at the Effective Time, each share of ITI common stock and preferred stock that was issued and outstanding immediately prior to the Effective Time was automatically exchanged for 0.5 shares of our common stock. We issued an aggregate of 22,134,647 shares of our common stock upon such exchange of the outstanding shares of ITI common stock and preferred stock to ITI's stockholders immediately prior to the Effective Time, which included no more than 35 non-accredited investors. In addition, at the Effective Time, we assumed the ITI 2003 Equity Incentive Plan, and all options to purchase ITI common stock then outstanding under the 2003 Equity Incentive Plan, and such options became exercisable for an aggregate of 1,462,380 shares of our common stock, subject to the vesting and other terms of such options. At the Effective Time, we also assumed the outstanding warrant to purchase ITI common stock described in paragraph C above, and such warrant became exercisable for 1,822 shares of our common stock.

F. From August 1, 2010 through the Effective Time, which occurred on August 29, 2013, ITI issued an aggregate of 519,936 shares of its common stock upon the exercise of stock options issued under the 2003 Equity Incentive Plan.

#### *Stock Option Grants*

From August 1, 2010 through the consummation of the Merger on August 29, 2013, ITI granted stock options under the 2003 Equity Incentive Plan to purchase an aggregate of 579,300 shares of common stock, net of forfeitures, at a weighted-average exercise price of \$2.99 per share, to certain of its employees, consultants and directors.

#### *Securities Act Exemptions*

We deemed the offers, sales and issuances of the securities described above under “– Original Issuances of Stock, Convertible Notes and Warrants” to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, relative to transactions by an issuer not involving a public offering.

We deemed the grants of stock options described above under “– Stock Option Grants” to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities

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Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All certificates representing the securities issued in the transactions described under “Recent Sales of Unregistered Securities” included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in “Recent Sales of Unregistered Securities.”

#### ***Shares Eligible for Future Sale***

Future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market or the possibility of these sales occurring could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As of September 30, 2013, we had outstanding 22,134,647 shares of common stock. All of these shares are restricted securities under Rule 144, in that they were issued in a private transaction not involving a public offering.

#### ***Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies***

Rule 144 is not available for the resale of securities initially issued by companies that are, or previously were, blank check companies like us, to their promoters or affiliates despite technical compliance with the requirements of Rule 144. Rule 144 also is not available for resale of securities issued by any shell companies (other than business combination-related shell companies) or any issuer that has been at any time previously a shell company. The SEC has provided an exception to this prohibition, however, if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and materials required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.

As a result, none of our stockholders is currently able to sell shares of our common stock in reliance on Rule 144. Assuming we continue to meet the requirements set forth above, Rule 144 will become available to our stockholders on September 5, 2014. Our stockholders may currently resell their shares of our common stock only pursuant to a registration statement that has been declared effective under the Securities Act or pursuant to another exemption from registration.

#### ***Lock-Up Provisions in Registration Rights Agreement***

The registration rights agreement contains lock-up provisions applicable to holders of our common stock. See “Certain Relationships and Related Person Transactions—Agreements with Stockholders—Lock-Up Provisions in Registration Rights Agreement.”

#### ***Registration Rights***

The holders of an aggregate of 21,961,496 shares of our common stock, or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the initial registration statement, except for shares held by affiliates. See “Description of Securities —Registration Rights” for additional information.

***Stock Options***

As of September 30, 2013, we had outstanding options to purchase 1,462,380 shares of our common stock at a weighted-average exercise price of \$1.94 per share, of which 1,118,155 shares were vested as of such date. We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to equity grants outstanding or reserved under the ITI 2003 Equity Incentive Plan, which we assumed in the Merger, and our 2013 Equity Incentive Plan. Accordingly, shares of our common stock issued under the 2003 Equity Incentive Plan and 2013 Equity Incentive Plan will be eligible for sale in the public market, subject to vesting restrictions. However, resales of certain shares held by our affiliates registered on the Form S-8 will be subject to volume limitations, manner of sale, notice and public information requirements of Rule 144. See “Equity Compensation Plan Information—2003 Equity Incentive Plan” and “Equity Compensation Plan Information—2013 Equity Incentive Plan” for additional information regarding these plans.

***Warrant***

As of September 30, 2013, we had one warrant outstanding to purchase 1,822 shares of our common stock at an exercise price of \$6.0264 per share. Any shares purchased pursuant to this warrant will be “restricted shares” and may be sold in the public market only if they are registered under the Securities Act or qualify for an exemption from such registration.

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**Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

The disclosures set forth in Item 4.01 below are hereby incorporated by reference into this Item 2.01.

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

The disclosures set forth in Item 2.01 above are hereby incorporated by reference into this Item 3.02.

**Item 4.01. Changes in Registrant's Certifying Accountant.**

Effective at the Effective Time of the Merger, Raich Ende Malter & Co. LLP, or REM, was dismissed as the independent registered public accounting firm that audits the financial statements of the Company. Effective as of the Effective Time, our board of directors engaged Ernst & Young LLP, or E&Y, as the independent registered public accounting firm to audit the Company's financial statements for the fiscal year ended December 31, 2013.

REM's audit report on the Company's financial statements for the period from August 29, 2012 (inception) through March 31, 2013, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

During the Company's most recent fiscal year (since inception) and any subsequent interim period prior to the date hereof, there were no disagreements with REM on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of REM, would have caused it to make reference to the subject matter thereof in connection with its report.

During the Company's most recent fiscal year (since inception) and any subsequent interim period prior to the date hereof, neither the Company nor anyone acting on its behalf consulted E&Y regarding the application of accounting principles to a specified transaction, either completed or proposed or the type of audit opinion that might be rendered on the Company's financial statements.

The Company has provided REM with a copy of this report prior to the filing hereof and has requested that REM furnish to the Company a letter addressed to the Securities and Exchange Commission stating whether REM agrees with the statements made by the Company in this report. REM has furnished such letter, which letter is filed as Exhibit 16.1 hereto, as required by Item 304(a)(3) of Regulation S-K.

**Item 5.01. Changes in Control of Registrant.**

The disclosures set forth in Item 2.01 above are hereby incorporated by reference into this Item 5.01.

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**Item 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers.**

Effective immediately following the Merger, Sharon Mates, Ph.D. was appointed to our board of directors, and together with the sole director of the Company, Samir N. Masri, constituted our board of directors. Effective September 9, 2013, the eleventh day after we filed with the SEC and transmitted to our former sole stockholder a Schedule 14f-1 reporting a change in the majority of our directors, our board of directors was reconstituted by the appointment of Christopher Alafi, Ph.D., Richard Lerner, M.D., Joel S. Marcus and Sir Michael Rawlins, M.D., FRCP, FMedSci, to serve with Dr. Mates as our directors, and the resignation of Mr. Masri as a director effective on such date.

Effective immediately following the Merger, our executive management team was also reconstituted by the appointment of Dr. Mates as our President and Chief Executive Officer, Lawrence J. Hineline as our Vice President of Finance, Chief Financial Officer and Secretary, Allen A. Fienberg, Ph.D. as our Vice President of Business Development, Lawrence P. Wennogle, Ph.D. as our Vice President, Drug Discovery and Kimberly E. Vanover, Ph.D. as our Vice President, Clinical Development, effective upon the resignation of Samir N. Masri as our Chief Executive Officer, Chief Financial Officer, President and Secretary.

Biographical and other information regarding these individuals is provided under the caption "Management and Directors" in Item 2.01 above, which is incorporated by reference into this Item 5.02.

**Item 5.03. Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.**

On August 29, 2013, we filed a Certificate of Ownership and Merger with the Secretary of State of the State of Delaware pursuant to which Intra-Cellular Therapies, Inc., our newly created wholly-owned subsidiary, merged with and into us with us remaining as the surviving corporation, which we refer to as the Name Change Merger. In connection with the Name Change Merger, and as set forth in the Certificate of Ownership and Merger, we changed our corporate name to "Intra-Cellular Therapies, Inc." The Certificate of Ownership and Merger is filed herewith as Exhibit 3.4.

On August 23, 2013, prior to the Merger, our sole director and our sole stockholder approved by written consent a restated certificate of incorporation to, among other things, reduce the number of authorized shares of preferred stock, provide for our Board of Directors to be divided into three classes, require that any action taken by our stockholders be at a duly called annual or special meeting of stockholders and not by written consent, and to require a supermajority vote of our stockholders for our stockholders to remove any of our directors, amend, alter or repeal, or adopt any provision inconsistent with, certain provisions contained in our restated certificate of incorporation, or to adopt, amend or repeal our restated bylaws. We filed a definitive information statement on Schedule 14C with the SEC to notify our former sole stockholder of this action. On or about November 7, 2013, the date that is 20 days after we mailed the information statement, we expect to file the restated certificate of incorporation with the Secretary of State of the State of Delaware. When the restated certificate of incorporation becomes effective, we will have authorized capital stock of 105,000,000 shares, of which will 100,000,000 shares will be designated as common stock, par value \$0.0001 per share, and of which 5,000,000 shares will be designated as preferred stock, par value \$0.0001 per share. A copy of the restated certificate of incorporation that we intend to file with the Secretary of State of the State of Delaware is filed herewith as Exhibit 3.2, and is incorporated herein by reference.

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Effective August 29, 2013, our sole director approved our restated bylaws to, among other things, provide for our Board of Directors to be divided into three classes, require that any action taken by our stockholders be at a duly called annual or special meeting of stockholders and not by written consent, and to require a supermajority vote of our stockholders for our stockholders to remove any of our directors or to adopt, amend or repeal any provision of our restated bylaws. A copy of our restated bylaws is filed herewith as Exhibit 3.5, and is incorporated hereby by reference.

As a result of the Merger, our board of directors has decided to change our fiscal year end from March 31 to December 31. Accordingly, we will file our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 with the SEC on or before March 31, 2014. As the transition period covers six months or more, in accordance with the SEC's transition report rules as set forth in Rule 13a-10 of the Securities Exchange Act of 1934, as amended, we will need to file a transition report on Form 10-K within 90 days of December 31, 2013 and our next Quarterly Report on Form 10-Q will contain the necessary financial information for the transition period.

**Item 5.06. Change in Shell Company Status.**

As described in Items 1.01 and 2.01 above, which are incorporated by reference into this Item 5.06, we ceased being a shell company (as defined in Rule 12b-2 under the Exchange Act) upon completion of the Merger.

**Item 9.01. Financial Statements and Exhibits.**

(a) As a result of its acquisition of ITI as described in Item 2.01, the registrant is filing herewith ITI's audited financial statements as of and for the years ended December 31, 2012 and 2011 and its unaudited financial statements as of June 30, 2013 and December 31, 2012 and for the three and six months ended June 30, 2013 and 2012 as Exhibit 99.1 to this Current Report on Form 8-K.

(b) Unaudited pro forma condensed combined financial statements for the year ended December 31, 2012 and as of and for the six months ended June 30, 2013 is attached as Exhibit 99.2 to this Current Report on Form 8-K.

(d) Exhibits.

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Current Report on Form 8-K, which Exhibit Index is incorporated herein by reference.

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**SIGNATURE**

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

INTRA-CELLULAR THERAPIES, INC.

Date: October 31, 2013

By: /s/ Sharon Mates, Ph.D.

Sharon Mates, Ph.D.

Chairman, President and Chief Executive Officer



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**EXHIBIT INDEX**

<u>Exhibit</u>	<u>Description</u>
2.1	Agreement and Plan of Merger, dated as of August 23, 2013, by and among the Registrant, ITI, Inc. and Intra-Cellular Therapies, Inc. (1)
2.2	Agreement and Plan of Merger, dated as of August 29, 2013, by and between the Registrant and Intra-Cellular Therapies, Inc., relating to the name change of the Registrant. (2)
3.1	Certificate of Incorporation of the Registrant, as filed with the Secretary of State of the State of Delaware on August 29, 2012. (3)
3.2	Form of Restated Certificate of Incorporation of the Registrant, to be filed with the Secretary of State of the State of Delaware. (2)
3.3	Certificate of Merger relating to the Merger of ITI, Inc. with and into Intra-Cellular Therapies, Inc., filed with the Secretary of State of the State of Delaware on August 29, 2013. (2)
3.4	Certificate of Ownership and Merger relating to the Merger of Intra-Cellular Therapies, Inc. with and into the Registrant, filed with the Secretary of State of the State of Delaware on August 29, 2013, relating to the name change of the Registrant. (2)
3.5	Restated Bylaws of the Registrant. (2)
4.1	Form of common stock certificate. (2)
4.2.1	Warrant to Purchase Common Stock dated April 19, 2013 issued to Alzheimer Drug Discovery Foundation, Inc. (2)
4.2.2	Amendment dated August 29, 2013 to Warrant to Purchase Common Stock dated April 19, 2013 issued to Alzheimer Drug Discovery Foundation, Inc. (2)
10.1.1**	License Agreement dated as of May 31, 2005 by and between Bristol-Meyers Squibb Company and Intra-Cellular Therapies, Inc.
10.1.2	Amendment No. 1 to License Agreement dated as of November 3, 2010 by and between Bristol-Meyers Squibb Company and Intra-Cellular Therapies, Inc. (2)
10.2**	License and Collaboration Agreement dated as of February 25, 2011 by and between Takeda Pharmaceutical Company Limited and Intra-Cellular Therapies, Inc.

<u>Exhibit</u>	<u>Description</u>
10.3*	Employment Agreement effective as of February 26, 2008 by and between Sharon Mates, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.4*	Employment Agreement effective as of February 26, 2008 by and between Lawrence J. Hinline and Intra-Cellular Therapies, Inc. (2)
10.5*	Employment Agreement effective as of February 26, 2008 by and between Allen Fienberg, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.6*	Employment Agreement effective as of February 26, 2008 by and between Lawrence Wennogle, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.7*	Offer Letter dated February 2, 2007 by Intra-Cellular Therapies, Inc. to Kimberly Vanover. (2)
10.8*	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of September 1, 2003 by and between Sharon Mates, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.9*	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of December 1, 2003 by and between Lawrence J. Hinline and Intra-Cellular Therapies, Inc. (2)
10.10*	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of June 3, 2002 by and between Allen Fienberg, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.11*	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of January 1, 2003 by and between Lawrence Wennogle, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.12*	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of March 5, 2007 by and between Kimberly E. Vanover, Ph.D. and Intra-Cellular Therapies, Inc. (2)
10.13*	Form of Indemnification Agreement by and between the Company and its directors and executive officers. (2)
10.14*	2003 Equity Incentive Plan, as amended. (2)
10.15*	Form of Stock Option Agreement under the 2003 Equity Incentive Plan, as amended. (2)
10.16*	2013 Equity Incentive Plan. (2)

<u>Exhibit</u>	<u>Description</u>
10.17	Redemption Agreement dated as of August 29, 2013 by and between the Registrant and NLBDIT 2010 Services, LLC. (2)
10.18	Indemnity Agreement dated as of August 29, 2013 by and among the Registrant, Intra-Cellular Therapies, Inc. and Samir N. Masri. (2)
10.19	Registration Rights Agreement dated as of August 29, 2013 by and among Intra-Cellular Therapies, Inc., the stockholders named therein and the Registrant. (2)
16.1	Letter from Raich Ende Malter & Co. LLP to the Securities and Exchange Commission, dated September 5, 2013. (2)
99.1	Audited financial statements of Intra-Cellular Therapies, Inc. as of and for the years ended December 31, 2012 and 2011 and unaudited financial statements of Intra-Cellular Therapies, Inc. as of June 30, 2013 and for the three and six months ended June 30, 2013 and 2012. (4)
99.2	Unaudited Pro Forma Condensed Combined Financial Statements for the year ended December 31, 2012 and as of and for the six months ended June 30, 2013. (4)
99.3	Press Release dated September 3, 2013. (2)

\* **Management contract or compensatory plan or arrangement.**

\*\* **Confidential treatment requested by the Registrant. Redacted portion filed separately with the Securities and Exchange Commission.**

- (1) Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 29, 2013 (File No. 000-54896).
- (2) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K filed with the SEC on September 5, 2013 (File No. 000-54896) and incorporated by reference herein.
- (3) Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 10 filed with the SEC on February 8, 2013 (File No. 000-54896).
- (4) Previously filed as an exhibit to the Registrant's Current Report on Form 8-K/A filed with the SEC on October 15, 2013 (File No. 000-54896) and incorporated by reference herein.

**LICENSE AGREEMENT**

**between**

**INTRA-CELLULAR THERAPIES, INC.**

**and**

**BRISTOL-MYERS SQUIBB COMPANY**

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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## 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,

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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.

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**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.

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**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.

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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 “Indemnitor” 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.

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**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.

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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.

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**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

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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.

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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.

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**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;

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(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.

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(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

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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).

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(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.

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**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

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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.

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**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

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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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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## 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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.



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**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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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:

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

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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 [\*\*\*].

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**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;

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**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.

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**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 with 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.

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**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

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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

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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

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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

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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

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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

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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

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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;

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**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

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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

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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

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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.

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**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.

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**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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**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

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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

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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.

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**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 [\*\*\*].

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**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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**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.

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**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.

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**14.2 Remedies.** Except as provided in Sections 8.7 and 14.3, if any dispute between the Parties relating to or arising out of 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

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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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

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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

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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.

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**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

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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]**

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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

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Appendix 1

BMS Core Patent Rights

[\*\*\*]

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Appendix 2

Summary of Initial Development Plan

[\*\*\*]

Appendix 2 pg. 1 of 2

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 2 pg. 2 of 2

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Appendix 3

Excluded Compounds

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Appendix 4

Licensed Compounds

[\*\*\*]

Appendix 4 pg. 1 of 5

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 4 pg. 2 of 5

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 4 pg. 3 of 5

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 4 pg. 4 of 5

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 4 pg. 5 of 5

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Appendix 5

[\*\*\*]

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**FOR IMMEDIATE RELEASE**

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

NEW YORK, NY—May XX<sup>th</sup>, 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

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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

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Appendix 7

Compound Samples to be Provided by BMS

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Appendix 8

Exceptions to Warranties

[\*\*\*]

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Appendix 9

BMS Other Patent Rights

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## LICENSE AND COLLABORATION AGREEMENT

This LICENSE AND COLLABORATION AGREEMENT (the “**Agreement**”) is entered into as of February 25, 2011 (the “**Effective Date**”) by and between **INTRA-CELLULAR THERAPIES, INC.**, a Delaware corporation with its principal place of business at Audubon Biomedical Science and Technology Park, 3960 Broadway, New York, NY 10032 (“**ITI**”), and **TAKEDA PHARMACEUTICAL COMPANY LIMITED**, a Japanese company having a place of business at 1-1, Doshomachi 4-Chome, Chuo-ku, Osaka 540-8645, Japan (“**Takeda**”). ITI and Takeda are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**”.

### RECITALS

**WHEREAS**, ITI is developing pharmaceutical products that inhibit Phosphodiesterase 1, including ITI’s proprietary compound referred to internally as IC200214 or ITI-214;

**WHEREAS**, Takeda possesses substantial resources and expertise in the development, marketing, and commercialization of pharmaceutical products; and

**WHEREAS**, ITI and Takeda desire to establish a collaboration for the research, development and commercialization of products containing ITI-214 or its backup compounds, in accordance with the terms and conditions set forth herein.

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1

#### DEFINITIONS

**1.1 “Acquiror”** has the meaning set forth in Section 15.5.

**1.2 “Affiliate”** means, with respect to a particular Party or other entity, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party or other entity. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise.

**1.3 “ADHD”** means Attention Deficit Hyperactivity Disorder recognized in the DSM-IV-TR.

**1.4 “Alliance Manager”** has the meaning set forth in Section 3.1.

**1.5 “Alzheimer’s Disease”** means Dementia of the Alzheimer’s Type (DAT) as recognized in DSM-IV-TR.

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**1.6 “Assigned Patents”** has the meaning set forth in Section 2.1(a)(i).

**1.7 “Business Day”** means a day other than Saturday, Sunday or any day that banks in Japan or New York, NY, U.S. are required or permitted to be closed.

**1.8 “Change of Control”** means, with respect to ITI, any of the following: (a) a Third Party acquires, directly or indirectly, the beneficial ownership of any voting security of ITI, or the percentage ownership of such person or entity in the voting securities of ITI is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then-outstanding voting securities of ITI, but excluding any such acquisition or increase resulting from the issuance of shares in a financing transaction; (b) a merger, consolidation, recapitalization, or reorganization of ITI is consummated, other than any such transaction which would result in stockholders or equity holders of ITI or an Affiliate of ITI immediately prior to such transaction owning at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) the stockholders or equity holders of ITI approve a plan of complete liquidation of ITI, or an agreement for the sale or disposition by ITI of all or a substantial portion of ITI’s assets, other than to an Affiliate, but excluding in each case (a)-(c) a merger or other transaction effected exclusively for the purpose of changing the corporate domicile of ITI.

**1.9 “Claims”** has the meaning set forth in Section 11.1.

**1.10 “Clinical Trial”** means any human clinical trial of a Product.

**1.11 “Commercialization”** means the marketing, promotion, sale and/or distribution of a Product in the Territory, including any post marketing surveillance. Commercialization shall include commercial activities conducted in preparation for Product launch. **“Commercialize”** has a correlative meaning.

**1.12 “Commercially Reasonable Efforts”** means, with respect to a Party’s obligations under this Agreement related to a particular Compound or Product, the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices it employs for its own products (in any case, such level shall not be below the standard level in the pharmaceutical industry) in the exercise of prudent scientific and business judgment that would be applied to the research, development or commercialization of a pharmaceutical product [\*\*\*]. Commercially Reasonable Efforts require that the Party: (a) in a timely manner assign responsibility for such obligations or tasks to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis, (b) set and timely seek to achieve specific and meaningful objectives for carrying out such obligations, and (c) timely make and implement decisions and allocate resources designed to advance progress with respect to such objectives.

**1.13 “Compound”** means any of the following: (a) the compound referred to by ITI as IC200214 or ITI-214, as set forth in Exhibit A (“**ITI-214**”); (b) any compound (i) in the ITI-002

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program that was identified by ITI prior to the Effective Date, whether or not covered or claimed in any Patent Controlled by ITI as of the Effective Date and (ii) that is identified by ITI under the Research Program, in each case of subsections (i) and (ii) that inhibits Phosphodiesterase 1, including any of its subtypes (“**PDE1**”) and meets the criteria set forth in Exhibit B (collectively, “**Back-Up Compounds**”), and (c) any pro-drug, metabolite, salt, free acid/base, solvate, ester, hydrate, anhydrous form, degradant, stereoisomer, polymorphic form, isotope or crystal form of any of the compounds in (a) or (b), in each case that retains the activity of the applicable compound in (a) or (b) (collectively, “**Variants**”).

**1.14 “Confidential Information”** of a Party means any and all Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, or electronic form. All Information disclosed by either Party pursuant to the Non-Disclosure Agreement between the Parties dated November 1, 2007, as amended and restated as of the Effective Date, (the “**Confidentiality Agreement**”) shall be deemed to be such Party’s Confidential Information disclosed hereunder.

**1.15 “Control”** means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement) to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other legally enforceable arrangement with any Third Party.

**1.16 “Co-Promotion Agreement”** has the meaning set forth in Section 6.4(b).

**1.17 “Co-Promotion Option”** has the meaning set forth in Section 6.4(a).

**1.18 “Co-Promotion Product”** has the meaning set forth in Section 6.4(b).

**1.19 “Develop”** or “**Development**” means all activities that relate to obtaining, maintaining or expanding Regulatory Approval of a Product. This includes: (i) nonclinical testing, toxicology, and Clinical Trials; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Governmental Authority to obtain, maintain and/or expand Regulatory Approval of a Product, and outside counsel, regulatory, and legal services related thereto; provided, however, that Development shall exclude Commercialization and the building of commercial inventory of a Product. For clarity, Development shall include Phase 4 Clinical Trials that are required by a Regulatory Authority as a condition of a Regulatory Approval. “**Develop**” has a correlative meaning.

**1.20 “Development Plan”** has the meaning set forth in Section 4.3(a).

**1.21 “Development Program”** has the meaning set forth in Section 4.3(a).

**1.22 “Dollar”** means a U.S. dollar, and “**\$**” shall be interpreted accordingly.

**1.23 “Dropped Product”** has the meaning set forth in Section 8.3(d)(ii).

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**1.24 “EMA”** means the European Medicines Agency or any successor entity.

**1.25 “EU” or “European Union”** means the European Union member states as then constituted. As of the Effective Date, the European Union member states are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom.

**1.26 “Excluded Information”** has the meaning set forth in Section 2.1(e).

**1.27 “Excluded Patents”** has the meaning set forth in Section 2.1(e).

**1.28 “Executive Officer”** means, with respect to ITI, its Chief Executive Officer, and with respect to Takeda, its Chief Scientific Officer.

**1.29 “FD&C Act”** means the U.S. Federal Food, Drug and Cosmetic Act, as amended.

**1.30 “FDA”** means the U.S. Food and Drug Administration or any successor entity.

**1.31 “Field”** means the prevention and treatment of all human Indications, including, but not limited to, Schizophrenia, Alzheimer’s Disease, ADHD and other central nervous system Indications. For clarity, the Field does not include diagnostic uses or animal health uses (it being understood that animal testing or diagnostic activities in the course of research or Development for human Indications, in accordance with the Research Plan or the Development Plan, are considered to be within the Field).

**1.32 “First Commercial Sale”** means, with respect to a Product, the first sale on a commercial basis (not compassionate use) to a Third Party of such Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction.

**1.33 “FTE”** means the equivalent of a full-time professional individual’s work, [\*\*\*], performing activities pursuant to this Agreement. In the case that any full time personnel of ITI works partially on work pursuant to this Agreement and partially on other work in a given time period, then the full-time equivalent to be attributed to such individual’s work hereunder shall be calculated based upon the percentage of such individual’s total work time in such time period that such individual spent working under this Agreement and the percentage of a [\*\*\*] ([\*\*\*) [\*\*\*] period that such time period equals. In the event that any part-time personnel of ITI works under this Agreement, the full time equivalent to be attributed to such work shall reflect appropriate adjustment for such personnel’s reduced total work time relative to full time personnel. FTE efforts shall include professional, scientific or technical work and shall not include general corporate and administrative overhead. ITI shall track FTEs using its standard practice and normal systems and methodologies.

**1.34 “FTE Rate”** means the rate of FTE costs incurred by ITI, which for the purpose of this Agreement shall initially be set at an annual rate of [\*\*\*] ([\*\*\*) per FTE. The FTE rate shall be changed annually commencing January 1, 2012 to reflect any year-to-year percentage increase or decrease in the Consumer Price Index for all Urban Consumers (CPI-U, New York-Northern New Jersey-Long Island, all items) from the Effective Date.

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**1.35 “Generic Product”** means, with respect to a Product in a particular regulatory jurisdiction, any pharmaceutical product that (a) (i) contains the same active pharmaceutical ingredients as such Product, in the same formulation and dosage form as such Product and for the same route of administration as such Product and is approved by the Regulatory Authority in such country (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction); or (ii) is A/B Rated (defined below) with respect to such Product or otherwise approved by the Regulatory Authority in such country as a substitutable generic for such Product (for an indication for which such Product obtained Regulatory Approval from the applicable Regulatory Authority in such jurisdiction) on an expedited or abbreviated basis in a manner that relied on or incorporated data submitted by Takeda or its Affiliate or sublicensee in connection with the Regulatory Approval for the Product in such jurisdiction; and (b) is sold in such jurisdiction by a Third Party that is not a sublicensee of Takeda or its Affiliates and did not purchase such product in a chain of distribution that included any of Takeda or its Affiliates or sublicensees. For purposes of this Section 1.35, “**A/B Rated**” means, for the U.S., “therapeutically equivalent” as determined by the FDA, applying the definition of “therapeutically equivalent” set forth in the preface to the then-current edition of the FDA publication “Approved Drug Products With Therapeutic Equivalence Evaluations” and, for outside the U.S., such equivalent determination by the applicable Regulatory Authority as is necessary to permit pharmacists or other individuals authorized to dispense pharmaceuticals under applicable Laws to substitute one product for another product in the absence of specific instruction from a physician or other authorized prescriber under applicable Laws.

**1.36 “GCP”** or “**Good Clinical Practices**” means the then-current standards, practices and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance,” including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.37 “GLP”** or “**Good Laboratory Practices**” means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and comparable regulatory standards promulgated by the EMA or other Regulatory Authority applicable to the Territory, as they may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

**1.38 “GMP”** or “**Good Manufacturing Practices**” means the then-current Good Manufacturing Practices required by the FDA, as set forth in the FD&C Act and the regulations promulgated thereunder, for the manufacture and testing of pharmaceutical materials, and comparable laws or regulations applicable to the manufacture and testing of pharmaceutical materials promulgated by other Regulatory Authorities, as they may be updated from time to time.

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**1.39 “Governmental Authority”** means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

**1.40 “ICH”** means International Conference on Harmonisation.

**1.41 “IND”** means (a) an Investigational New Drug Application as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA, or (b) the equivalent application to the equivalent agency in any other regulatory jurisdiction, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.42 “Indemnified Party”** has the meaning set forth in Section 11.3.

**1.43 “Indemnifying Party”** has the meaning set forth in Section 11.3.

**1.44 “Indication”** means a separately defined, well-categorized class of human disease or condition for which a separate MAA (including any extensions or supplements) may be filed with a Regulatory Authority.

**1.45 “Information”** means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, clinical test data and data resulting from non-clinical studies), CMC information, stability data and other study data and procedures.

**1.46 “Initiation”** of a Clinical Trial means the first dosing of the first subject in such Clinical Trial.

**1.47 “ITI Indemnitees”** has the meaning set forth in Section 11.2.

**1.48 “ITI Know-How”** means all Information, other than Excluded Information, Controlled by ITI or its Affiliates as of the Effective Date or during the Term (other than as a result of a license from Takeda) that is necessary or reasonably useful for the Development, manufacture or Commercialization of Compounds or Products in the Field. For clarity, ITI Know-How excludes Information contained within the ITI Patents, and the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate after the Effective Date due to an acquisition by such Third Party or its Affiliate of ITI (that is, a parent company of ITI or an Affiliate of such parent company), subject to the terms of Section 15.5.

**1.49 “ITI Patent”** means any Patent (other than a Joint Patent or an Excluded Patent) that (a) is Controlled by ITI or its Affiliates as of the Effective Date or at any time during the Term (other than as a result of a license from Takeda), and (b) claims the composition of matter,

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manufacture or use of one or more Compounds or Products or that would otherwise be infringed, absent a license, by the manufacture, use or sale of any Compound or Product. For clarity, the use of "Affiliate" in this definition shall exclude any Third Party that becomes an Affiliate after the Effective Date due to an acquisition by such Third Party or its Affiliate of ITI (that is, a parent company of ITI or an Affiliate of such parent company), subject to the terms of Section 15.5. The list of ITI Patents as of the Effective Date is attached hereto as Exhibit C-1. For clarity, the ITI Patents include the Sole Assigned Patents.

**1.50 "ITI Prosecuted Patents"** has the meaning set forth in Section 9.3(a)(i).

**1.51 "ITI Technology"** means the ITI Know-How, ITI Patents and ITI's interest in the Joint Patents.

**1.52 "Joint Assigned Patents"** has the meaning set forth in Section 2.1(a)(i).

**1.53 "Joint Inventions"** has the meaning set forth in Section 9.1.

**1.54 "Joint Patents"** has the meaning set forth in Section 9.1.

**1.55 "Joint Patent Committee" or "JPC"** means the committee formed by the Parties in accordance with Section 3.4.

**1.56 "Joint Research Committee" or "JRC"** means the committee formed by the Parties in accordance with Section 3.3.

**1.57 "Joint Steering Committee" or "JSC"** means the committee formed by the Parties as described in Section 3.2.

**1.58 "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.

**1.59 "Manufacture"** means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing any Compound or Product in bulk or finished form for Development, manufacturing finished Product for Commercialization, packaging, in-process and finished Product testing, release of Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Product, and regulatory activities related to any of the foregoing. "Manufacturing" has a correlative meaning.

**1.60 "Manufacturing Cost"** means (i) with respect to a Compound or Product that is Manufactured by a Third Party, the actual purchase price paid by a Party or its Affiliate to such Third Party for such Compound or Product, including a Party's reasonable overhead and administrative expenses, and (ii) with respect to a Compound or Product that is Manufactured directly by a Party or its Affiliate, the cost of direct labor and direct materials, product testing costs incurred in connection with Manufacturing, start-up and on-going validation costs directly

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associated with the Manufacture of the Product or Compound, facility costs including depreciation, and overhead, such calculation being based upon accepted industry standards and GAAP (as defined below).

**1.61 “Marketing Authorization Application” or “MAA”** means an application to the appropriate Regulatory Authority for approval to market a Product (but excluding Pricing Approval) in any particular jurisdiction, including an NDA in the U.S.

**1.62 “MHLW”** means the Japanese Ministry of Health, Labour and Welfare or any successor entity.

**1.63 “NDA”** means a New Drug Application, as defined in the FD&C Act, as amended, and applicable regulations promulgated thereunder by the FDA.

**1.64 “Net Sales”** means, with respect to any Product, the gross amounts invoiced and/or received by Takeda, its Affiliates and their respective sublicensees for sales of such Product to unaffiliated Third Parties, less the following deductions, to the extent reasonable and customary, provided to unaffiliated entities and actually allowed and taken with respect to such sales:

(a) reasonable cash, trade or quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations and national, state, or local government;

(b) credits, rebates or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections or returns of such Product, including in connection with recalls, and the actual amount of any write-offs for bad debt (provided that an amount subsequently recovered will be treated as Net Sales);

(c) freight, postage, shipping, transportation and insurance charges, in each case actually allowed or paid for delivery of such Product; and

(d) taxes (other than income taxes), duties, tariffs, mandated contribution or other governmental charges levied on the sale of such Product, including VAT, excise taxes and sales taxes.

Notwithstanding the foregoing, amounts received or invoiced by Takeda, its Affiliates, or their respective sublicensees for the sale of such Product among Takeda, its Affiliates or their respective sublicensees for resale shall not be included in the computation of Net Sales hereunder. For purposes of determining Net Sales, a Product shall be deemed to be sold when invoiced. Net Sales shall be accounted for in accordance with standard Takeda practices for operation by Takeda, its Affiliates or sublicensees, as practiced in the relevant country in the Territory, but in any event in accordance with U.S. generally accepted accounting principles (“GAAP”), consistently applied in such country in the Territory. For clarity, a particular deduction may only be accounted for once in the calculation of Net Sales.

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Takeda, its Affiliates, and their respective sublicensees will not sell any Product in combination with or as part of a bundle with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product as compared with the weighted-average discount applied to the other products, as a percent of the respective list prices (or if not available, a good faith estimate thereof) of such products and the Product prior to applying the discount.

In the case of any pharmaceutical composition, branded or generic, containing a Product in combination with any other clinically active ingredient(s) that is not a Product, whether packaged together or in the same therapeutic formulation, in any country, Net Sales for such combination product in such country shall be calculated as follows:

(i) If the Product and other clinically active ingredient(s) each are sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such combination product by the fraction  $A/(A+B)$ , where A is the public or list price in such country of the Product sold separately in the same formulation and dosage, and B is the sum of the public or list price in such country of such other clinically active ingredient(s) sold separately in the same formulation and dosage, during the applicable calendar year.

(ii) If the Product is sold independently of the other clinically active ingredient(s) therein in such country, but the public or list price of such other clinically active ingredient(s) cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such combination product by the fraction  $A/C$ , where A is the public or list price in such country of such Product sold independently and C is the public or list price in such country of the entire combination product.

(iii) If the other clinically active ingredient(s) are sold independently of the Product therein in such country, but the public or list price of such Product cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of such combination product by the fraction  $[1-B/C]$ , where B is the public or list price in such country of such other clinically active ingredient(s) and C is the public or list price in such country of the entire combination product.

**1.65 “Patents”** means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

**1.66 “Pharmacovigilance Agreement”** has the meaning set forth in Section 5.5.

**1.67 “Phase 1 Clinical Trial”** means a Clinical Trial of a Product in the Field with the endpoint of determining initial tolerance, safety, pharmacokinetic or pharmacodynamic information in single dose, single ascending dose, multiple dose and/or multiple ascending dose regimens, which is prospectively designed to generate sufficient data (if successful) to commence a Phase 2 Clinical Trial of such Product, as further defined in 21 C.F.R. 312.21(a) for the U.S., as amended from time to time, or the corresponding foreign regulations.

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**1.68 “Phase 2 Clinical Trial”** means a Clinical Trial of a Product in the Field to determine initial efficacy and dose range and/or regimen finding before embarking on a Phase 3 Clinical Trial, as further defined in 21 C.F.R. 312.21(b) for the U.S., as amended from time to time, or the corresponding foreign regulations.

**1.69 “Phase 3 Clinical Trial”** means a pivotal Clinical Trial of a Product (whether or not denominated a “Phase 3” Clinical Trial under applicable regulations) in the Field with a defined dose or a set of defined doses of such Product designed to ascertain efficacy and safety of such Product for the purpose of enabling the preparation and submission of an MAA to the competent Regulatory Authorities in a country of the Territory, as further defined in 21 C.F.R. 312.21(c) for the U.S., as amended from time to time, or the corresponding foreign regulations.

**1.70 “Phase 4 Clinical Trial”** means a Clinical Trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product, or (b) conducted due to a request or requirement of a Regulatory Authority.

**1.71 “Pricing Approval”** means such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged and/or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price and/or reimbursement of pharmaceutical products.

**1.72 “Product”** means any pharmaceutical product, including all forms, presentations, doses and formulations, containing a Compound alone or in combination with other therapeutically active ingredients.

**1.73 “Product Infringement”** has the meaning set forth in Section 9.4(a).

**1.74 “Product Marks”** has the meaning set forth in Section 9.11.

**1.75 “Regulatory Approval”** means all approvals, including Pricing Approvals if applicable, necessary for the commercial sale of a Product in the Field in a given country or regulatory jurisdiction.

**1.76 “Regulatory Authority”** means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

**1.77 “Regulatory Exclusivity”** means any exclusive marketing rights or data exclusivity rights conferred by any Governmental Authority with respect to a Product in a country or jurisdiction in the Territory, other than a Patent right, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997, in the EU under Directive 2001/83/EC, or rights similar thereto in other countries or regulatory jurisdictions in the Territory.

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**1.78 “Regulatory Materials”** means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to Develop, manufacture, market, sell or otherwise Commercialize a Product in a particular country or jurisdiction.

**1.79 “Remedial Action”** has the meaning set forth in Section 5.6.

**1.80 “Research Plan”** has the meaning set forth in Section 4.2(a).

**1.81 “Research Program”** has the meaning set forth in Section 4.2(a).

**1.82 “Research Term”** has the meaning set forth in Section 4.2(d).

**1.83 “Royalty Term”** has the meaning set forth in Section 8.5(b).

**1.84 “Schizophrenia”** means schizophrenia as recognized in the DSM-IV-TR.

**1.85 “Selected Compound”** has the meaning set forth in Section 2.1(a)(ii).

**1.86 “Sole Assigned Patents”** has the meaning set forth in Section 2.1(a)(i).

**1.87 “Sole Inventions”** has the meaning set forth in Section 9.1.

**1.88 “Takeda Indemnitees”** has the meaning set forth in Section 11.1.

**1.89 “Takeda Know-How”** means all Information Controlled by Takeda or its Affiliates as of the Effective Date or during the Term (other than as a result of a license from ITI) that is necessary or reasonably useful for the Development, Manufacture or Commercialization of Compounds or Products in the Field. For clarity, Takeda Know-How excludes Information contained within the Takeda Patents, and the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate after the Effective Date due to an acquisition by such Third Party or its Affiliate of Takeda (that is, a parent company of Takeda or an Affiliate of such parent company), subject to the terms of Section 15.5.

**1.90 “Takeda Patent”** means any Patent (other than a Joint Patent) that (a) is Controlled by Takeda or its Affiliates as of the Effective Date or at any time during the Term (other than as a result of a license or assignment from ITI), and (b) claims the composition of matter, manufacture or use of one or more Compounds or Products or that would otherwise be infringed, absent a license, by the manufacture, use or sale of any Compound or Product. For clarity, the use of “Affiliate” in this definition shall exclude any Third Party that becomes an Affiliate after the Effective Date due to an acquisition by such Third Party or its Affiliate of Takeda (that is, a parent company of Takeda or an Affiliate of such parent company), subject to the terms of Section 15.5. For clarity, the Takeda Patents do not include any Assigned Patents.

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**1.91 “Takeda Prosecuted Patents”** has the meaning set forth in Section 9.3(b)(i).

**1.92 “Takeda Sublicense Agreement”** has the meaning set forth in Section 2.1(d)(ii).

**1.93 “Takeda Technology”** means the Takeda Know-How, Takeda Patents and Takeda’s interest in the Joint Patents.

**1.94 “Takeda Withholding Tax Action”** has the meaning set forth in Section 8.10(c).

**1.95 “Term”** has the meaning set forth in Section 13.1.

**1.96 “Territory”** means all countries of the world.

**1.97 “Third Party”** means any entity other than ITI or Takeda or an Affiliate of either of them.

**1.98 “U.S.”** means the United States of America, including all possessions and territories thereof.

**1.99 “Valid Claim”** means a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) included within the ITI Patents (including the Sole Assigned Patents) or Joint Patents (including the Joint Assigned Patents), to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise.

**1.100 “Variants”** has the meaning set forth in Section 1.13.

## **ARTICLE 2 ASSIGNMENT / LICENSES**

### **2.1 Assignments and Licenses to Takeda under ITI Technology.**

#### **(a) Assignments to Takeda.**

**(i)** Subject to the terms and conditions of this Agreement, ITI hereby assigns to Takeda all of its right, title and interest in and to each ITI Patent existing as of the Effective Date that is solely owned by ITI and that claims ITI-214 or a Variant thereof (the “**Sole Assigned Patents**”). The Sole Assigned Patents as of the Effective Date are listed on Exhibit D. Upon ITI’s receipt of the upfront and research funding payment from Takeda under Section 8.1, ITI shall execute and deliver to Takeda all documents necessary to perfect the assignment of the Sole Assigned Patents to Takeda. As of the Effective Date, ITI is preparing a patent application directed to a [\*\*\*], and upon filing such patent application, and any other ITI Patent or Joint Patent that claims ITI-214 or a Variant thereof, ITI shall assign to Takeda all of its right, title and interest in and to each such patent application (including all foreign equivalents thereof).

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Following such assignment, the applicable Patents shall be considered Sole Assigned Patents, if previously ITI Patents, or “**Joint Assigned Patents**” if previously Joint Patents, and the Sole Assigned Patents and Joint Assigned Patents shall be collectively referred to as the “**Assigned Patents**”. Takeda shall be responsible, at its expense, for recording all such assignments, and ITI shall reasonably cooperate, at ITI’s expense, with Takeda’s efforts to do so. All such recordations shall accurately reflect all of ITI’s rights with respect to such Assigned Patents.

(ii) If Takeda notifies ITI in writing during the course of the Research Program, or pursuant to Section 2.5(b), that Takeda has selected a Back-Up Compound as a candidate for Development in any country of the Territory (each, a “**Selected Compound**”), then ITI shall promptly assign to Takeda all of its right, title and interest in and to each then-existing ITI Patent solely owned by ITI and/or its Affiliates and each Joint Patent, each as specified in Takeda’s notice, that claims the Selected Compound or a Variant thereof. Following such assignment, the applicable Patents shall be considered Sole Assigned Patents, if previously ITI Patents, or Joint Assigned Patents if previously Joint Patents. ITI shall execute and deliver to Takeda all documents necessary to perfect the assignment of such Assigned Patents to Takeda within a reasonable period of time after such assignment. Takeda shall be responsible, at its expense, for recording all such assignments, and ITI shall reasonably cooperate, at Takeda’s expense, with Takeda’s efforts to do so. All such recordations shall accurately reflect all of ITI’s rights with respect to the Assigned Patents.

(iii) Notwithstanding the assignment described in this Section 2.1(a), the Assigned Patents shall be included in and treated as a part of the ITI Patents or Joint Patents under this Agreement, as applicable, and such assignment shall in no way alter Takeda’s royalty obligations to ITI under Article 8 or ITI’s rights under Sections 9.3(a) and 9.8 to prepare, file, prosecute, maintain and defend the Sole Assigned Patents as ITI Patents. Except as provided in the last sentence of Section 9.1: (A) Takeda shall not practice the Assigned Patents outside of the scope of the licenses granted to Takeda in Section 2.1(b), (B) Takeda shall have the right to grant licenses under the Assigned Patents only in accordance with its sublicensing rights under Section 2.1(d), (C) Takeda shall not encumber the Assigned Patents or assign the Assigned Patents to any Affiliate or Third Party, and (D) Takeda shall not practice the Assigned Patents beyond the scope of the uses permitted under the licenses granted in Section 2.1(b).

(iv) For any Assigned Patents that cease to claim the applicable Compounds (ITI-214 or a Selected Compound) at any time during the Term by virtue of an amendment of the claims, Takeda shall assign, and hereby does assign effective as of the date that (x) ITI notifies Takeda in writing that such Patent should no longer be an Assigned Patent and (y) Takeda approves such assignment in writing (such approval not to be withheld by Takeda without cause; and provided that Takeda’s failure to respond within [\*\*\*] ([\*\*\*)] [\*\*\*] of receipt of ITI’s notice shall be deemed an approval), to ITI Takeda’s entire right, title and interest in and to each such Sole Assigned Patent, and one-half of its right, title and interest in and to each such Joint Assigned Patent, and Takeda appoints, effective as of the date of such approval by Takeda, ITI as its attorney in fact solely to make such re-assignments and authorizes ITI to make such re-assignments. In each case, Takeda shall execute and deliver to ITI a deed(s) of such assignment, in a mutually agreeable form, within [\*\*\*] ([\*\*\*)] [\*\*\*] after the date of approval. ITI shall be responsible for recording all such assignments, and Takeda and its

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successors and assigns shall (A) reasonably cooperate with ITI's efforts to do so, including satisfying the assignment and recording requirements of relevant patent offices, and (B) reimburse ITI for all reasonable expenses incurred by ITI in connection with this Section 2.1(a)(iv). In addition, Takeda hereby grants ITI an exclusive, fully sublicensable license under its interest in each such Sole Assigned Patent and a non-exclusive, fully sublicensable license under its interest in each such Joint Assigned Patent during the period from the date such Patent ceased to claim the applicable Compound until such Patent is actually re-assigned to ITI.

**(b) Licenses to Takeda.** Subject to the terms and conditions of this Agreement, ITI hereby grants Takeda an exclusive (even as to ITI except as provided in Section 2.1(c) below), royalty-bearing license, with the right to sublicense solely as provided in Section 2.1(d), under the ITI Technology (including the Assigned Patents until such Assigned Patents are assigned to Takeda), to research, Develop, make, have made, use, sell, offer for sale, import and otherwise Manufacture or Commercialize Compounds and Products in the Field in the Territory.

**(c) ITI Retained Rights.** Notwithstanding the rights assigned or granted to Takeda in Sections 2.1(a) and 2.1(b) and without limiting the generality of Section 2.4, ITI retains the following: (i) the right to practice the ITI Technology in the Territory to exercise its rights or to fulfill its obligations under this Agreement, including the Manufacturing, Development and co-promotion of Compounds and Products; and (ii) the right to practice and license the ITI Technology (including the Assigned Patents licensed to ITI under Section 2.2(b)) only outside the scope of the license granted to Takeda in Section 2.1(b). For clarity, each Party may use and provide to Third Parties Compound(s) as a Reagent but only in its respective field (in the case of Takeda, in the Field, and in the case of ITI, outside the Field), including the research, development, manufacture and sale of Products in such respective field as permitted under this Agreement. For the avoidance of doubt, ITI shall not transfer, provide or sell Compounds to a Third Party as a Reagent except in connection with the research, development, manufacture or sale of an animal health or diagnostic product. As used herein, "**Reagent**" means a Compound in pure form and not packaged or formulated for use as a diagnostic or therapeutic product.

**(d) License/Sublicense Rights.**

**(i)** Subject to the terms and conditions of this Agreement, Takeda shall have the right to grant a license under the Assigned Patents, and a sublicense of the license granted in Section 2.1(b), to its Affiliates or Third Parties. Takeda shall remain primarily responsible for all of its licensees' and sublicensees' activities and any and all failures by its licensees and sublicensees to comply with the applicable terms of this Agreement.

**(ii)** Takeda shall, within [\*\*\*] ([\*\*\*) [\*\*\*] after granting any license or sublicense of the right to Commercialize the Products under Section 2.1(b) above, notify ITI of the grant of such license or sublicense, summarizing the license scope and territory (each agreement granting such license or sublicense, a "**Takeda Sublicense Agreement**"). Each Takeda Sublicense Agreement shall be consistent with the terms and conditions of this Agreement and shall provide that the sublicensee shall be bound by and subject to all applicable terms and conditions of this Agreement in the same manner and to the same extent as Takeda is

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bound thereby. Takeda shall use Commercially Reasonable Efforts to include provisions in each Takeda Sublicense Agreement providing that Takeda and ITI shall have the same rights, ownership and/or licenses to all inventions and Information (including all data, know-how, inventions, Regulatory Materials and Regulatory Approvals) generated by such sublicensee to the same extent as if such invention or Information was generated by Takeda, which rights, ownership and/or licenses shall survive the termination of the Takeda Sublicense Agreement. If, despite using Commercially Reasonable Efforts, Takeda is not able to include such provisions in any Takeda Sublicense Agreement, Takeda shall be released from further obligation under the preceding sentence with respect to such Sublicense Agreement, but prior to Takeda's execution of such agreement, Takeda will use good faith efforts to discuss with ITI whether there is a solution reasonably acceptable to both Parties.

**(e) Future Third Party Licenses.** The ITI Technology licensed to Takeda in Section 2.1(b) will include Patents or Information licensed to ITI by a Third Party after the Effective Date only if the following procedure is complied with:

**(i)** ITI discloses to Takeda for review, reasonably in advance of ITI's anticipated entry into the applicable agreement between ITI and such Third Party, the substantive terms of such license agreement (which ITI hereby covenants to do), at least to the extent Takeda can reasonably understand the contents of the applicable Patents and Information, the scope of the license and the financial terms thereof; provided that upon Takeda's reasonable request, Takeda may participate in ITI's negotiation with the Third Party, provided that ITI shall have the sole right to agree to any terms with such Third Party (which terms will bind Takeda only if agreed by Takeda in accordance with sub-section (ii) below), or Takeda may negotiate a direct license with the Third Party; and

**(ii)** Takeda provides ITI with written notice, prior to ITI's entry into such license agreement, in which (A) Takeda assumes all payment obligations under such license agreement to the extent arising out of the use, Development, Manufacture or Commercialization of any Compound or Product by or on behalf of Takeda, as well as all other obligations of such license agreement that are applicable to sublicensees, and (B) Takeda acknowledges in writing that its sublicense under such license agreement is subject to the terms and conditions of such license agreement. For the avoidance of doubt, if only such Third Party's Patents cover a particular Product in a country, and the remaining ITI Patents and the Joint Patents do not cover such Product in such country, then the royalty term under Section 8.5(b)(i) shall not be extended on account of such Third Party's Patents.

Any applicable Patents and Information for which the above conditions are not met shall be deemed "**Excluded Patents**" and "**Excluded Information**," respectively.

**(f) Additional Patents.** The Parties acknowledge that as of the Effective Date, ITI has an exclusive license under the Patents set forth on Exhibit C-2 and that such Patents are not included in the ITI Patents. ITI covenants that during the Term, ITI shall not grant any Third Party a license under such Patents to research, Develop, make, have made, use, sell, offer for sale, import and otherwise Manufacture or Commercialize Compounds and Products in the Field in the Territory. If Takeda determines that a license under any of such

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Patents would be necessary for Takeda to practice the licenses granted to Takeda in Section 2.1(b), then Takeda shall notify ITI, and ITI shall grant Takeda a sublicense under its license to the applicable Patents, and such sublicense would be considered a future Third Party license subject to the terms of Section 2.1(e).

## 2.2 Licenses to ITI.

**(a) License to ITI under Takeda Technology.** Subject to the terms and conditions of this Agreement, Takeda hereby grants to ITI a non-exclusive, fully-paid, royalty-free license, without the right to grant sublicenses (except to Affiliates and subcontractors upon written notice to Takeda, as permitted under Section 4.9), under the Takeda Technology (except for the Takeda Technology licensed by a Third Party) during the Term, for the sole purpose of conducting any and all activities assigned to ITI under the Research Plan, the Development Plan or the Commercialization Plans.

**(b) License to ITI under Assigned Patents.** Takeda hereby grants to ITI a fully-paid, royalty-free, perpetual, irrevocable, worldwide license, with the right to grant sublicenses through multiple tiers, under the Assigned Patents, for any and all purposes outside the scope of the license granted to Takeda under Section 2.1(b). Such license shall be exclusive for the Sole Assigned Patents and non-exclusive for the Joint Assigned Patents.

**2.3 Negative Covenant.** Takeda covenants that it will not, and will not permit any of its Affiliates or sublicensees to, use or practice any ITI Technology outside the scope of the license granted to it under Section 2.1(b). ITI covenants that it will not, and will not permit any of its Affiliates or sublicensees to, use or practice any Takeda Technology outside the scope of the license granted to it under Section 2.2.

**2.4 No Implied Licenses.** Except as explicitly set forth in this Agreement, neither Party shall be deemed by estoppel or implication to have granted the other Party any license or other right to any intellectual property of such Party.

## 2.5 Exclusivity.

**(a)** [\*\*\*] hereby covenants that [\*\*\*] (i) [\*\*\*]; and (ii) [\*\*\*].

**(b)** [\*\*\*].

**(c)** In the event of any Change of Control of ITI (or successor entity thereto, applying the definition of Change of Control to such successor in place of ITI), Section 2.5(a) and (b) shall not apply or otherwise restrict the activities of the Acquiror of ITI or its Affiliates (except for ITI to the extent ITI survives such acquisition as a separate entity) with respect to any product owned or controlled by such Acquiror or its Affiliates (other than ITI) prior to or as of the date of such Change of Control or thereafter if such product does not use any ITI Know-How or is not claimed by any ITI Patent.

**(d)** If Takeda, during the Term, acquires or is acquired by a Third Party, and such transaction would result in Takeda breaching the terms of Section 2.5(a), then Takeda shall

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elect one of the following by written notice to ITI within [\*\*\*] ([\*\*\*) [\*\*\*] after the closing of the transaction, in which case Takeda will be deemed not to be in breach of Section 2.5(a): (i) [\*\*\*], (ii) [\*\*\*], or (iii) [\*\*\*].

### ARTICLE 3 GOVERNANCE

**3.1 Alliance Managers.** Within [\*\*\*] ([\*\*\*) [\*\*\*] after the Effective Date, each Party shall appoint and notify the other Party of the identity of a representative having the appropriate qualifications, including a general understanding of pharmaceutical development and commercialization issues, to act as its alliance manager under this Agreement (the “**Alliance Manager**”). The Alliance Managers will serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress of the Parties’ research, Development and Commercialization of Compounds and Products. The Alliance Managers will also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

#### **3.2 Joint Steering Committee.**

**(a) Formation and Role.** Within [\*\*\*] ([\*\*\*) [\*\*\*] after the Effective Date, the Parties shall establish a joint steering committee (the “**Joint Steering Committee**” or “**JSC**”) for the overall coordination and oversight of the Parties’ activities under this Agreement. The role of the JSC shall be high-level, strategic oversight and discussion of the Parties’ activities, in particular with respect to the Development and co-promotion of Products for and in the U.S. and, to the extent related to Development of Products for the U.S., Development of Products for that part of the EU subject to the jurisdiction of EMA (it being understood that such Development for the EU is anticipated to be closely tied to Development for the U.S.). For that purpose and to the extent reasonably necessary, the JSC will:

**(i)** coordinate the activities of the Parties under this Agreement, including facilitating communications and discussion between the Parties with respect to the research under the Research Program, Development of Products for the U.S. and EU, and Commercialization of Products for the U.S. if ITI exercises a Co-Promotion Option under Section 6.4;

**(ii)** review, discuss and approve the Development Plan and any proposed amendments or revisions to such plan;

**(iii)** review and fully discuss the research of Back-Up Compounds, the Development of Products for the U.S. and EU, and the Commercialization of Products in such regions, and any other ongoing activities;

**(iv)** select Back-Up Compounds for further Development;

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(v) coordinate the Product manufacturing and supply activities of the Parties, including the transition of manufacturing responsibilities from ITI to Takeda pursuant to Section 7.4;

(vi) review and discuss the draft Commercialization Plan for each Co-Promotion Product;

(vii) review, discuss and coordinate the Commercialization activities of ITI and Takeda with respect to Co-Promotion Products, including pre-launch and post-launch activities and any co-promotion activities by the Parties;

(viii) resolve disputes arising from the JRC or JPC; and

(ix) perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as determined by the Parties in writing.

The JSC shall have only the powers expressly assigned to it in this Section 3.2 and elsewhere in this Agreement, and shall have no power to amend, modify, or waive compliance with this Agreement. For clarity, the JSC shall not have the power to make any tactical or day-to-day operational decisions with respect to either Party's activities under this Agreement, and each Party shall have the right to make such decisions with respect to its own activities, reasonably and subject to the terms and conditions of this Agreement.

**(b) Members.** Each Party shall initially appoint [\*\*\*] ([\*\*\*]) [\*\*\*] to the JSC, each of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. The JSC shall have a chairperson, who shall be selected alternately, on an annual basis, by ITI or Takeda. The initial chairperson shall be selected by ITI. The role of the chairperson shall be to convene and preside at the meetings of the JSC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JSC representatives.

**(c) Meetings.** The JSC shall meet at least [\*\*\*] ([\*\*\*]) [\*\*\*] per calendar quarter until the First Commercial Sale of the Product in the U.S. and at least [\*\*\*] ([\*\*\*]) [\*\*\*] per calendar year thereafter, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference or teleconference) by at least [\*\*\*] ([\*\*\*]) [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JSC no later than [\*\*\*] ([\*\*\*]) [\*\*\*] [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision. No later than [\*\*\*] ([\*\*\*]) [\*\*\*] prior to any meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of

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such meeting. The JSC may meet in person, by videoconference or by teleconference, provided however, during the Research Term at least [\*\*\*] ([\*\*\*) [\*\*\*] per calendar year shall be in person unless the Parties mutually agree in writing to waive such requirement in lieu of a videoconference or teleconference. In-person JSC meetings shall be held at locations in the U.S. alternately selected by ITI and by Takeda. Each Party shall bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least [\*\*\*] ([\*\*\*) [\*\*\*] of each Party is present or participating in such meeting. The chairperson of the JSC shall be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, all material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to each member of the JSC for review and approval within [\*\*\*] ([\*\*\*) [\*\*\*] after each JSC meeting. Such minutes shall be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within [\*\*\*] ([\*\*\*) [\*\*\*] of receipt.

**(d) Decision Making.** The JSC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. The JSC shall strive to seek consensus in its actions and decision making process. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC is still unable after a period of [\*\*\*] ([\*\*\*) [\*\*\*] to reach a unanimous decision on such matter, then either Party may refer such matter to the Parties' Executive Officers for attempted resolution by good faith resolution within [\*\*\*] ([\*\*\*) [\*\*\*] after such matter has been referred to the Executive Officers; provided, however, that the Parties acknowledge and agree that (i) the purpose of the JSC is to facilitate the efficient Development of Products primarily for the U.S. and (ii) if either Party reasonably believes and provides such belief that such [\*\*\*] ([\*\*\*) [\*\*\*] or [\*\*\*] ([\*\*\*) [\*\*\*] delay would hinder or delay any Development activities under the Development Plan or that have been committed to a Regulatory Authority by a particular date, then the Parties shall reduce such time periods as reasonably necessary to prevent such hindrance or delay. If the Executive Officers are not able to resolve such matter within such [\*\*\*] ([\*\*\*) [\*\*\*] period or the reduced period, then the Takeda Executive Officer shall have the right to decide such matter; provided, however, that:

**(i)** no amendment to the Research Plan that materially changes the nature or scope of each item or task assigned to ITI under Figure 1 of the Initial Research Plan, or three (3) year time period of the Research Term, may be adopted or approved without the prior written consent of ITI, not to be unreasonably withheld or delayed; and

**(ii)** with respect to the content of the Development Plan, the Takeda Executive Officer shall not make any determination that would materially change the nature or scope of ITI's responsibilities explicitly assigned to ITI as provided thereunder without ITI's prior written consent, not to be unreasonably withheld or delayed.

Notwithstanding the foregoing, with respect to disputes arising from the JPC (as defined in Section 3.4) and referred to the JSC for resolution, the JSC's decision will be non-binding and advisory only, and will not be subject to escalation to the Executive Officers. All disputes with respect to matters under the purview of the JPC shall be resolved in accordance with the terms of Article 9 and, if necessary, Section 14.3.

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### 3.3 Joint Research Committee.

**(a) Formation and Role.** Within [\*\*\*] ([\*\*\*]) [\*\*\*] after the Effective Date, the Parties shall establish a joint research committee (the “**Joint Research Committee**” or “**JRC**”). The JRC shall exist during the Research Term only and shall have overall responsibility for the performance of the Research Program and implementation of the Research Plan, and shall establish priorities and schedules for research activities with respect to Compounds (including Back-Up Compounds), consistent with the applicable target product profile approved by the JSC. The JRC shall review, discuss and approve the Research Plan and any proposed amendments thereto.

**(b) Members.** Each Party shall initially appoint [\*\*\*] ([\*\*\*]) [\*\*\*] to the JRC, each of whom will be an employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JRC’s responsibilities. The JRC may change its size from time to time by mutual consent of its members, and each Party may replace its representatives at any time upon written notice to the other Party. The JRC shall have a chairperson, who shall be selected alternately, on an annual basis, by ITI or Takeda. The initial chairperson shall be selected by ITI. The role of the chairperson shall be to convene and preside at the meetings of the JRC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JRC representatives.

**(c) Meetings.** The JRC shall meet at least [\*\*\*] ([\*\*\*]) [\*\*\*] per calendar quarter during the Research Term unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JRC (by videoconference or teleconference) by at least [\*\*\*] ([\*\*\*]) [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JRC no later than [\*\*\*] ([\*\*\*]) [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision. No later than [\*\*\*] ([\*\*\*]) [\*\*\*] prior to any meeting of the JRC, the chairperson of the JRC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JRC may meet in person, by videoconference or by teleconference. In-person JRC meetings shall be held at locations in the U.S. alternately selected by ITI and by Takeda. Each Party shall bear the expense of its respective JRC members’ participation in JRC meetings. Meetings of the JRC shall be effective only if at least [\*\*\*] ([\*\*\*]) [\*\*\*] of each Party is present or participating in such meeting. The chairperson of the JRC shall be responsible for preparing reasonably detailed written minutes of all JRC meetings that reflect, without limitation, all material decisions made at such meetings. The JRC chairperson shall send draft meeting minutes to each member of the JRC for review and approval within [\*\*\*] ([\*\*\*]) [\*\*\*] after each JRC meeting. Such minutes shall be deemed approved unless one or more members of the JRC objects to the accuracy of such minutes within [\*\*\*] ([\*\*\*]) [\*\*\*] of receipt.

**(d) Decision Making.** The JRC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. The JRC shall strive to seek consensus in its actions and decision making process. If after reasonable discussion and

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good faith consideration of each Party's view on a particular matter before the JRC, the JRC is still unable after a period of [\*\*\*] ([\*\*\*]) [\*\*\*] to reach a unanimous decision on such matter, then the Parties shall refer such matter to the JSC for resolution; provided, however, that the Parties acknowledge and agree that (i) the purpose of the JRC is to facilitate the efficient research of Compounds and (ii) if either Party reasonably believes and provides such belief that such [\*\*\*] ([\*\*\*]) [\*\*\*] delay would hinder or delay any activities under the Research Plan, then the Parties shall reduce such time period as reasonably necessary to prevent such hindrance or delay.

### 3.4 Joint Patent Committee.

**(a) Formation and Role.** Within [\*\*\*] ([\*\*\*]) [\*\*\*] after the Effective Date, the Parties will establish and convene a joint patent committee (the "Joint Patent Committee" or "JPC") for the overall coordination and oversight of the strategy for the preparation, filing, prosecution and maintenance of the ITI Prosecuted Patents and Joint Patents. The JPC's role shall be advisory only, and all decisions with respect to the preparation, filing, prosecution and maintenance of the ITI Prosecuted Patents and Joint Patents shall be in accordance with the terms of Article 9.

**(b) Members.** Each Party shall initially appoint [\*\*\*] ([\*\*\*]) [\*\*\*] to the JPC, at least one (1) of whom will be an officer or employee of the applicable Party having sufficient seniority within such Party to make decisions arising within the scope of the JPC's responsibilities. Each Party may replace its representatives at any time upon written notice to the other Party. The JPC shall have a chairperson, who shall be selected alternately, on an annual basis, by ITI or Takeda. The initial chairperson shall be selected by ITI. The role of the chairperson shall be to convene and preside at the meetings of the JPC and to ensure the preparation of meeting minutes, but the chairperson shall have no additional powers or rights beyond those held by other JPC representatives.

**(c) Meetings.** The JPC shall meet at least [\*\*\*] ([\*\*\*]) [\*\*\*] per calendar quarter during the Research Term unless the Parties mutually agree in writing to a different frequency for such meetings. During the Term, either Party may also call a special meeting of the JPC (by videoconference or teleconference) by at least [\*\*\*] ([\*\*\*]) [\*\*\*] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting, and such Party shall provide the JPC no later than [\*\*\*] ([\*\*\*]) [\*\*\*] prior to the special meeting with materials reasonably adequate to enable an informed decision. No later than [\*\*\*] ([\*\*\*]) [\*\*\*] prior to any meeting of the JPC, the chairperson of the JPC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JPC may meet in person, by videoconference or by teleconference. In-person JPC meetings shall be held at locations in the U.S. alternately selected by ITI and by Takeda. Each Party shall bear the expense of its respective JPC members' participation in JPC meetings. Meetings of the JPC shall be effective only if at least one (1) representative of each Party is present or participating in such meeting. The chairperson of the JPC shall be responsible for preparing reasonably detailed written minutes of all JPC meetings that reflect, without limitation, all material matters discussed at such meetings. The JPC chairperson shall send draft meeting minutes to each member of the JPC for review and approval

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within [\*\*\*] ([\*\*\*]) [\*\*\*] after each JPC meeting. Such minutes shall be deemed approved unless one or more members of the JPC objects to the accuracy of such minutes within [\*\*\*] ([\*\*\*]) [\*\*\*] of receipt.

**(d) JPC Decisions and Actions.** The JPC shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. The JPC shall strive to seek consensus in its actions and decision making process. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JPC, the JPC is still unable after a period of [\*\*\*] ([\*\*\*]) [\*\*\*] to reach a unanimous decision on such matter, then the matter shall be referred to the JSC for resolution; provided that in any event, the JPC's decisions and any resolution by the JSC of disputes arising from the JPC shall be advisory only; further provided, however, that the Parties acknowledge and agree that (i) the purpose of the JPC is to facilitate the prosecution of ITI Prosecuted Patents and Joint Patents in a manner that maximizes the scope of protection afforded the Compounds and Products and (ii) if either Party reasonably believes and provides such belief that such [\*\*\*] ([\*\*\*]) [\*\*\*] delay would adversely affect the Parties' rights under any such Patents, then the Parties shall reduce such time period as reasonably necessary to prevent such adverse effect.

**3.5 Discontinuation of Participation in a Committee.** At any time and for any reason, either Party shall have the right to withdraw from participation in the JSC, JRC or JPC (each, a "Committee") upon written notice to the other Party, which notice shall be effective immediately upon receipt. Following such withdrawal and subject to this Section 3.5, the applicable Committee shall be disbanded and all decisions expressly delegated to such Committee shall be made by a representative of the Parties subject to the applicable escalation procedures in Sections 3.2(d), 3.3(d) and 3.4(d). For clarity, the withdrawal by a Party under this Section 3.5 shall only limit such Party's rights and obligations under this Article 3 with respect to participation and decision-making in the applicable Committee.

## ARTICLE 4 RESEARCH AND DEVELOPMENT

**4.1 Overview.** The Parties desire and intend to collaborate with respect to the research of Compounds in the Field and the Development of Products in the Field, under the direction of the JRC and JSC, and pursuant to a Research Plan and a Development Plan, respectively.

### 4.2 Research Program.

**(a) General.** ITI shall undertake a defined program to identify and characterize Back-Up Compounds in the Field using appropriate professional researchers and technicians, and pursuant to a comprehensive written research plan (the "**Research Plan**") and the terms of this Section 4.2 (such program, the "**Research Program**"). In addition, Takeda may conduct activities under the Research Plan in its discretion and at its expense and shall undertake those activities allocated to Takeda under the Initial Research Plan (defined below). In the event of any inconsistency between the Research Plan and this Agreement, the terms of this Agreement shall prevail.

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**(b) Initial Research Plan and Amendments.** The Parties have agreed to the initial Research Plan, a copy of which is attached hereto as Exhibit E (the “**Initial Research Plan**”). Each Party shall reasonably consider the other Party’s suggested amendments to the Research Plan. From time to time during the Research Term (at least on an annual basis), the JRC shall prepare amendments, as appropriate, to the then-current Research Plan, which amendments shall be approved and adopted by the JRC (or JSC, if applicable, in accordance with Section 3.2(d)(i)). Such amendments shall reflect any agreed changes, re-prioritization of studies within, reallocation of resources with respect to, or additions to the Research Program. Once approved by the JRC (or, if applicable, JSC), each updated or amended Research Plan shall become effective and supersede the previous Research Plan as of the date of such approval or at such other time as decided by the JRC. The JRC shall record each Back-Up Compound identified in the Research Program in the minutes for the meeting immediately following the identification of such Back-Up Compound.

**(c) Performance; Diligence.** ITI shall use Commercially Reasonable Efforts to conduct the Research Program in accordance with the then-current Research Plan and in a timely and effective manner using its competent researchers and technicians. ITI shall be solely responsible (using a portion of the upfront payment made by Takeda under Section 8.1) for all costs and expenses incurred by ITI to conduct items 1-5 (excluding 5a), 6, 7 and 8 (excluding 8a and 8b) as described on Figure 1 of the Initial Research Plan. If Takeda either (i) requests an amendment to the Research Plan that would increase the costs to ITI to conduct the Research Program, and if the Research Plan is so amended in accordance with the decision making procedures of Article 3, or (ii) requests that ITI perform any activity described on the Initial Research Plan other than noted in the immediately prior sentence), then Takeda shall be solely responsible for all reasonable additional costs and expenses of ITI resulting from such amendment or request and the performance by ITI of such activities. Takeda shall pay such costs as it does ITI’s Development costs pursuant to Sections 4.5 and 8.2.

**(d) Research Term.** The Research Program has an initial term of [\*\*\*] ([\*\*\*) [\*\*\*] commencing on the Effective Date (the “**Research Term**”).

#### **4.3 Development Program.**

**(a) General.** Takeda agrees to undertake a collaborative program to conduct nonclinical Development of Compounds and clinical Development of Products in the Field in accordance with the terms of this Section 4.3 (such program, the “**Development Program**”). The Parties shall conduct such collaborative Development pursuant to a comprehensive written Development plan (the “**Development Plan**”). Such Development Plan shall include a detailed plan for all nonclinical and clinical Development activities conducted by the Parties and anticipated under the Development Program (including all Development activities that are necessary for Regulatory Approval in the U.S. for at least one Indication (and in the EU and Japan if the data obtained through such Japan or EU-related activities is applicable to the Development and/or co-promotion for the U.S., including if such relevant Japan or EU-related Development activities are conducted earlier than such activities would be conducted for the U.S., or if ITI conducts any preclinical activities for EU Development)), regulatory strategy and activities, and the timeline regarding such activities. In the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail.

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**(b) Initial Development Plan and Amendments.** The Parties have agreed on the initial Development Plan for ITI-214, a copy of which is attached hereto as Exhibit F. From time to time during the Research Term and the Development of Products for the U.S. and EU (at least on an annual basis), the JSC shall prepare amendments, as appropriate, to the then-current Development Plan. Such amendments shall reflect any agreed changes, re-prioritization of studies within, reallocation of resources with respect to, or additions to the Development Program. Upon deciding to commence Development of any Back-Up Compound, or to commence Development of any Compound for a new Indication, the JSC shall amend the Development Plan accordingly. Once approved by the JSC, each updated or amended Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval or at such other time as decided by the JSC. In the event that the Parties mutually agree, ITI may conduct certain activities under the Development Plan.

**(c) Development Responsibilities.** Except for those activities allocated to ITI under the Development Plan by mutual written agreement of the Parties, Takeda shall be solely responsible for conducting all activities under the Development Program.

**(d) Performance.** Each Party shall use Commercially Reasonable Efforts to conduct the Development activities assigned to it under the Development Plan in a timely and effective manner.

**4.4 Diligence.** Takeda shall use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for each Product in the Field in the Territory. Without limiting the generality of the foregoing, Takeda agrees that (a) it will initially develop and seek Regulatory Approval for the Product in at least one of the following three (3) Indications: Schizophrenia, Alzheimer's Disease or ADHD; and (b) not later than the Initiation of the first Phase 3 Clinical Trial for the Product in the initial Indication, Takeda shall use Commercially Reasonable Efforts to initiate pre-clinical and/or clinical activities reasonably designed to evaluate the use of the Product for Indications other than the initial Indication. For the avoidance of doubt, Takeda may select more than one (1) Compound to be developed in the Development Program under the Development Plan, and may position any of them as a backup(s) to follow the first prioritized Compound.

**4.5 Development Costs.** Takeda shall be responsible for all its costs and expenses in the conduct of the Development Program and shall reimburse ITI for Development activities to be conducted by ITI under the Development Plan and other activities as described in Section 4.2(c) according to the terms of Section 8.2, together with the reimbursement for supply of Compound or Product in accordance with Sections 7.1 and 7.2.

**4.6 Data Exchange and Use.** Without unreasonable delay after the Effective Date, ITI shall provide, upon Takeda's reasonable request, Takeda with copies of or access to any data related to Compounds as specified by Takeda, to the extent such data is in existence as of the Effective Date and was not previously provided to Takeda. Each Party shall without

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unreasonable delay provide the other Party with a summary and description of all data and results generated from its research and Development activities under this Agreement. In addition, upon reasonable request from the other Party, the requested Party shall provide the other Party, at such other Party's expense, with complete copies of any of such data and results. Takeda shall have the right to use, without additional consideration, all data and results generated by ITI under this Agreement, which shall be included in the ITI Know-How, in accordance with the license granted in Section 2.1(b), and subject to the terms of this Agreement. Takeda shall have sole ownership of all data and results generated by Takeda under this Agreement, which shall be included in the Takeda Know-How. For the avoidance of doubt, such data and results will be included in the Takeda Technology and subject to the applicable terms of this Agreement, including assignment or license to ITI pursuant to Section 13.6(b) upon termination of this Agreement.

**4.7 Records and Reports.** Each Party shall maintain complete, current and accurate records of all research and Development activities conducted by it hereunder, and all data and other Information resulting from such activities. Such records shall fully and properly reflect all work done and results achieved in the performance of the research and Development activities in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all non-clinical studies and Clinical Trials in formal written study records according to applicable Laws, including applicable national and international guidelines such as ICH, GCP, GLP and GMP. Each Party shall have the right to review (with respect to Clinical Trial reports, before finalization) and copy such records maintained by the other Party at reasonable times and to obtain access to the originals to the extent necessary or useful for regulatory and patent purposes, to the extent such Party has the right to conduct regulatory and patent activities under this Agreement. Each Party shall provide the JSC with written reports detailing its research and Development activities under the Research Plan and the Development Plan and the results of such activities at each regularly scheduled JSC meeting. The Parties shall discuss the status, progress and results of each Party's research and Development activities under the Research Plan and Development Plan at such JSC meetings.

**4.8 Compliance with Laws.** Each Party shall conduct its activities under this Agreement in good scientific manner and in compliance in all material respects with all applicable Laws, including applicable national and international guidelines such as ICH, GCP, GLP and GMP.

**4.9 Subcontracts.** Each Party may perform any of its Research Program or Development Program obligations under this Agreement through one or more subcontractors or consultants, provided that (a) such Party remains responsible for the work allocated to, and payment to, such subcontractors and consultants as it selects to the same extent it would if it had done such work itself; (b) the subcontractor undertakes in writing obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the subcontractor agrees in writing to assign all intellectual property developed in the course of performing any such work under the Research Program or Development Program to the Party retaining such subcontractor.

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**ARTICLE 5**  
**REGULATORY MATTERS**

**5.1 Regulatory Responsibilities.** ITI shall prepare the IND for ITI-214 for filing by Takeda in accordance with the Development Plan, which IND shall reflect all timely and reasonable comments by Takeda to the draft IND, and Takeda shall be responsible for all reasonable costs and expenses incurred by ITI to conduct such activities as provided in Section 4.5. Subject to the terms and conditions of this Agreement, Takeda shall be solely responsible for filing the IND for ITI-214, using the IND files prepared by ITI, and also for preparing and filing any and all other Regulatory Materials for each Product in the Field in the Territory, at its sole expense, in accordance with the Development Plan. [\*\*\*]. ITI shall assist and cooperate with Takeda in connection with the preparation of such Regulatory Materials, as reasonably requested by Takeda and at Takeda's sole expense. Except as expressly contemplated by this Agreement or otherwise agreed to in writing by the Parties, ITI shall not submit any Regulatory Materials or seek Regulatory Approvals for the Compounds or the Products in the Territory and shall not communicate with respect to the Compounds or the Products with any Regulatory Authority, unless so required to comply with applicable Laws, in which case ITI shall promptly notify Takeda of such requirement under applicable Laws and, to the extent practicable and permitted under applicable Laws, shall submit any proposed communication to Takeda for prior approval or, if not practicable or permitted, shall provide Takeda with a copy or summary thereof as soon as reasonably practicable thereafter.

**5.2 Regulatory Reports.** Takeda shall keep ITI informed of major regulatory developments relating to Compounds and Products in the U.S., Japan and EU through regular reports at the JSC meetings and shall promptly notify ITI of any Regulatory Approval received for each Product in the Territory. For each Product for which the Co-Promotion Option under Section 6.4 has not expired unexercised, Takeda shall provide ITI with the opportunity to review and comment on draft material regulatory filings for Products submitted to FDA in the U.S. and EMA in EU at least [\*\*\*] ([\*\*\*]) [\*\*\*] in advance of their intended date of submission to the applicable Regulatory Authority, and shall consider in good faith any comments thereto timely provided by ITI; provided, however, that Takeda shall have the right to make the final decision on all such regulatory filings; and provided further that Takeda may reasonably reduce such [\*\*\*] ([\*\*\*]) [\*\*\*] review period as necessary if such time period would hinder or delay any regulatory filing activities that are committed to a Regulatory Authority or set forth in the Development Plan or would otherwise materially adversely affect Takeda's regulatory strategy for the applicable Product. Takeda shall promptly notify ITI of any material Regulatory Materials (other than routine correspondence) submitted to or received from any Regulatory Authority in the U.S. and EU and shall provide ITI with copies thereof within [\*\*\*] ([\*\*\*]) [\*\*\*] after submission or receipt. Takeda shall provide ITI with reasonable advance notice of all meetings, conferences, and discussions scheduled with any Regulatory Authority in the U.S. concerning a Co-Promotion Product, and shall consider in good faith any input from ITI in preparing for such meetings, conferences or discussion. To the extent permitted by applicable Laws, ITI may, upon Takeda's request or consent, participate in any such meetings, conferences or discussions, and Takeda shall facilitate such participation. If ITI elects not to participate in any such meetings, conferences or discussions, Takeda shall provide ITI with written summaries of such meetings, conferences or discussions in English as soon as practicable after the conclusion thereof.

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**5.3 Regulatory Costs.** Takeda shall be solely responsible for all costs and expenses related to the preparation, filing and maintenance of all Regulatory Materials and Regulatory Approvals for Products in the Territory, including reasonable costs and expenses incurred by ITI in providing requested assistance with respect to the preparation of such Regulatory Materials, as provided in Section 4.5.

**5.4 Notification of Threatened Action.** Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may materially affect the Development, Commercialization or regulatory status of a Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action. If ITI and Takeda are not able to agree on the procedure, Takeda shall have the right to decide the appropriate action.

**5.5 Adverse Event Reporting and Safety Data Exchange.** Following ITI's exercise of the Co-Promotion Option pursuant to Section 6.4, the Parties shall define and finalize the methods and procedures that the Parties shall employ with respect to Products to protect patient safety and promote the appropriate treatment of safety information of the Co-Promotion Product in a written pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). These responsibilities shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports, pregnancy reports, and any other information concerning the safety of any Co-Promotion Product. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under applicable Laws. Furthermore, such agreed procedure shall be consistent with relevant ICH guidelines, except where such guidelines may conflict with existing local regulatory reporting or safety reporting requirements, in which case the local reporting requirements shall prevail. Takeda shall maintain an adverse event database for the Products in the Territory, at Takeda's expense. With respect to all Products that are not Co-Promotion Products, the Parties will discuss and finalize the methods and procedure to exchange safety information (AE and SAE) for such Products at reasonable timing after the Effective Date, to satisfy ITI's reasonable needs for such safety information. Takeda shall be responsible for reporting quality complaints, adverse events and safety data related to Products to applicable Regulatory Authorities in the Territory, as well as responding to safety issues and to all requests of Regulatory Authorities relating to Products in the Territory. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and permitted sublicensees to comply with such obligations.

**5.6 Recalls.** If, in the course of conducting co-promotion activities under a Co-Promotion Agreement, ITI becomes aware of information that indicates that a unit or batch of any Product may not conform to the specifications therefor, or that potential adulteration, misbranding, or other issues have arisen that relate to the safety or efficacy of Products, ITI shall promptly notify Takeda and provide the details of such information. Upon Takeda's reasonable request, ITI will assist Takeda in Takeda's gathering and evaluating such information as is necessary to determine the necessity of conducting a recall, corrective action or other regulatory action with respect to a Co-Promotion Product in the U.S. or any other Product in the Territory

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taken by virtue of applicable Laws (a “**Remedial Action**”). Takeda shall, and shall ensure that its Affiliates and sublicensees will, maintain adequate records to trace the manufacture, distribution and use of the Products. Takeda shall have the exclusive right to decide whether any Remedial Action with respect to Products, including Co-Promotion Products, in the Field and in the Territory should be commenced, and Takeda shall notify ITI, in advance if practicable, and if not practicable, thereafter and without unreasonable delay, of such Remedial Action and shall have the obligation, at its expense, to control and coordinate all efforts (including assistance by ITI as provided above in this Section 5.6) necessary to conduct such Remedial Action for the Field and in the Territory.

## ARTICLE 6 COMMERCIALIZATION

**6.1 Commercialization Responsibilities.** Subject to Section 6.4, Takeda will have the exclusive right to and be solely responsible for all aspects of the Commercialization of each Product in the Field in the Territory, including: (a) developing and executing a commercial launch and pre-launch plan, (b) negotiating with applicable Governmental Authorities regarding the price and reimbursement status of the Product; (c) marketing and promotion; (d) booking sales and distribution and performance of related services; (e) handling all aspects of order processing, invoicing and collection, inventory and receivables; (f) providing customer support, including handling medical queries, and performing other related functions; and (g) conforming its practices and procedures to applicable Laws relating to the marketing, detailing and promotion of Products in the Territory. Takeda shall bear all of the costs and expenses incurred in connection with such Commercialization activities. The strategy for the commercial launch in the U.S. of each Product shall be described in a comprehensive plan that describes the pre-launch, launch and subsequent Commercialization activities for such Product in the U.S. (including pricing, advertising, education, planning, marketing, sales force training and allocation) (each such plan, a “**Commercialization Plan**”). Takeda shall provide the JSC with a draft Commercialization Plan for each Product [\*\*\*] ([\*\*\*]) [\*\*\*] prior to the anticipated First Commercial Sale of such Product in the U.S. With respect to the Commercialization Plan for a Co-Promotion Product, Takeda shall consider ITI’s JSC representatives’ comments thereto in good faith.

**6.2 Commercial Diligence.** Takeda shall use Commercially Reasonable Efforts to Commercialize each Product in each country in the Territory in which it receives Regulatory Approval. Without limiting the generality of the foregoing, Takeda shall use Commercially Reasonable Efforts to achieve First Commercial Sale of each Product in the U.S. or EU within [\*\*\*] ([\*\*\*]) [\*\*\*] after the applicable Regulatory Approval of such Product.

**6.3 Commercialization Reports.** Takeda shall update the JSC periodically at each regularly scheduled JSC meeting regarding Takeda’s Commercialization activities with respect to the Products in the Territory. Each such update shall summarize Takeda’s significant Commercialization activities with respect to each Product in the Territory pursuant to this Agreement, covering subject matter at a level of detail sufficient to enable ITI to determine Takeda’s compliance with its diligence obligations pursuant to Section 6.2. In addition, on an annual basis, Takeda shall provide an updated Commercialization Plan for each Product to the JSC.

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**6.4 Co-Promotion.** ITI shall have the option to co-promote each Product in the U.S. as set forth below.

**(a) Co-Promotion Option.** Takeda hereby grants to ITI the option (the “**Co-Promotion Option**”) to co-promote each Product in the U.S. in accordance with Takeda’s then-applicable Commercialization Plan, which option may be exercised by ITI upon written notice to Takeda, on a Product-by-Product basis [\*\*\*]. No later than [\*\*\*] ([\*\*\*]) [\*\*\*], Takeda shall provide ITI with all Information in its Control which was not previously provided to ITI and to the extent reasonably necessary for ITI to determine whether to exercise the Co-Promotion Option for such Product and shall reasonably respond to ITI’s reasonable requests for additional Information. ITI shall be responsible for Takeda’s reasonable costs to copy and deliver such Information to ITI.

**(b) Co-Promotion Agreement.** Upon the exercise of the Co-Promotion Option by ITI for a particular Product (a “**Co-Promotion Product**”), the Parties shall negotiate in good faith (with each Party not to unreasonably withhold or delay its consent to such agreement) to agree on the commercially reasonable terms for both Parties of a definitive co-promotion agreement consistent with the terms of this Agreement [\*\*\*] ([\*\*\*]) [\*\*\*] ([\*\*\*]([\*\*\*]) [\*\*\*]) (the “**Co-Promotion Agreement**”). Together with the Commercialization Plan, the Co-Promotion Agreement would include provisions for, without limitation, the target call list and responsible call number for the ITI sales force (provided that ITI may not use a contract sales organization (CSO) to fulfill its obligations under the Co-Promotion Agreement, except with the consent of Takeda, not to be withheld unreasonably, and in such case only for a reasonable transition period), training of the ITI sales force by Takeda, creation and use of promotional materials, and other appropriate provisions for such a co-promotion arrangement. If the Parties successfully agreed on the material terms of such Co-Promotion Agreement especially terms affecting matters described in the Commercialization Plan by the applicable deadline, the Parties shall continue in good faith the negotiation to execute the Agreement [\*\*\*] ([\*\*\*]) [\*\*\*]. Upon execution of a Co-Promotion Agreement, the Parties will establish a joint co-promotion committee to coordinate and oversee the Parties’ co-promotion of Co-Promotion Products, which committee would have procedures and a meeting schedule equivalent to those of the JSC as described in Section 3.2, except that such committee would refer unresolved disputes to the JSC for resolution.

**(c) Co-Promotion Terms.** The Co-Promotion Agreement for a Co-Promotion Product shall provide that the Parties shall each provide sales force efforts (i.e., detailing equivalents) for the detailing of such Co-Promotion Product in a manner reasonably acceptable to the Parties and consistent with Takeda’s then current Commercialization Plan. ITI shall have the right to provide [\*\*\*] ([\*\*\*]) of the overall detailing activity in the U.S., or such higher percentage as agreed by Takeda (which agreement shall not be withheld unreasonably), taking into account ITI’s then-current capabilities, and subject to financial terms for the co-promotion of such Co-Promotion Product including those as set forth in the following sentence. Takeda would pay ITI for its promotion efforts on a per-detail basis, [\*\*\*].

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**ARTICLE 7**  
**MANUFACTURE AND SUPPLY**

**7.1 Responsibilities.** ITI shall be responsible for the supply of ITI-214 in the quantities in ITI's inventory and being manufactured for ITI for nonclinical and Phase 1 Clinical Trial use as of the Effective Date, in accordance with the terms of ITI's existing supply arrangements, without cost to Takeda. At Takeda's request, ITI shall conduct, through its contract manufacturer, an additional production run to manufacture an additional batch of ITI-214, and Takeda shall be responsible for all reasonable expenses therefor. At Takeda's request, ITI shall cooperate with Takeda to assign to Takeda ITI's interest in its existing supply agreement with its contract manufacturer for ITI-214. Further, ITI will conduct those other Manufacturing activities as agreed by the Parties and set forth in the Development Plan. Takeda shall be responsible for all other Manufacture and supply of Compounds and Products in bulk and finished form for use under this Agreement, for Development and Commercialization purposes. The Parties will execute a quality agreement reasonably acceptable to both Parties to the extent necessary to comply with applicable Laws (to include, as required a certification by ITI) regarding any Compound or Product provided by ITI to Takeda for Clinical Trial use under this Agreement.

**7.2 Manufacturing Costs.** Takeda shall be responsible for all its costs and expenses for the Manufacture of the Compounds and Products, subject to the terms of this Section 7.2, and will reimburse ITI for any supply of the Compounds and Products in accordance with ITI's Manufacturing Cost incurred in connection with such supply and for any other Manufacturing activities in accordance with the terms of Section 8.2. For the avoidance of doubt and subject to Section 7.1, ITI will supply, at its expense (and not subject to reimbursement by Takeda), any inventory of ITI-214 that has been manufactured for ITI prior to the Effective Date for use by the Parties under this Agreement.

**7.3 Subcontracts.** Each Party may perform any of its manufacturing and supply obligations under this Agreement through one or more Third Party manufacturers, provided that (a) such Party remains responsible for the work allocated to, and payment to, such Third Party manufacturer as it selects to the same extent it would if it had done such work itself; (b) the Third Party manufacturer undertakes in writing obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties pursuant to Article 12 hereof, and (c) the Third Party manufacturer agrees in writing to assign all intellectual property developed in the course of performing any such manufacturing to the Party retaining such Third Party manufacturer. In addition to the foregoing, Takeda shall use Commercially Reasonable Efforts to include in each agreement with a Third Party manufacturer of Product a provision requiring that such manufacturing agreement be freely assignable to ITI if this Agreement is terminated. A Party may also subcontract work on terms other than those set forth in this Section 7.3, with the prior approval of the other Party, not to be unreasonably withheld or delayed.

**7.4 Transfer of Manufacturing Technology.** ITI shall transfer to Takeda or a Third Party manufacturer reasonably designated by Takeda all ITI Know-How Controlled by ITI or its Affiliate, and any contracts with a Third Party manufacturer of any Compound (on Takeda's

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request and to the extent assignable and related to a Compound), as of the date of transfer that is necessary or reasonably useful for Takeda or such Third Party manufacturer (as appropriate) to replicate the process employed by or on behalf of ITI as of such date to Manufacture ITI-214 and, as applicable, other Compounds and Products, such transfer to occur in a timely manner commencing at a time and on a schedule reasonably agreed by the Parties in writing. For the avoidance of doubt, nothing in this Section 7.4 with respect to ITI's obligation to transfer manufacturing know-how to Takeda shall limit ITI's right to use any manufacturing know-how in order to fulfill ITI's obligations in accordance with this Agreement. The reasonable costs and expenses incurred by ITI, including any internal personnel costs, in carrying out such transfer shall be reimbursed by Takeda on a calendar quarter basis within [\*\*\*] ([\*\*\*)] [\*\*\*] after receipt of invoice therefor from ITI together with documentary evidence therefor. In addition, ITI shall make available to Takeda, on a reasonable consultation basis, advice of its technical personnel as may reasonably be requested by Takeda in connection with such transfer of ITI Know-How. Takeda agrees to reimburse ITI for the fully-burdened charges for the time and expenses of such personnel when consulting for Takeda. If such consulting is held at Takeda's or Takeda's designated manufacturer's site, Takeda shall reimburse ITI for reasonable travel expenses incurred by personnel of ITI at the request of Takeda while rendering services under this Section 7.4.

**7.5 Use of Manufacturing Information.** Takeda and/or its Affiliates and Third Party manufacturer shall use any Information transferred pursuant to Section 7.4 in accordance with the license granted in Section 2.1(b) and solely for the purpose of manufacturing Compounds and Products for uses permitted under this Agreement, and for no other purpose (provided, however, that, for the avoidance of doubt, such restriction shall not apply to the extent of any applicable exclusions in Article 12). Takeda acknowledges and agrees that ITI may condition its agreement to transfer any ITI Know-How to a Third Party manufacturer on the execution of a confidentiality agreement between such Third Party manufacturer and ITI that contains terms substantially equivalent to those of Article 12 of this Agreement.

## ARTICLE 8 COMPENSATION

**8.1 Upfront and Research Funding Payment.** Within five (5) Business Days of the Effective Date, Takeda shall pay to ITI a one-time, non-refundable and non-creditable upfront payment of [\*\*\*] ([\*\*\*)] [\*\*\*].

**8.2 ITI Development and Manufacturing Activities.** Takeda shall fund all internal FTE costs (at the FTE Rate) and all amounts reasonably paid by ITI to Third Parties, in each case as incurred by ITI to conduct the Development Program, including all activities under Sections 5.1 and 7.1, and to conduct any activity under the Research Program other than the activities described in Section 4.2(c) (specified on Figure 1 of the Initial Research Plan as to be performed by ITI). Within [\*\*\*] ([\*\*\*)] [\*\*\*] after each calendar quarter during the Research Term and the Development Program, ITI shall send to Takeda an invoice for all internal FTE costs ITI incurred in such quarter to conduct the applicable activities under the Research Plan and all activities allocated to ITI in the Development Plan in accordance with the Development Plan. Also, within [\*\*\*] ([\*\*\*)] [\*\*\*] after each month during the Research Term and the Development

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Program, ITI shall send to Takeda an invoice for all amounts paid to Third Parties during such month to conduct the Development Program and the applicable activities under the Research Plan. Together with such quarterly and monthly invoices, ITI shall submit an appropriate report to Takeda setting forth respectively the actual FTE costs (at the FTE Rate) or reasonable amounts paid by ITI to Third Parties, in each case as incurred by ITI during the previous quarter or month, respectively, under the Development Plan or to conduct the applicable activities under the Research Plan. Takeda shall pay each such invoice within [\*\*\*] ([\*\*\*) [\*\*\*] after receipt thereof.

**8.3 Development Milestone Payments.** Takeda shall make each of the following non-refundable, non-creditable development milestone payments to ITI upon the achievement by Takeda, its Affiliates or their respective sublicensees of the following development events. Takeda shall pay to ITI each such amount within [\*\*\*] ([\*\*\*) [\*\*\*] after the achievement of the applicable milestone event. Each of the below milestone payments shall be made [\*\*\*].

(a) [\*\*\*]. [\*\*\*] shall pay [\*\*\*] ([\*\*\*) [\*\*\*]. This payment will be made by [\*\*\*].

(b) **Schizophrenia, Alzheimer’s Disease and ADHD.** Takeda shall make the following development milestone payments for the achievement of the applicable milestone events by a Product in each of the following three (3) Indications: Schizophrenia, Alzheimer’s Diseases and ADHD. For clarity, each of the following development milestone payments shall be made [\*\*\*] and shall be paid [\*\*\*].

<u>Development Milestone Event</u>	<u>Milestone Payment</u> [***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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(c) **Other Indications.** Takeda shall make the following development milestone payments for [\*\*\*]. For clarity, [\*\*\*], regardless of [\*\*\*].

<u>Development Milestone Event</u>	<u>Milestone Payment</u> [***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(d) **Clarifications.**

(i) Only if a milestone event for [\*\*\*] or for [\*\*\*], as described under sub-section (b) or (c) above, is achieved for a given Indication and Takeda has not yet made a milestone payment for a preceding milestone for the same Indication, the preceding milestone event is deemed achieved, and the corresponding milestone payment is due and payable together with the payment of the milestone payment for the subsequent milestone event. Other than that each milestone is independent and will not trigger any other milestone payment hereunder.

(ii) If: (A) a Product is abandoned during Development after one (1) or more of the milestone payments under sub-section (b) or (c) above has been made for such Product (a “**Dropped Product**”) for a given Indication; and (B) another Product containing a different Compound, or combination of different Compounds, with or without another active ingredient, is Developed for the same Indication as a replacement for such Dropped Product, then only those milestone payments under sub-section (b) or (c), as applicable, that were not previously made with respect to such Dropped Product and Indication shall be payable with respect to the replacement Product.

**8.4 Sales Milestones.** Takeda shall make each of the following one-time, non-refundable, non-creditable sales milestone payments to ITI when the aggregate Net Sales by Takeda, its Affiliates and their respective sublicensees of Products in the Territory in a period of any calendar year first reach the amount specified below. Takeda shall pay to ITI such amount within [\*\*\*] ([\*\*\*) [\*\*\*] after the calendar year in which such event is achieved for the first time. For clarity, the milestone payments in this Section 8.4 shall be additive such that [\*\*\*] milestones below are met in the same period of calendar year, Takeda shall pay to ITI a payment of [\*\*\*] ([\*\*\*)). Each of the below milestone payments shall be made only once for the first occurrence of each milestone event with respect to the Compounds or Products, regardless of their formulations, preparations, backups and derivatives (if any).

<u>Sales Milestone Event</u>	<u>Milestone Payment</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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## 8.5 Royalties.

(a) **Royalty Rates.** Subject to Section 8.5(c) below, Takeda shall pay to ITI non-refundable, non-creditable royalties on aggregate annual Net Sales of all Products in the Territory during the applicable Royalty Terms, as calculated by multiplying the applicable royalty rate by the corresponding amount of incremental Net Sales of all Products in the Territory in each calendar year.

<u>Annual Net Sales of Products in the Territory</u>	<u>Royalty Rate</u>
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For example, [\*\*\*].

(b) **Royalty Term.** Royalties shall be paid under this Section 8.5, on a country-by-country and Product-by-Product basis, during the period of time beginning from the First Commercial Sale of such Product in such country until the latest of: (i) the expiration of the last-to-expire Valid Claim in such country claiming the composition of matter, or claiming a method of use of the Product for an Indication for which Regulatory Approval has been obtained; (ii) the expiration of Regulatory Exclusivity in such country covering such Product; and (iii) the [\*\*\*] ([\*\*\*]) [\*\*\*] of the First Commercial Sale of such Product in such country (the “**Royalty Term**”).

(c) **Generic Reduction.** If, in any country in the Territory during the Royalty Term for a Product, unit sales quantity of all Generic Products to such Product in such country in a [\*\*\*], then from the first day of the next subsequent [\*\*\*] and for so long as such condition is satisfied in such country, the royalty rate applicable to Net Sales of such Product in such country shall be [\*\*\*] ([\*\*\*]) of the rate set forth in Section 8.5(a), applying the royalty tier in effect at the time the sale is made in such country. All such determinations of unit sales shall be based upon a mutually acceptable calculation method using market share data provided by a reputable and mutually agreed upon provider, such as IMS Health. Notwithstanding the foregoing, if there is a

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Valid Claim and/or Regulatory Exclusivity covering such Product in the country where a Generic Product is being marketed, the first sentence of this Section 8.5(c) shall only apply if Takeda is conducting Commercially Reasonable Efforts to enforce such Valid Claim and/or Regulatory Exclusivity to enjoin the sale of such Generic Product and shall cease to apply if such sales are enjoined in such country.

**(d) Royalty Reports and Payments.** Within [\*\*\*] ([\*\*\*) [\*\*\*] following the end of the 2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup> calendar quarters of each calendar year, commencing with the calendar quarter in which the First Commercial Sale of any Product is made anywhere in the Territory, Takeda shall provide ITI with a reasonably detailed report containing the following information for the applicable calendar quarter, on a country-by-country and Product-by-Product basis: (i) the gross sales of such Product in the Territory, (ii) a reasonable calculation of the tentative amount of Net Sales in the Territory showing total amount of deductions, to the extent practicable, provided for in the definition of “Net Sales”, subject to a final adjustment to be made by Takeda at the end of Takeda’s fiscal year (April 1 to March 31), (iii) a calculation of the royalty payment due on such sales, (iv) the exchange rate for such country, and (v) the application of the reduction and adjustment, if any, made in accordance with the terms of Section 8.5(c). Concurrent with the delivery of the applicable quarterly report, Takeda shall pay in Dollars all amounts due to ITI pursuant to Section 8.5 with respect to Net Sales by Takeda, its Affiliates and their respective sublicensees for such calendar quarter. Within sixty (60) days following the end of each March, Takeda shall provide ITI with a report containing the following information for the preceding one (1) year (from April 1 to March 31), on a country-by-country and Product-by-Product basis: (i) gross sales of such Product in the Territory, (ii) a reasonable calculation of Net Sales in the Territory showing total amount of deductions for such fiscal year, including the 1st calendar quarter, to the extent practicable, provided for in the definition of “Net Sales”, (iii) a calculation of the royalty payment due on such sales, (iv) the exchange rate for such country, (v) the application of the reduction and adjustment, if any, made in accordance with the terms of Section 8.5(c), and (vi) a calculation of the necessary adjustment for the difference between amount of royalty calculated based on tentative Net Sales and those based on the Net Sales finally adjusted. Concurrent with the delivery of such annual report, Takeda shall pay in Dollars all amounts due to ITI pursuant to Section 8.5 with respect to Net Sales for the 1st calendar quarter, as adjusted to reflect Takeda’s calculation of Net Sales for Takeda’s most recently completed fiscal year. Notwithstanding the foregoing, in the event ITI becomes a public reporting company (through acquisition or otherwise), the Parties shall discuss in good faith the timing of reports under this Section 8.5(d) (but not the timing of the corresponding payment obligation) and shall agree reasonably to adjust such timing as necessary for ITI to be able to comply with all requirements under applicable Laws or the rules of the applicable security exchange on which the shares of ITI or its Affiliate are listed; provided, however, that ITI shall inform Takeda of such necessity of change reasonably beforehand, and any agreed change must be practically feasible for Takeda.

#### **8.6 Third Party Payments.**

**(a)** [\*\*\*]. [\*\*\*].

**(b)** [\*\*\*]. [\*\*\*].

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**8.7 Foreign Exchange.** The rate of exchange to be used in computing the amount of currency equivalent in Dollars of Net Sales invoiced in other currencies shall be made at the average of the closing exchange rates reported in *The Wall Street Journal* over the applicable reporting period.

**8.8 Payment Method; Late Payments.** All payments due to ITI hereunder shall be made in Dollars by wire transfer of immediately available funds into an ITI's bank account set forth in Exhibit H. If ITI does not receive payment of any undisputed sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to ITI until the date of payment at the per annum rate of [\*\*\*] ([\*\*\*]) [\*\*\*].

**8.9 Records; Audits.** Takeda and its Affiliates and sublicensees will maintain complete and accurate records in sufficient detail to permit ITI to confirm the accuracy of the calculation of royalty payments, Takeda's compliance with Section 1.64 and the achievement of milestone events. ITI and its Affiliates will maintain complete and accurate records in sufficient detail to permit Takeda to confirm the accuracy of the calculation of FTEs and Third Party payments for research, Development or Manufacturing reimbursed by Takeda under Section 7.1, 7.2, 7.4 or 8.2. Upon reasonable prior notice, such records shall be available during regular business hours for a period of [\*\*\*] ([\*\*\*]) [\*\*\*] from the end of the calendar year to which they pertain for examination, [\*\*\*], by an independent certified public accountant selected by the auditing Party and reasonably acceptable to the audited Party, for the sole purpose of verifying the accuracy of the financial reports furnished by the other Party pursuant to this Agreement. Any such auditor shall not disclose the audited Party's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by the audited Party or the amount of payments due by one Party to the other Party under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [\*\*\*] ([\*\*\*]) [\*\*\*] from the accountant's report, plus interest (as set forth in Section 8.8) from the original due date. The auditing Party shall bear the full cost of such audit unless such audit discloses an underpayment by the audited Party of more than [\*\*\*] ([\*\*\*]) of the amount due, in which case the audited Party shall bear the full cost of such audit.

**8.10 Taxes.**

**(a) Taxes on Income.** Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

**(b) Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by Takeda to ITI under this Agreement. To the extent Takeda is required to deduct and withhold taxes on any payment to ITI, Takeda shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to ITI an official tax certificate or other evidence of such withholding sufficient to enable ITI to claim such payment of taxes. ITI shall provide Takeda any tax forms that may be reasonably necessary in order for Takeda not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other

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with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. If reasonably necessary, Takeda shall require its sublicensees in the Territory to cooperate with ITI in a manner consistent with this Section 8.10(b).

**(c) Taxes Resulting From Takeda Action.** If Takeda is required to make a payment to ITI that is subject to a deduction or withholding of tax, then (i) if such withholding or deduction obligation arises as a result of any action by Takeda, including any assignment or sublicense, or any failure on the part of Takeda to comply with applicable Laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the Parties hereto (a “**Takeda Withholding Tax Action**”), then the sum payable by Takeda (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that ITI receives a sum equal to the sum which it would have received had no such Takeda Withholding Tax Action occurred, and (ii) otherwise, the sum payable by Takeda (in respect of which such deduction or withholding is required to be made) shall be made to ITI after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the proper Governmental Authority in accordance with applicable Laws.

**(d) Certification.** A Party (including any entity to which this Agreement may be assigned, as permitted under Section 15.5) receiving a payment pursuant to this Agreement shall provide the remitting Party appropriate certification from relevant governmental authorities that such Party is a tax resident of that jurisdiction, if such receiving Party wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

## ARTICLE 9 INTELLECTUAL PROPERTY MATTERS

**9.1 Ownership of Inventions.** Each Party shall own any inventions, whether or not patentable, made solely by its own employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein (“**Sole Inventions**”). The Parties shall jointly own any inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all intellectual property rights therein (“**Joint Inventions**”). Inventorship shall be determined in accordance with U.S. patent laws. All Patents claiming patentable, jointly owned Joint Inventions shall be referred to herein as “**Joint Patents**”. Except to the extent either Party is restricted by the licenses granted to the other Party under this Agreement, each Party shall be entitled to practice and exploit the Joint Inventions and Joint Patents without the duty of accounting or seeking consent from the other Party.

**9.2 Disclosure of Inventions.** Each Party shall promptly disclose to the other Party, and in any event prior to any Patent filing with respect to such inventions, all Sole Inventions and Joint Inventions, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that are either Sole

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Inventions or Joint Inventions, and all Information relating to such inventions to the extent necessary or useful for the preparation, filing and maintenance of any Patent with respect to such invention.

### **9.3 Prosecution of Patents.**

#### **(a) ITI Prosecuted Patents.**

(i) Subject to Section 9.3(a)(ii) below, as between the Parties, ITI shall have the first right to prepare, file, prosecute and maintain ITI Patents (including the Sole Assigned Patents) in the Territory and any Patents for which the responsibility for prosecution and maintenance has been assumed by ITI pursuant to Section 9.3(b)(ii) below (the “**ITI Prosecuted Patents**”). ITI shall provide Takeda reasonable opportunity to review and comment on such prosecution efforts regarding such ITI Prosecuted Patents, as follows. In any case, the countries and jurisdictions for which the ITI Prosecuted Patents are filed and maintained shall be decided by Takeda after considering ITI’s reasonable opinion in good faith; provided, however, that if ITI desires to prosecute or maintain an ITI Prosecuted Patent in a country or jurisdiction that Takeda has not selected, then ITI shall have the right to do so at its expense, and such ITI Prosecuted Patent shall no longer be considered an ITI Patent and shall be excluded from the license to Takeda under Section 2.1(b), and if such Patent is an Assigned Patent, Takeda shall assign such Patent to ITI in accordance with the procedures in Section 2.1(a)(iv); provided, however, that the above treatment of such excluded Patents is for the purpose to preserve ITI’s patent coverage under such excluded Patents which may be exercised only outside the Field or upon and following termination or expiration of the Term, and ITI shall not use or make a Third Party use such excluded Patents against Takeda as regard to the Compound and Product in the Field during the Term. ITI shall provide Takeda with copies of all material communications from any patent authority regarding such ITI Prosecuted Patents, and shall provide Takeda, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. ITI shall consider in good faith and shall implement as appropriate any reasonable comments thereto provided by Takeda in connection with the prosecution of ITI Prosecuted Patents to the extent applicable to the Products in the Field. Takeda shall be solely responsible for all reasonable Third Party costs and expenses incurred by ITI in connection with the preparation, prosecution and maintenance of the ITI Prosecuted Patents. ITI shall consult with Takeda on its choice of patent attorney for the prosecution of the ITI Prosecuted Patents and shall reasonably consider Takeda’s preference. ITI shall invoice Takeda for such costs and expenses on a calendar quarterly basis, and Takeda shall pay each such invoice within [\*\*\*] ([\*\*\*) [\*\*\*] after receipt thereof. On an annual basis, ITI shall provide Takeda with an estimated budget for such costs and expenses. If ITI anticipates incurring any expenses significantly in excess of such budget, ITI shall notify Takeda as soon as practicable.

(ii) If ITI decides to cease the prosecution or maintenance of any ITI Prosecuted Patents, it shall notify Takeda in writing sufficiently in advance so that Takeda may, at its discretion, assume the responsibility for the prosecution or maintenance of such Patents, at Takeda’s cost and expense. If Takeda assumes such responsibility, then such Patents shall be included in the Takeda Prosecuted Patents and the terms of Section 9.3(b) shall apply to such Patents.

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**(b) Takeda Prosecuted Patents.**

(i) Subject to Section 9.3(b)(ii) below, as between the Parties, Takeda shall have the first right to prepare, file, prosecute and maintain Takeda Patents and Joint Patents in the Territory, and any Patents for which the responsibility for prosecution and maintenance has been assumed by Takeda pursuant to Section 9.3(a)(ii) above (the “**Takeda Prosecuted Patents**”), at Takeda’s cost and expense. Takeda shall provide ITI reasonable opportunity to review and comment on such prosecution efforts regarding such Takeda Prosecuted Patents (other than Takeda Patents), as follows. Takeda shall provide ITI with copies of all material communications from any patent authority regarding such Takeda Prosecuted Patents (other than Takeda Patents), and shall provide ITI, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. Takeda shall consider in good faith and shall implement as appropriate any reasonable comments thereto provided by ITI in connection with the prosecution of Takeda Prosecuted Patents (other than Takeda Patents). Takeda shall use Commercially Reasonable Efforts to obtain the broadest claim coverage for the Takeda Prosecuted Patents, and shall not undertake any patent prosecution or enforcement action in the Territory which ITI reasonably determines to be detrimental to the practice, prosecution or enforcement of ITI Patents outside the Territory.

(ii) If Takeda decides to cease the prosecution or maintenance of any Takeda Prosecuted Patents (other than Takeda Patents), it shall notify ITI in writing sufficiently in advance so that ITI may, at its discretion, assume the responsibility for the prosecution or maintenance of such Patents, at ITI’s cost and expense. If ITI assumes such responsibility, then such Patents shall be included in the ITI Prosecuted Patents and the terms of Section 9.3(a) shall apply to such Patents, except that ITI shall be solely responsible for all costs and expenses for the preparation, prosecution and maintenance of such Patents.

(c) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party’s request and expense, in the patent prosecution efforts provide above in this Section 9.3, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

**9.4 Enforcement of ITI Patents and Joint Patents.**

(a) **Notification.** If either Party become aware of any existing or threatened infringement of the ITI Patents or Joint Patents in the Field in the Territory, which infringing activity involves (i) the using, making, importing, offering for sale or selling the Compounds or Products or a competitive product, or (ii) the filing of an ANDA under Section 505(j) of the FD&C Act naming a Compound or Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV), or otherwise adversely affects or is reasonably expected to adversely affect the Commercialization of any Product in the Territory (a “**Product Infringement**”), it shall promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Product Infringement.

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**(b) Enforcement Rights.** For any Product Infringement, each Party shall share with the other Party all Information available to it regarding such alleged infringement. Takeda shall have the first right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement, at Takeda's cost and expense. Takeda shall have a period of [\*\*\*] ([\*\*\*]) [\*\*\*] after its receipt or delivery of notice under Section 9.4(a) to elect to so enforce the ITI Patents or Joint Patents in the Territory, and [\*\*\*] ([\*\*\*]) [\*\*\*] thereafter to commence such enforcement (or to settle or otherwise secure the abatement of such Product Infringement). If Takeda fails to commence a suit to enforce the applicable ITI Patents or Joint Patents or to settle or otherwise secure the abatement of such Product Infringement within such period, then ITI shall have the right, but not the obligation, to commence a suit or take action to enforce such ITI Patents or Joint Patents against such Product Infringement in the Territory at its own cost and expense. In this case, Takeda shall take appropriate actions in order to enable ITI to commence a suit or take the actions set forth in the preceding sentence.

**(c) Collaboration.** Each Party shall provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. The enforcing Party shall keep the other Party regularly informed of the status and progress of such enforcement efforts, shall reasonably consider the other Party's comments on any such efforts, and shall seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which consent shall not be unreasonably withheld or delayed. The non-enforcing Party shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but such Party shall at all times cooperate fully with the enforcing Party.

**(d) Settlement.** Takeda shall not settle any claim, suit or action that it brought under Section 9.4(b) in any manner that would negatively impact the applicable ITI Patents, without the prior written consent of ITI, which consent shall not be unreasonably withheld or delayed. Nothing in this Article 9 shall require ITI to consent to any settlement that is reasonably anticipated by ITI to have a substantially adverse impact upon any ITI Patent.

**(e) Expenses and Recoveries.** The enforcing Party bringing a claim, suit or action under Section 9.4(b) shall be solely responsible for any expenses incurred by such Party as a result of such claim, suit or action. If such Party recovers monetary damages in such claim, suit or action, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and [\*\*\*].

**(f) Infringement Other Than a Product Infringement.** For any and all infringement of any ITI Patents other than a Product Infringement, as between the Parties, ITI shall have the sole and exclusive right to bring an appropriate suit or other action against any person or entity engaged in such other infringement, in its sole discretion, and shall bear all

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related expenses and retain all related recoveries; provided, however, that if such action might affect the validity of the ITI Patents, ITI shall update and reasonably consult with Takeda about the infringement and suit or other action.

**9.5 Enforcement of Takeda Patents.** Takeda shall have the sole right, but not the obligation, to bring an appropriate suit or other action against any person or entity allegedly infringing any Takeda Patents. ITI shall provide reasonable assistance to Takeda in such enforcement, at Takeda's request and expense. Takeda shall keep ITI regularly informed of the status and progress of such enforcement efforts, and shall reasonably consider ITI's comments on any such efforts.

**9.6 Patents Licensed From Third Parties.** Each Party's rights under this Article 9 with respect to the prosecution, maintenance and enforcement of any ITI Patent that is licensed by ITI from a Third Party shall be subject to the rights of such Third Party to prosecute, maintain and enforce such Patent.

**9.7 Infringement of Third Party Rights in the Territory.** Subject to Article 11, if any Product used or sold by Takeda, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory, Takeda shall promptly notify ITI and the Parties shall agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action. Takeda shall be solely responsible for the defense of any such infringement claims, at Takeda's cost and expense, provided that the provisions of Section 9.4 shall govern the right of Takeda to assert a counterclaim of infringement of any ITI Patents or Joint Patents.

**9.8 Parties' Patent Rights.** If any ITI Prosecuted Patent, Takeda Prosecuted Patent, or Joint Patent becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 9.4 or 9.5, in which case the provisions of Section 9.4 or 9.5, as applicable, shall govern), then ITI shall control such defense with respect to the ITI Prosecuted Patents and Takeda shall control such defense with respect to the Takeda Prosecuted Patents. Takeda shall be responsible for all reasonable and documented costs and expenses incurred by either Party under this Section 9.8. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Laws, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have a backup right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in defending any such Third-Party action shall be allocated between the Parties as provided in Section 9.4(e).

**9.9 Patent Marking.** Takeda and its Affiliates and sublicensees shall mark each Product marketed and sold by Takeda or its Affiliates or sublicensee hereunder with appropriate

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patent numbers or indicia; provided, however, that Takeda shall only be required to so mark such Product to the extent such markings or such notices would affect recoveries of damages or equitable remedies available under applicable Laws with respect to infringement of Patents in the Territory or are required by applicable Laws on a country-by-country basis.

**9.10 Patent Term Extension.** Takeda may file, at its own discretion and costs and in consultation with ITI, any applications for extension of term of any of the Assigned Patent(s) in a country(ies) or area(s) in the Territory. ITI will assist with all reasonable requests made by Takeda in support of any application for patent term extensions or supplementary protection certificates relating to the Assigned Patent(s). Takeda shall use Commercially Reasonable Efforts to obtain and maintain such patent extensions.

**9.11 Trademarks.** Takeda shall have the right to brand the Products in the Territory using Takeda related trademarks and any other trademarks and trade names it determines appropriate for the Products in consultation with ITI, which may vary by country or within a country (“**Product Marks**”), provided that Takeda shall not, and shall ensure that its Affiliates and sublicensees will not, make any use of the trademarks or house marks of ITI (including ITI’s corporate name) or any trademark confusingly similar thereto. Takeda shall own all rights in the Product Marks and shall register and maintain, at its own cost and expense, the Product Marks in the countries and regions in the Territory that it determines reasonably necessary.

**9.12 Registration of Exclusive License.** Upon the request of Takeda as a licensee under this Agreement, ITI as a licensor under this Agreement, at the expense of Takeda, shall execute all such documents and instruments and take such other actions as are reasonably necessary for Takeda to register its license before the Governmental Authorities in the countries where Takeda is the exclusive licensee under any ITI Patent or ITI’s interest in the Joint Patents pursuant to this Agreement.

**9.13 Orange Book Listing.** Upon ITI’s receipt of a notice of allowance (or equivalent) of an applicable ITI Patent, ITI shall promptly provide Takeda with all information reasonably required by Takeda to list such ITI Patent in the Orange Book maintained by the FDA or similar or equivalent patent listing source, if any, in other countries in the Territory (collectively, “**Orange Book and Equivalents**”). Takeda shall, at its own discretion, promptly file, consistent with applicable Laws, all appropriate information with the Regulatory Authorities in applicable countries where Takeda deems necessary, including the U.S., to list applicable ITI Patents, Joint Patents and Takeda Patents in the Orange Book and Equivalents, and Takeda shall use Commercially Reasonable Efforts to obtain and maintain such listings.

## **ARTICLE 10 REPRESENTATIONS AND WARRANTIES; COVENANTS**

**10.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants to the other Party as follows:

**(a) Corporate Existence.** As of the Effective Date, it is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated.

**(b) Corporate Power, Authority and Binding Agreement.** As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

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**10.2 Additional Representations and Warranties of ITI.** ITI represents and warrants to Takeda as follows, as of the Effective Date:

**(a) Title; Encumbrances.** It has sufficient legal and/or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreement, encumbrances, charges or claim of any kind (except for the U.S. Government's rights under 35 U.S.C. §§ 200-213, to the extent applicable), of the ITI Technology to grant the licenses to Takeda as purported to be granted pursuant to this Agreement;

**(b) Notice of Infringement or Misappropriation.** It has not received any written notice from any Third Party asserting or alleging, nor does ITI have any knowledge of any basis for such assertion or allegation, that any research or development of the Compounds or Products by ITI prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party; and

**(c) No Proceeding.** There are no pending, and to ITI's knowledge, no threatened, adverse actions, suits or proceedings against ITI involving ITI Technology, the Compounds or the Product.

**(d) Disclosure.** ITI has made available to Takeda all material written information in ITI's possession or Control as of the Effective Date and requested by Takeda in writing relating to ITI-214 and the Back-Up Compounds identified by ITI prior to the Effective Date. In addition, as of the Effective Date, ITI has made available to Takeda all material toxicological data known to ITI related to ITI-214 and the Back-Up Compounds identified by ITI prior to the Effective Date. All such information provided by ITI is, to ITI's best knowledge, true and correct.

**10.3 Mutual Covenants.**

**(a) No Debarment.** In the course of the Development of the Product, each Party shall not use any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Each Party shall notify the other Party promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

**(b) Compliance.** Each Party and its Affiliates shall comply in all material respects with all applicable Laws in the Development and Commercialization of Products and performance of its obligations under this Agreement, including, to the extent applicable to such Party and its activities hereunder, the statutes, regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time.

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**10.4 Disclaimer.** Takeda understands that the Compounds and Products are the subject of ongoing clinical research and development and that ITI cannot assure the safety or usefulness of any Compound or Product. In addition, ITI makes no warranties except as set forth in this Article 10 concerning the ITI Technology. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## **ARTICLE 11 INDEMNIFICATION**

**11.1 Indemnification by ITI.** ITI shall defend, indemnify, and hold Takeda and its Affiliates and their respective officers, directors, employees, and agents (the “**Takeda Indemnitees**”) harmless from and against any and all Third Party claims, suits, proceedings, damages, expenses (including court costs and reasonable attorneys’ fees and expenses) and recoveries (collectively, “**Claims**”) to the extent that such Claims arise out of, are based on, or result from (a) ITI’s performance of the Research Plan or activities allocated to ITI under the Development Plan, or co-promotion activities conducted by ITI, excluding supply of Compound or Product under Article 7, (b) ITI’s supply of Compound or Product to Takeda under Article 7, but solely to the extent of the amount that ITI may recover from the applicable Third Party manufacturer under the applicable agreement, (c) the breach of any of ITI’s obligations under this Agreement, including ITI’s representations and warranties set forth herein, or (d) the willful misconduct or negligent acts of ITI, its Affiliates, or the officers, directors, employees, or agents of ITI or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Takeda Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and ITI’s defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity set forth in Section 11.2(b) or 11.2(c) for which Takeda is obligated to indemnify the ITI Indemnitees under Section 11.2.

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**11.2 Indemnification by Takeda.** Takeda shall defend, indemnify, and hold ITI and its Affiliates and their respective officers, directors, employees, and agents (the “**ITI Indemnitees**”) harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) the Development or Commercialization of Compounds or Products by or on behalf of Takeda or its Affiliates or its or their sublicensees, including Claims based upon product liability, except to the extent arising out of, based on or resulting from the promotion activities for the Co-Promotion Product conducted by ITI, or (b) the breach of any of Takeda’s obligations under this Agreement, including Takeda’s representations and warranties set forth herein, or (c) the willful misconduct or negligent acts of Takeda, its Affiliates, or the officers, directors, employees, or agents of Takeda or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the ITI Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 and Takeda’s defense of the relevant Claims is prejudiced by such failure, or (ii) any Claim arises from, is based on, or results from any activity set forth in Section 11.1(c) or 11.1(d) for which ITI is obligated to indemnify the Takeda Indemnitees under Section 11.1.

**11.3 Indemnification Procedures.** The Party claiming indemnity under this Article 11 (the “**Indemnified Party**”) shall give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) promptly after learning of such Claim. The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 11.

**11.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY WITH RESPECT TO ANY LIABILITY TO A THIRD PARTY UNDER SECTION 11.1 OR 11.2. FOR THE AVOIDANCE OF DOUBT, THE FOREGOING LIMITATION OF LIABILITY WILL APPLY TO ANY OTHER DAMAGES FOR LIABILITY OF ONE PARTY TO THE OTHER PARTY.

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**11.5 Insurance.** Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by such Party and for the [\*\*\*] ([\*\*\*)] [\*\*\*] period thereafter. It is understood that such insurance shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 11. Each Party shall provide the other Party with written evidence of such insurance upon request. Each Party shall provide the other Party with written notice at least [\*\*\*] ([\*\*\*)] [\*\*\*] prior to the cancellation, non-renewal or material change in such insurance.

## **ARTICLE 12 CONFIDENTIALITY**

**12.1 Confidentiality.** Each Party agrees that, during the Term and for a period of [\*\*\*] ([\*\*\*)] [\*\*\*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (which includes the exercise of any rights or the performance of any obligations hereunder) any Confidential Information furnished to it by the other Party pursuant to this Agreement, except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties. The foregoing confidentiality and non-use obligations shall not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

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

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

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

(d) was disclosed to the receiving Party or its Affiliate by a Third Party who has a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party; or

(e) was independently discovered or developed by the receiving Party or its Affiliate without access to or aid, application or use of the other Party's Confidential Information, as evidenced by a contemporaneous writing.

Notwithstanding the definition of "Confidential Information" in Article 1, all Information generated under the Development Program, whether generated by one or both Parties, shall be deemed the Confidential Information of Takeda, and all Information generated under the Research Program shall be deemed the Confidential Information of both Parties. In addition, the exceptions set forth in subsections (a) and (e) shall not apply to Information generated during or

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resulting from the Research Program or Development Program, which Information shall be deemed Confidential Information regardless of whether such Information satisfies the criteria set forth in one or both subsections.

**12.2 Authorized Disclosure.** Notwithstanding the obligations set forth in Section 12.1, a Party may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting Patents as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of a Product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its employees, agents, consultants, contractors, licensees or sublicensees on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; provided that in each case, the disclosees are bound by written obligations of confidentiality and non-use consistent with those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; provided that in connection with such disclosure, such Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential; or

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena or order.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 12.2(a) or 12.2(d), such Party shall promptly notify the other Party such required disclosure and shall use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure.

**12.3 Technical Publication.** Neither Party may publish peer reviewed manuscripts, or give other forms of public disclosure such as abstracts and presentations, of results of studies carried out under this Agreement, without the opportunity for prior review by the other Party, except to the extent required by applicable Laws. A Party seeking publication shall provide the other Party the opportunity to review and comment on any proposed publication that relates to a Compound or Product [\*\*\*] ([\*\*\*]) [\*\*\*] prior to its intended submission for publication. The other Party shall provide the Party seeking publication with its comments in writing, if any, [\*\*\*] ([\*\*\*]) [\*\*\*] after receipt of such proposed publication. The Party seeking publication shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party's request to remove any and all of such other Party's Confidential Information

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from the proposed publication. In addition, the Party seeking publication shall delay the submission for a period [\*\*\*] ([\*\*\*]) [\*\*\*] in the event that the other Party can demonstrate reasonable need for such delay, including the preparation and filing of a patent application. If the other Party fails to provide its comments to the Party seeking publication within [\*\*\*] ([\*\*\*]) [\*\*\*], such other Party shall be deemed not to have any comments, and the Party seeking publication shall be free to publish in accordance with this Section 12.3 after the [\*\*\*] ([\*\*\*]) [\*\*\*] has elapsed. The Party seeking publication shall provide the other Party a copy of the manuscript at the time of the submission. Each Party agrees to acknowledge the contributions of the other Party and its employees in all publications as scientifically appropriate.

#### **12.4 Publicity; Term of Agreement.**

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 12.4.

(b) The Parties shall make a joint public announcement of the execution of this Agreement in the form attached as Exhibit I, which shall be issued on or promptly after the Effective Date.

(c) After release of such press release, if either Party desires to make a public announcement concerning the material terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. A Party commenting on such a proposed press release shall provide its comments, if any, within [\*\*\*] ([\*\*\*]) [\*\*\*] after receiving the press release for review. In addition, where required by applicable Laws, including regulations promulgated by applicable security exchanges, such Party shall have the right to make a press release announcing the achievement of each milestone under this Agreement as it is achieved, and the achievements of Regulatory Approvals in the Territory as they occur, subject only to the review procedure set forth in the preceding sentence. In relation to the other Party's review of such an announcement, such other Party may make specific, reasonable comments on such proposed press release within the prescribed time for commentary, but shall not withhold its consent to disclosure of the information that the relevant milestone has been achieved and triggered a payment hereunder. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that has already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 12.4, provided such information remains accurate as of such time.

(d) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party

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intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

**12.5 Equitable Relief.** Each Party acknowledges that its breach of this Article 12 will cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated in damages in an action at law. By reasons thereof, each Party agrees that the other Party shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of the obligations relating to Confidential Information set forth in this Article 12 by the other Party.

### **ARTICLE 13 TERM AND TERMINATION**

**13.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect on a Product-by-Product and country-by-country basis, until the expiration of the Royalty Term of such Product in such country (the "**Term**"). Upon the expiration of the Royalty Term for a Product in a particular country, the licenses granted by ITI to Takeda under Section 2.1(b) with respect to such Product and such country shall become fully-paid, royalty free and exclusive.

**13.2 Unilateral Termination by Takeda.** Takeda may terminate this Agreement in its entirety for any or no reason (a) upon [\*\*\*] ([\*\*\*]) [\*\*\*] ITI if such notice is delivered prior to the First Commercial Sale of a Product anywhere in the Territory, or (b) upon [\*\*\*] ([\*\*\*]) [\*\*\*] to ITI if such notice is delivered after the First Commercial Sale of a Product anywhere in the Territory.

**13.3 Termination by ITI for Patent Challenge.** ITI may terminate this Agreement in its entirety immediately upon written notice to Takeda if Takeda or its Affiliates or sublicensees (directly or indirectly, individually or in association with any other person or entity) challenges the validity, enforceability or scope of any ITI Patent (including any Sole Assigned Patent) anywhere in the world.

#### **13.4 Termination for Breach.**

**(a) General.** Except as explicitly provided in Section 13.4(c) (country-by-country termination right), each Party shall have the right to terminate this Agreement in its entirety immediately upon written notice to the other Party if the other Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail, fails to cure such material breach within [\*\*\*] ([\*\*\*]) [\*\*\*] from the date of such notice (or within [\*\*\*] ([\*\*\*]) [\*\*\*] from the date of such notice in the event such material breach is solely based on the breaching Party's failure to pay any amounts due hereunder), subject to subsection (c) below.

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**(b) Material Breach by ITI.** If Takeda has the right to terminate this Agreement pursuant to Section 13.4(a) for ITI's material breach, Takeda may elect not to terminate this Agreement and instead to retain this Agreement in effect, in which case ITI shall continue to be liable to Takeda for any uncured material breach, and Takeda shall be entitled to pursue all legal and equitable remedies arising from such material breach that are available to it. Following a final, non-appealable judgment pursuant to Section 14.3 (unless ITI in writing does not dispute Takeda's determination of ITI's material breach) of ITI's material breach of this Agreement, Takeda may elect, in lieu of receiving a payment of damages from ITI, to offset Takeda's future payment obligations to ITI under this Agreement by the amount of damages determined and awarded to Takeda pursuant to Section 14.3 (or agreed to in writing by the Parties). If Takeda has the right to terminate this Agreement pursuant to Section 13.4(a) for ITI's material breach and elects to terminate this Agreement under Section 13.4(a), then the Parties agree and acknowledge that a court assessing damages to Takeda under Section 14.3 shall take into consideration all relevant factors in establishing a reasonable and appropriate determination of damages to Takeda, including the investment made by Takeda in the Product prior to the date of termination, the magnitude and effect of the breach by ITI.

**(c) Material Breach by Takeda.** Notwithstanding Section 13.4(a), if Takeda materially breaches its obligations under this Agreement (but excluding any incidental or immaterial obligations) including, but not limited to, using Commercially Reasonable Efforts under Section 4.4 or 6.2 for a particular country among the U.S. or Major Countries (defined below) following the First Commercial Sale of a Product in either the U.S. or a Major Country, and such material breach is not solely based on Takeda's failure to pay any amounts due hereunder, and Takeda in good faith disputes such termination, then the effective date of such termination under Section 13.4(a) shall be extended for an additional [\*\*\*] [\*\*\*] [\*\*\*] (for a total of [\*\*\*] [\*\*\*] [\*\*\*]), or as long as the procedure under Section 14.3 continues until finally completed, in the event that either Party invokes the procedures in Section 14.3 hereof, provided that Takeda has provided a written plan that is reasonably calculated to effect a prompt cure only if such prompt cure is reasonable available, and such plan is acceptable to ITI (not to be unreasonably withheld, conditioned or delayed) and Takeda carries out such plan. After the expiration of such effective date (or such earlier date as Takeda no longer disputes such material breach), ITI shall have a right to terminate this Agreement in the following manner:

(A) if the material breach concerns the U.S., ITI may terminate the agreement in its entirety;

(B) if the material breach concerns one or more of the Major Countries (defined below), ITI may terminate only with respect to such Major Country(ies);

(C) if the material breach concerns a country other than the U.S. or a Major Country, ITI may not terminate this Agreement with respect to such country as long as a material breach of this Agreement did not occur in the U.S., and in such case following an allegation by ITI of material breach by Takeda in a country other than the U.S. or a Major Country and expiration of the applicable cure period, Takeda shall, promptly after receiving from ITI the reasonably detailed contents of such allegation of ITI, elect either to terminate this Agreement with respect to the applicable country (in such case Takeda will be released from any liability or claims by ITI under this Section as regard to alleged material breach for such terminated country) or to dispute

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the allegation under Section 14.3, and if Takeda is finally determined by a court to have materially breached this Agreement, then ITI shall have the right to receive damages and all other remedies determined by the court and Takeda shall have the right to terminate this Agreement with respect to such country (and in any case if Takeda terminates this Agreement with respect to such country, Takeda shall fulfill the applicable obligations under Section 13.6 as applicable for such country); and

(D) with respect to a material breach concerning the U.S. or a Major Country, ITI may elect not to terminate this Agreement and instead to retain this Agreement in effect, in which case Takeda shall continue to be liable to ITI for any uncured material breach, and ITI shall be entitled to pursue all legal and equitable remedies arising from such material breach that are available to it.

For purposes of this Section 13.4(c), "Major Country" shall mean each of the United Kingdom, Germany, France, Italy, Spain, Portugal, Turkey, Switzerland, Belgium, Austria, Denmark, Sweden, Japan, South Korea, China, Hong Kong, Taiwan, Thailand, Indonesia, Philippine, Canada, Mexico, Brazil, and, if and when Takeda establishes in the future an Affiliate which conducts selling and marketing activities at commercial level in any other country in the Territory, such country.

(d) If ITI has the right to terminate this Agreement for Takeda's material breach and elects to terminate this Agreement as provided herein, then the Parties agree and acknowledge that a court will consider and decide the damages, if any, and also, such assessing damages may take into consideration, at the court's discretion, all relevant factors in establishing a reasonable and appropriate determination of damages and/or remedies to ITI, including the investment made by ITI/Takeda in the Product prior to the date of termination, the magnitude and effect of the breach by Takeda in the calculation of damages, and scope of rights transferred by Takeda as provided in Section 13.6 hereof (such as transfer of Regulatory Approvals and funding on-going clinical studies) during the consideration of remedies for ITI.

**13.5 Termination for Safety.** Takeda may terminate this Agreement in its entirety or with respect to a particular Product upon [\*\*\*] ([\*\*\*]) [\*\*\*] prior written notice to ITI (a) if senior executives responsible for Takeda's Pharmacovigilance and Clinical Science functions determine in good faith that the risk/benefit profile of such Product(s) is such that the Product(s) cannot continue to be Developed or administered to subjects/patients safely (and not for commercial reasons), or (b) upon the occurrence of serious adverse events related to the use of such Product(s) that cause Takeda to reasonably conclude that the continued use of such Product(s) by subjects/patients will result in subjects/patients being exposed to a product whose risks outweigh its benefits. Following notice of termination under this Section 13.5, the Parties shall cooperate to wind down all Development and Commercialization activities with respect to the terminated Product(s).

**13.6 Effect of Termination.** Upon any termination (but not expiration) of this Agreement, all licenses and rights granted to Takeda under this Agreement shall terminate, and Takeda shall return, transfer and assign to ITI or its designee all materials, Information, Regulatory Materials, Regulatory Approvals, licenses, third party agreements and other items as are reasonably necessary for ITI to continue the Development and Commercialization of

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Compounds and Products; provided, however, that (i) upon termination of this Agreement under Section 13.5 with respect to a Product and not the Agreement in its entirety, the foregoing and sub-sections (a) – (d), (e) (first sentence only), (f) and (g) below shall apply to the terminated Product(s) only; (ii) upon termination of this Agreement under Section 13.4(c) with respect to a Major Country, the foregoing and sub-sections (a) – (d) below shall apply to the terminated Major Country only; and (iii) in case of termination of this Agreement by Takeda under Section 13.4(a), Takeda may request reasonable up-front and royalty payments as compensation for the assignment of Regulatory Materials developed by Takeda or Product Marks and a license under Takeda Technology. Without limiting the generality of the foregoing, the following rights and consequences shall apply upon any termination (in addition to any other rights and obligations under this Agreement with respect to such termination), except that sub-sections (e) (except for the first sentence) and (h) shall not apply in the event of a termination under Section 13.5:

**(a) Regulatory Materials; Data.** To the extent permitted by applicable Laws, Takeda shall transfer and assign to ITI all Regulatory Materials, Regulatory Approvals, and related data and Information relating to the Products and Compounds and shall treat the foregoing as “Confidential Information” of ITI (and not of Takeda) under Section 12; provided that Takeda will be allowed to retain any such materials that a Regulatory Authority requires Takeda to retain under applicable Laws.

**(b) Takeda License.** Takeda hereby grants to ITI, effective upon such termination, an exclusive, fully paid, worldwide, fully transferrable, irrevocable license (with the right to grant sublicenses through multiple tiers) under the Takeda Technology as in existence as of the date of termination solely to research, Develop, make, have made, use, sell, offer for sale, import and otherwise Manufacture or Commercialize the Compounds and Products.

**(c) Assignment to ITI of Assigned Patents.** Takeda shall assign and does hereby assign to ITI, effective on the effectiveness of such termination, its entire right, title and interest in and to each Sole Assigned Patent, and one-half of its right, title and interest in and to each Joint Assigned Patent, and Takeda appoints ITI its attorney in fact solely to make such re-assignments and authorizes ITI to make such re-assignments. In each case, Takeda shall execute and deliver to ITI a deed(s) of such assignment, in a mutually agreeable form, within [\*\*\*] ([\*\*\*)] [\*\*\*] after the effective date of termination. ITI shall be responsible for recording all such assignments, and Takeda and its successors and assigns shall (i) reasonably cooperate with ITI’s efforts to do so, including satisfying the assignment and recording requirements of relevant patent offices and (ii) reimburse ITI for all reasonable and documented out-of-pocket expenses incurred by ITI in connection with this Section 13.6(c). In addition, Takeda hereby grants ITI an exclusive license under its interest in the Sole Assigned Patents and a non-exclusive license under its interest in the Joint Assigned Patents during the period from the effective date of termination until the applicable Assigned Patents are actually re-assigned to ITI. If this Agreement is terminated under Section 13.5 with respect to a Product but not with respect to this Agreement in its entirety, then this Section 13.6(c) shall apply to Assigned Patents claiming the terminated Product(s) only.

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**(d) Trademarks.** Takeda shall assign to ITI all right, title and interest in and to the Product Marks (excluding any such marks that include, in whole or part, any corporate name or logo of Takeda) throughout the Territory.

**(e) Manufacture and Supply.** Takeda shall transfer the then-current manufacturing process for the Products to ITI or its designee (which will be designated as soon as reasonably practical but in no event later than [\*\*\*] ([\*\*\*]) [\*\*\*] following the effective date of the termination of this Agreement). At ITI's request, Takeda shall supply, or cause to be supplied, to ITI all then-available quantities of Products. Takeda will use Commercially Reasonable Efforts to supply additional quantities of Products for a period of the earlier of (i) the date ITI is able to manufacture or have manufacture Products (including through an assignment of any Third Party supply contract from Takeda) or (ii) one (1) year following the effective date of termination; provided that ITI shall use Commercially Reasonable Efforts to effect such assumption (or transition) as promptly as practicable. Such supply shall be at a price equal to Takeda's fully-burdened manufacturing costs or acquisition cost of the Product. Any such supply will be made pursuant to a mutually acceptable supply agreement between the Parties. In the event that Takeda has one or more agreements with Third Party manufacturers with respect to the manufacture of a Product, at ITI's request, Takeda shall use Commercially Reasonable Efforts to transfer its rights and obligations under such agreement(s) to ITI upon any such termination.

**(f) Transition Assistance.** Takeda shall provide such assistance, at no cost to ITI (except in the event of a termination of this Agreement for ITI's breach, in which case such assistance shall be provided at Takeda's then-current FTE rates), as may be reasonably necessary or useful for ITI to continue Developing, manufacturing and/or Commercializing Products throughout the Territory, to the extent Takeda is then performing or having performed such activities, including assigning or amending as appropriate, upon request of ITI, any agreements or arrangements with Third Party vendors to manufacture, Develop, distribute, sell or otherwise Commercialize Products. To the extent that any such contract between Takeda and a Third Party is not assignable to ITI, Takeda shall reasonably cooperate with ITI to arrange to continue to provide such services for a reasonable time after termination. Takeda shall not, during such applicable notice period, take any action that could reasonably be expected to have a material adverse impact on the further Development and Commercialization of any Product.

**(g) Ongoing Clinical Trials.** Takeda shall transfer to ITI the management and continued performance of all Clinical Trials for Products ongoing as of the effective date of such termination, provided that Takeda shall be responsible to fund (during the Term and following such termination) any then-ongoing Clinical Trials of Products as set forth in the then-current Development Plan, until such activities are completed as contemplated in such plan, unless such Clinical Trials are required to be terminated by a Regulatory Authority under applicable Laws; provided that Takeda shall not be responsible to fund any such expenses to the extent that ITI is reimbursed therefor by a Third Party licensee.

**(h) Inventories.** ITI shall have the right to purchase from Takeda any and all of the inventory of Products held by Takeda as of the effective date of termination at a price equal to Takeda's actual cost to acquire or manufacture such inventory. ITI shall notify Takeda within [\*\*\*] ([\*\*\*]) [\*\*\*] after the effective date of termination whether ITI elects to exercise such right.

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(i) **Takeda Dispute Rights in the event of ITI Material Breach.** In the event that Takeda terminates this Agreement pursuant to Section 13.4(a) for a material breach by ITI, Takeda may invoke the dispute resolution procedures of Section 14.3 to dispute the equitable basis for providing ITI the rights under Section 13.6(a), (b) and (d) without additional compensation to Takeda. The Parties agree that Takeda shall have the right to petition such court to resolve any dispute regarding fair and equitable compensation for such rights to ITI given the consideration of all relevant factors, provided that a court shall not be permitted to restrict or withhold the grant of such rights to ITI.

For clarity, except in the case of termination under Section 13.5, Takeda shall continue to perform all obligations under this Agreement with respect to the Development, Manufacture and Commercialization of Products until the effective date of termination and shall not modify in any material respects such activities from past practices during such period.

**13.7 Survival.** Termination or expiration of this Agreement shall not affect any rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions shall survive any expiration or termination of this Agreement: 4.5 (solely as to unpaid amounts), 5.6 (solely as to any pending claims between the Parties applicable and the transition of such activities in accordance with the terms of the Agreement for any Remedial Action then existing), 8.2 (solely as to unpaid amounts), 8.6, 8.7, 8.8, 8.9, 8.10 (for the applicable statute of limitation period for any tax Laws), 9.1, 9.2, 10.4, 12.1, 12.2, 12.4, 12.5, 13.4(b) (solely as to the last sentence thereof), 13.4(c) (solely as to the last sentence thereof which is equivalent with that survived in 13.4(b)), 13.5 (solely as to the last sentence thereof) 13.6 and 13.7 and Articles 1 (solely as to any defined terms used in any provision surviving hereunder), 11, 14 and 15.

#### **ARTICLE 14 DISPUTE RESOLUTION**

**14.1 Disputes.** The Parties recognize that disputes as to certain matters may from time to time arise that relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 14 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement.

**14.2 Internal Resolution.** With respect to all disputes arising between the Parties under this Agreement, including any alleged breach under this Agreement or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within [\*\*\*] ([\*\*\*)] [\*\*\*] after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Executive Officers of the Parties for attempted resolution by good faith negotiations within [\*\*\*] ([\*\*\*)] [\*\*\*] after such notice is received, including at least one (1) in-person meeting of the Executive Officers within [\*\*\*] ([\*\*\*)] [\*\*\*] after such notice is received.

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**14.3 Dispute Resolution.** If the Executive Officers of the Parties are not able to resolve such dispute referred to them under Section 14.2 within such [\*\*\*] ([\*\*\*)] [\*\*\*] period, then each Party shall have the right to pursue any legal or equitable remedy available to it under applicable Laws; provided that any litigation arising under this Agreement shall be brought in a United States District Court for the Southern District of New York located in New York, New York, U.S. (or, if there is no applicable federal subject matter jurisdiction, a state court located in New York, New York, U.S.). Each Party hereby agrees to the exclusive jurisdiction of such courts and waives any objections as to the personal jurisdiction or venue of such courts. Each Party irrevocably waives any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

**14.4 Patent and Trademark Disputes.** Notwithstanding Section 14.3, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent covering the manufacture, use, importation, offer for sale or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

## **ARTICLE 15 MISCELLANEOUS**

**15.1 Entire Agreement; Amendment.** This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth in this Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

**15.2 Force Majeure.** Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, and failure of plant or

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machinery (provided that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [\*\*\*] [\*\*\*] [\*\*\*], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement in order to mitigate the delays caused by such force majeure.

**15.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 15.3, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by confirmed facsimile or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested.

If to ITI:                    Intra-Cellular Therapies, Inc.  
Audubon Biomedical Science and Technology Park  
3960 Broadway  
New York, NY 10032  
Attn: Sharon Mates, Ph.D.  
Chairman & Chief Executive Officer  
Fax: (212) 923-3388

With a copy to (which shall not constitute notice):

Cooley LLP  
One Freedom Square  
Reston Town Center  
11951 Freedom Drive  
Reston, VA 20190-5656  
Attn: Kenneth J. Krisko  
Fax: 703/456-8100

If to Takeda:                TAKEDA PHARMACEUTICAL COMPANY LIMITED 1-  
1, Doshomachi 4-Chome, Chuo-ku  
Osaka 540-8645  
  
Attn: Senior Vice President,  
Global Licensing & Business Development Department  
Fax: +81 6 6204 2328

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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With a copy to (which shall not constitute notice):

TAKEDA PHARMACEUTICAL COMPANY LIMITED 1-  
1, Doshomachi 4-Chome, Chuo-ku  
Osaka 540-8645  
Attn: Senior Vice President, Legal Department  
Fax: +81 6 6204 2055

**15.4 No Strict Construction; Headings.** This Agreement has been prepared jointly by the Parties and shall not be strictly construed against either Party. 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. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Except where the context otherwise requires, the use of any gender shall be applicable to all genders, and the word “or” is used in the inclusive sense (and/or). The term “including” as used herein means including, without limiting the generality of any description preceding such term.

**15.5 Assignment.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party’s consent to its Affiliates or to a Third Party successor to substantially all of the business of such Party to which this Agreement relates (such Third Party, an “**Acquiror**”), whether in a merger, sale of stock, sale of assets or other transaction. Any successor or assignee of rights and/or obligations permitted hereunder shall, in writing to the other Party, expressly assume performance of such rights and/or obligations. In the event of any permitted assignment of this Agreement by Takeda, Takeda shall assign to such permitted assignee or to ITI (in accordance with Section 13.6(c) as if a termination had occurred) Takeda’s entire right, title and interest in and to each Assigned Patent to which Takeda obtained an ownership interest pursuant to Section 2.1(a). The ITI Technology, in the case of ITI as assignor or transferor, or the Takeda Technology, in the case of Takeda as assignor or transferor, shall exclude any Patents and Information Controlled by any Acquiror (or any Affiliate thereof, excluding a Party hereto as a result of such transaction) prior to the acquisition or developed outside of any activities under this Agreement. Any permitted assignment shall be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.5 shall be null, void and of no legal effect.

**15.6 Performance by Affiliates.** Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**15.7 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.8 Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, 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.

**15.9 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**15.10 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**15.11 English Language; Governing Law.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

**15.12 Counterparts.** This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

{Signature page follows}

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IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized officers as of the Effective Date.

**TAKEDA PHARMACEUTICAL COMPANY LIMITED**

**INTRA-CELLULAR THERAPIES, INC.**

By: /s/ Yasuchika Hasegawa  
Name: Yasuchika Hasegawa  
Title: President and CEO

By: /s/ Sharon Mates, Ph.D.  
Name: Sharon Mates, Ph.D.  
Title: Chairman and CEO

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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**LIST OF EXHIBITS:**

Exhibit A:	ITI-214 Structure
Exhibit B:	PDE1 Inhibitor Criteria
Exhibit C-1:	ITI Patents as of the Effective Date
Exhibit C-2:	Additional Patents
Exhibit D:	Sole Assigned Patents as of the Effective Date
Exhibit E:	Initial Research Plan
Exhibit F:	Initial Development Plan
Exhibit G:	Third Party Agreements as of the Effective Date
Exhibit H:	ITI Bank Account
Exhibit I:	Joint Press Release

Portions of this Exhibit, indicated by the mark “[\*\*\*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**EXHIBIT A**

**ITI-214 STRUCTURE**

\*\*\*

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**EXHIBIT B**  
**PDE1 INHIBITOR CRITERIA**

\*\*\*

Exhibit B pg. 1 of 3

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\*\*\*

Exhibit B pg. 2 of 3

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\*\*\*

Exhibit B pg. 3 of 3

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**EXHIBIT C-1**

**ITI PATENTS AS OF THE EFFECTIVE DATE**

[\*\*\*]

Exhibit C-1 pg. 1 of 2

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\*\*\*

Exhibit C-1 pg. 2 of 2

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**EXHIBIT C-2**

**ADDITIONAL PATENTS**

\*\*\*

Portions of this Exhibit, indicated by the mark "[\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**EXHIBIT D**

**SOLE ASSIGNED PATENTS AS OF THE EFFECTIVE DATE**

\*\*\*

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**EXHIBIT E: INITIAL RESEARCH PLAN**

**Summary**

\*\*\*

Exhibit E pg. 1 of 7

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Page 1 of 7

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Exhibit E pg. 2 of 7

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Page 2 of 7

**Figure 1.**

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Exhibit E pg. 3 of 7

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Page 3 of 7



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Exhibit E pg. 4 of 7

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Page 4 of 7

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Exhibit E pg. 5 of 7

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Page 5 of 7

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Exhibit E pg. 6 of 7

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Page 6 of 7

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Exhibit E pg. 7 of 7

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Page 7 of 7

**EXHIBIT F**  
**INITIAL DEVELOPMENT PLAN**

[\*\*\*]

Exhibit F pg. 1 of 3

ITI and Takeda will conduct its activities described in this Development Plan below as such Party's role. [\*\*\*]

**A. ITI activities**

[\*\*\*]

**B. Takeda activities**

[\*\*\*]

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\*\*\*

Exhibit F pg. 2 of 3

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\*\*\*

Exhibit F pg. 3 of 3

Portions of this Exhibit, indicated by the mark "\*\*\*," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**Exhibit F-1**

\*\*\*

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**EXHIBIT G**

**THIRD PARTY AGREEMENTS AS OF THE EFFECTIVE DATE**

[\*\*\*]

Agreement between [\*\*\*].

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**EXHIBIT H**  
**ITI BANK ACCOUNT**

[\*\*\*]

[\*\*\*]

Account Name: [\*\*\*]

Routing Number: [\*\*\*]

Account Number: [\*\*\*]

SWIFT Code: [\*\*\*]

If any problems call [\*\*\*] at [\*\*\*].

Portions of this Exhibit, indicated by the mark "[\*\*\*]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

## EXHIBIT I

## JOINT PRESS RELEASE

FOR IMMEDIATE RELEASE

**Intra-Cellular Therapies Announces Completion of Phase I Single Rising Dose Trial of First-in-Class Selective Phosphodiesterase 1 (PDE1) Inhibitor and Reports Top-line Safety and Pharmacokinetic Findings**

**NEW YORK, Feb. 19, 2013/PRNewswire/** — Intra-Cellular Therapies, Inc. (“ITI”) today announced the completion of a Phase I single rising dose study of its phosphodiesterase 1 (PDE1) inhibitor, ITI-214. ITI-214, a novel, first-in-class selective PDE1 inhibitor, was discovered by ITI and is in development under an exclusive collaboration with Takeda Pharmaceutical Company Limited for the treatment of Cognitive Impairment Associated with Schizophrenia (CIAS).

The primary objectives of the Phase I study were to determine the safety, tolerability and pharmacokinetic profile of single oral doses of ITI-214 in healthy volunteers. The study was conducted as a randomized, double-blind, placebo-controlled study in 70 subjects. The results indicated that ITI-214 was safe and well-tolerated across a broad range of single oral doses. Moreover, ITI-214 demonstrates a favorable pharmacokinetic profile consistent with once-a-day dosing. The study represents a significant milestone as it is the first demonstration of the safety of a PDE1 inhibitor in a Phase 1 clinical trial.

“We are pleased with the advancement of ITI-214 in clinical development,” stated Sharon Mates, Ph.D., Chairman and Chief Executive Officer of Intra-Cellular Therapies. “The data obtained for ITI-214 support its continued development for the treatment of Cognitive Impairment Associated with Schizophrenia and other neuropsychiatric and neurological disorders.”

**About Schizophrenia**

Schizophrenia is a major neuropsychiatric disorder that affects over one percent of the world population with an illness that begins in late adolescence and lasts a lifetime. Its best known symptoms are “positive symptoms”, which include hallucinations and delusions; but other mental functions are also affected, including social and motivational skills (“negative symptoms”) and cognitive behaviors, like inattention and poor memory. Current antipsychotics are effective primarily on reducing positive symptoms but are largely ineffective at reducing negative and cognitive symptoms. The medical need in this disease area is enormous.

**About PDE1 Inhibitors**

These compounds are unique, orally available, investigational drugs being developed for the treatment of cognitive impairments accompanying schizophrenia and other neurological and neuropsychiatric disorders, including Alzheimer’s disease, Attention Deficit Hyperactivity Disorder and Parkinson’s disease. These compounds may also have the potential to improve motor dysfunction associated with these disorders. These compounds are very selective for the PDE1 subfamily relative to other PDE subfamilies. They have no known significant off target activities at other enzymes, receptors or ion channels.

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**About Intra-Cellular Therapies, Inc.**

Intra-Cellular Therapies, Inc. (ITI) is a biopharmaceutical company that is developing novel drugs for the treatment of diseases and disorders of the Central Nervous System (CNS). The Company was formed in 2002 to exploit intracellular signaling pathways of the brain in its efforts to develop novel CNS therapeutics. The Company's initial efforts were built on the insights generated from the Nobel Prize winning science of Dr. Paul Greengard at The Rockefeller University, the scientific founder of ITI. Using novel technologies developed at ITI, the Company has developed a pipeline of drugs that have the potential to treat a wide range of diseases associated with the CNS. Additional information about ITI is available through its corporate website, [www.intracellulartherapies.com](http://www.intracellulartherapies.com).

**CONTACT:**

Allen A. Fienberg, Ph.D., Vice President, Business Development, Intra-Cellular Therapies, Inc., +1-212-923-3344; or Lisa Burns (Investors), or Justin Jackson (Media), both of Burns McClellan, Inc., +1-212-213-0006, [jjackson@burnsmc.com](mailto:jjackson@burnsmc.com).

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