INTRA-CELLULAR THERAPIES, INC.

FORM 10-K
(Annual Report)

Filed 03/12/15 for the Period Ending 12/31/14

Address	430 EAST 29TH STREET
	NEW YORK, NY 10016
Telephone	212-923-3344
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

OR

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

For the transition period from _____to _____

Commission file number: 001-36274

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

Delaware	**36-4742850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

430 East 29th Street
New York, New York 10016
(Address of principal executive offices) (Zip Code)

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

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.0001 Par Value Per Share	**The NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Exchange Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ [Do not check if a smaller reporting company]	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $240,663,855.

As of March 11, 2015, the registrant had 34,928,424 shares of common stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated by reference from the Registrant's Proxy Statement for the 2015 Annual Meeting of Stockholders.

PART I

All brand names or trademarks appearing in this report are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this report is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners. Unless the context requires otherwise, references in this report to the "Company," "we," "us," and "our" refer to Intra-Cellular Therapies, Inc. and its wholly-owned subsidiary, ITI, Inc.

Item 1. BUSINESS

Overview

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. We are developing our lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder, depression and other neuropsychiatric and neurological disorders. ITI-007 is in Phase 3 clinical development 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 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled Phase 2 clinical trial in patients with an acutely exacerbated episode of schizophrenia. In December 2013, we announced the clinical results from this Phase 2 trial. In this Phase 2 trial, 335 patients were 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 endpoint for this clinical trial was change from baseline to Day 28 on the Positive and Negative Syndrome Scale, or PANSS, total score. In this study, ITI-007 met the trial's pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the PANSS total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety. Additional 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 proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Subject to further discussions with the U.S. Food and Drug Administration, or FDA, we also plan to initiate separate additional trials in bipolar disorder in 2015. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. In addition to our Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned New Drug Application, or NDA, for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017.

In addition, in the fourth quarter of 2014, we announced the topline data from ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease. The completion of this study marks an important milestone in our strategy to develop low doses of ITI-007 for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results to date indicate that ITI-007 is safe and well-tolerated across a range of low doses, has linear- and dose-related pharmacokinetics and improves cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position ITI-007 as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions. We plan to initiate additional clinical programs evaluating ITI-007 in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer's disease, in 2015.

We are currently conducting an open-label positron emission tomography, or PET, study of ITI-007 examining brain receptor occupancy and assessing occupancy of striatal D2 receptors. In this study, patients with stable schizophrenia will be treated with ITI- 007 for 14 days. We expect topline data from this study in 2015. We believe this study will further characterize ITI-007 and provide additional insight into the molecule's unique mechanism and clinical profile.

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-HT2A 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-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer's disease, Huntington'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-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be useful for the treatment of 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 additional diseases that include 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.

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme phosphodiesterase type 1, or PDE1. PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) and Takeda Pharmaceutical Company Limited, or Takeda, entered into a license and collaboration agreement, or the Takeda License Agreement, 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. On October 31, 2014, we entered into an agreement with Takeda terminating the Takeda License Agreement, or the Termination Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding obligations in connection with the development program. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. Over approximately the next

12 months, we will refine our strategy for the PDE1 inhibitor program. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE1 program to include the later stage portfolio. We do not anticipate a significant increase in our operating expenses related to our PDE development programs over the next twelve months. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical 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.

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 CNS disorders, including Nobel laureate, Dr. Paul Greengard, one of our co-founders.

We were originally incorporated in the State of Delaware in August 2012 under the name "Oneida Resources Corp." Prior to a reverse merger that occurred on August 29, 2013, or the Merger, Oneida Resources Corp. was a "shell" company registered under the Securities Exchange Act of 1934, or the Exchange Act, with no specific business plan or purpose until it began operating the business of ITI, Inc., or 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 CNS. 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 continues as the business of the Company.

Our corporate headquarters and laboratory are located at 430 East 29th Street, New York, New York 10016, and our telephone number is (212) 923-3344. We also have an office in Towson, Maryland. We maintain a website at www.intracellulartherapies.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the 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.

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
- we seek to develop drugs that either can differentiate themselves in competitive markets by addressing aspects of CNS disease which are 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 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 PDE inhibitor compounds, such as ITI-214, for the treatment of CNS and other disorders; 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, 2014 and 2013, we incurred $21.2 million and $23.0 million in research and development expenses, respectively.

Given the nature of our research and development and business activities, we do not expect that compliance with federal, state and local environmental laws will result in material costs or have a significant negative effect on our operations.

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 residual 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. 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. Indeed, the side effects associated with current antipsychotic medications often make some of the residual phase symptoms, such as negative symptoms and social function, worse. There is an unmet medical need for new therapies that have improved side effect and efficacy profiles.

According to the National Institute of Mental Health, over 1% of the world’s population suffers from schizophrenia, and more than 2.5 million Americans suffer from the illness in any given year. Worldwide sales of antipsychotic drugs used to treat schizophrenia exceeded $13 billion in 2013. 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 and other symptoms associated with social function impairment. Many patients with schizophrenia have deficits in social function. Social function is the ability to recognize, understand, process and use external cues to solve problems, maintain work performance, and conduct interpersonal relationships. Deficits in social function often remain after positive symptoms, such as hallucinations and delusions, have resolved in these patients. 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-HT2A 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.

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.

Behavioral Disturbances in Dementia, Including Alzheimer's Disease

It has been estimated that 44.4 million people worldwide were living with dementia in 2013, including over 5.2 million patients with Alzheimer's disease in the United States. This number is expected to increase to 75.6 million by 2030 and to increase to 135.5 million by 2050. While the diagnostic criteria for Alzheimer's disease and other dementias 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. 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.

The FDA has not approved any drug to treat the behavioral symptoms of dementia, including 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 dementia. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with dementia. We believe there is a large unmet medical need for a safe and effective therapy to treat the behavioral symptoms in patients with dementia, including Alzheimer's disease.

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 $4.9 billion in 2013. In 2013, global sales of CNS therapeutics for dementia and Alzheimer's disease reached $5.1 billion.

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 44.4 million people worldwide were living with dementia in 2013. This number is expected to increase to 75.6 million by 2030 and to increase to 135.5 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, depression, sleep disorders, and psychosis. Studies have suggested that approximately 60% of patients with Alzheimer's disease experience agitation/aggression, up to 87% of patients experience depression, approximately 60% of patients experience sleep disturbances, particularly as an increased likelihood of day-night reversal, and approximately 20% to 51% of Alzheimer's disease patients may develop psychosis at some point in the disease process, commonly consisting of hallucinations and delusions. The diagnosis of Alzheimer's disease psychosis is associated with more rapid cognitive and functional decline and institutionalization. Sleep disturbances increase the likelihood of day-night reversion, increased agitation and increased caregiver stress that strongly influences decisions for nursing home placement.

The 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 $2.3 billion in 2013.

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.

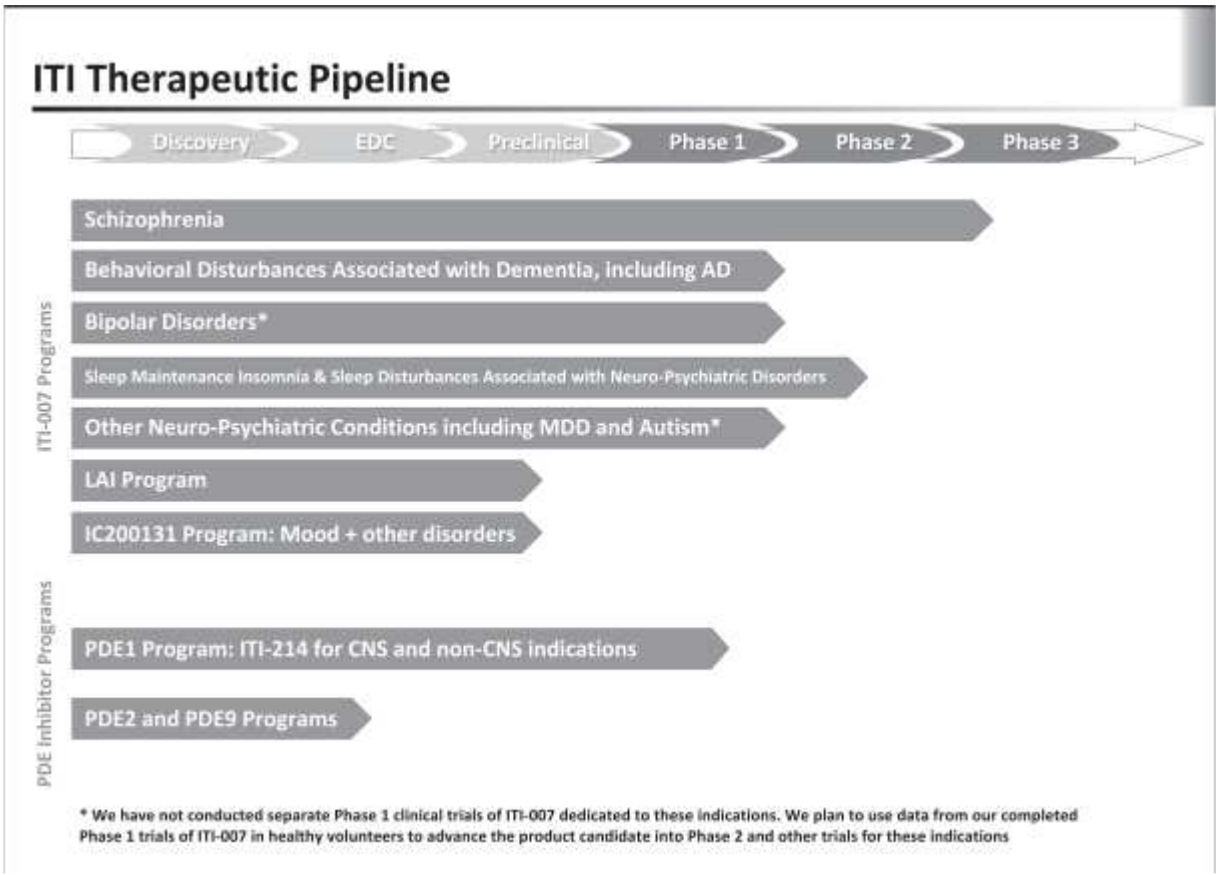
Depression

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 $9.3 billion in 2013. 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-007 Program

Our lead product candidate, ITI-007, possesses mechanisms of action that we believe have the potential to yield a first-in-class antipsychotic therapy. ITI-007 is in Phase 3 clinical trials for the treatment of schizophrenia. In our pre-clinical and clinical trials to date, we have demonstrated that ITI-007 combines potent serotonin 5-HT2A receptor antagonism, dopamine receptor phosphoprotein modulation, or DPPM, glutamatergic modulation and serotonin reuptake inhibition into a single drug candidate for the treatment of acute and residual schizophrenia. At dopamine D2 receptors, ITI-007 has been demonstrated to have dual properties and to act as both a post-synaptic antagonist and a pre-synaptic partial agonist. ITI-007 has also been demonstrated to stimulate phosphorylation of glutamatergic NMDA NR2B, or GluN2B, receptors in a mesolimbic specific manner. We believe that this regional selectivity in brain areas thought to mediate the efficacy of antipsychotic drugs, together with serotonergic, glutamatergic, and dopaminergic interactions, may result in antipsychotic

efficacy for positive, negative, affective and cognitive symptoms associated with schizophrenia. The serotonin reuptake inhibition could allow for antidepressant activity for the treatment of schizoaffective disorder, co-morbid depression, and/or as a stand-alone treatment for major depressive disorder. We believe ITI-007 may also be useful for the treatment of bipolar disorder and other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism and other CNS diseases.

We believe these features of ITI-007 may be able to improve the quality of life of patients with schizophrenia and enhance social function to allow them to integrate more fully into their families and their workplaces. 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 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 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 and can lead to poorer social function.

Phase 2 Clinical Trial (ITI-007-005)

ITI-007 exhibited antipsychotic efficacy in ITI-007-005, a randomized, double-blind, placebo and active controlled Phase 2 clinical trial in patients with an acutely exacerbated episode of schizophrenia. In December 2013, we announced the clinical results from this Phase 2 trial. In this Phase 2 trial, 335 patients were 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 received study treatment orally once daily in the morning for 28 days. Of those randomized, 311 patients were included in the intent-to-treat primary analysis. Subject participation lasted 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 endpoint for this clinical trial was change from baseline to Day 28 on the PANSS total score. 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 positive symptoms, such as delusions, suspiciousness, and hallucinations; negative symptoms, such as blunted affect, social and emotional withdrawal, and stereotyped thinking; and general psychopathology, such as anxiety, tension, depression, and active social avoidance.

Secondary endpoints in this trial included weekly assessments of the PANSS total score 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), individual item response on the PANSS, and the Calgary Depression Scale for Schizophrenia. Safety and tolerability were also assessed.

In December 2013, we announced that topline results from the ITI-007-005 study indicated that ITI-007 met the trial's pre-specified primary endpoint, improving symptoms associated with schizophrenia as measured by a statistically significant and clinically meaningful decrease in the PANSS total score. The trial also met key secondary outcome measures related to efficacy on PANSS subscales and safety.

Many patients with schizophrenia have deficits in social function. Social function is the ability to recognize, understand, process and use external cues to solve problems, maintain work performance and conduct interpersonal relationships. Deficits in social function often remain after positive symptoms, such as hallucinations and delusions, have resolved in these patients. In the Phase 2 trial, ITI-007 exhibited a differentiating response profile across a broad range of symptoms that we believe is consistent with improvements in these social functioning deficits. The study also showed that ITI-007 was well-tolerated at the tested doses. ITI-007 demonstrated a favorable safety profile in the study without characteristic antipsychotic drug side effects or any serious adverse events.

ITI-007 at a dose of 60 mg demonstrated a statistically significant improvement in psychosis ($p = 0.017$) on the trial's pre-specified primary endpoint, which was change from baseline on the PANSS total score, compared to placebo. The primary statistical analysis was pre-specified and used a Mixed-Effect Model Repeated Measure

method for handling missing data in the intent-to-treat, or ITT, study population and a Bonferroni procedure to correct for multiple two-sided comparisons (each dose of ITI-007 compared to placebo). The trial's pre-specified sensitivity analysis on the primary endpoint used the analysis of covariance, or ANCOVA, model and last observation carried forward, or LOCF, method for handling missing data for the ITT population and confirmed the positive outcome with statistically significant improvements compared to placebo in patients receiving the 60 mg dose of ITI-007 ($p = 0.011$). ITI-007 at a dose of 60 mg also significantly improved the positive symptom subscale ($p < 0.05$) and the general psychopathology subscale ($p < 0.05$) on the PANSS after 28 days of treatment using the ANCOVA-LOCF on the ITT population.

The improvement in the PANSS total score in the 120 mg dose group did not reach statistical significance. We believe that it is possible that sedation, the most frequent side effect in the 120 mg dose group, interfered with the ability to detect an efficacy signal at this dose administered once daily in the morning. Approximately 32.5% of subjects randomized to 120 mg of ITI-007 experienced sedation/somnolence, compared to 21% of subjects randomized to risperidone, 17% of subjects randomized to 60 mg of ITI-007, and 13% randomized to placebo. We believe that nighttime administration may be more appropriate for testing the effectiveness of the 120 mg dose of ITI-007 in this patient population. In the trial, the 60 mg dose of ITI-007 was effective when administered once daily in the morning.

Consistent with preliminary indications from the interim analysis and with the drug candidate's pharmacological profile, ITI-007 at a dose of 60 mg significantly improved certain items on the negative symptom and general psychopathology subscales consistent with improved social function. The study was statistically powered only on the primary endpoint. ITI-007 did significantly improve many secondary endpoints, although the study was not designed for significance on secondary endpoints and was not powered to detect statistical differences in subgroup analyses.

A high percentage (74%) of randomized subjects completed trial participation. Only 19% of subjects discontinued from study treatment during the 28 day study treatment period, and an additional 7% of subjects completed study treatment but were lost to follow up.

In the Phase 2 trial, ITI-007 was well-tolerated. The most frequent AE was sedation, as described above. There were no serious adverse events related to ITI-007. There were no clinically meaningful changes in safety measures with ITI-007. Notably, ITI-007 demonstrated a favorable metabolic profile with no increase of blood levels of glucose, insulin, cholesterol or triglycerides over a four week treatment period. Moreover, in contrast to risperidone, 60 mg of ITI-007 was effective with no difference from placebo on weight change parameters, prolactin levels, extrapyramidal symptoms (EPS) or akathisia. ITI-007 was not associated with EPS as measured by the Simpson-Angus Scale, Barnes Akathisia Rating Scale, or Abnormal Involuntary Movement Scale. There was no increase in suicidal ideation or behavior with ITI-007.

Proposed Phase 3 Clinical Trials and Regulatory Plans

We are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60 mg or 40 mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Subject to further discussions with the FDA, we also plan to initiate separate additional trials in bipolar disorder in 2015. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. We expect that the planned trials in

bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. However, the FDA may not agree with our clinical development plans to conduct well-controlled clinical trials in bipolar disorder that overlap in time with our Phase 3 clinical trials in schizophrenia. In addition to our Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned NDA for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017. Additional meetings with the FDA may be requested, as needed, to discuss in greater detail our plans for schizophrenia and bipolar disorder, and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses. Our clinical plans may change based on any discussions with the FDA, the relative success and cost of our research, preclinical and clinical development programs, whether we are able to enter into future collaborations, and any unforeseen delays or cash needs. 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 could increase, which would have a material adverse effect on our business, financial condition and results of operations.

PET study of ITI-007 in patients with stable schizophrenia

We are currently conducting an open-label positron emission tomography, or PET, study of ITI-007 examining brain receptor occupancy and assessing occupancy of striatal D2 receptors. In this study, patients with stable schizophrenia will be treated with ITI-007 for 14 days. We expect topline data from this study in 2015. We believe this study will further characterize ITI-007 and provide additional insight into the molecule's unique mechanism and clinical profile.

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. In the fourth quarter of 2014, we announced the topline data from ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease. The ITI-007-200 clinical trial was conducted in two parts. Part 1 was a randomized, double-blind, placebo-controlled multiple ascending dose evaluation of ITI-007 in healthy geriatric subjects. In each of three cohorts in Part 1, approximately 10 subjects were randomized to receive ITI-007 (N=8) or placebo (N=2) orally once daily in the morning for seven days. Doses of ITI-007 up to and including 30 mg were evaluated in three cohorts in Part 1. In Part 2, eight patients with dementia were randomized to receive 9 mg ITI-007 (N=5) or placebo (N=3) orally once a day in the evening for seven days. The primary objectives of the study were to evaluate the safety, tolerability and pharmacokinetics of ITI-007 in the elderly and in the target dementia patient population. Secondary measures were included to explore the effects of ITI-007 on cognition and agitation. The Hopkins Verbal Learning Test-R (HVLT-R) was used to assess cognition in healthy geriatric subjects and dementia patients. The results demonstrated impaired verbal learning and memory (recall and recognition memory) by dementia patients relative to healthy geriatric subjects. Moreover, the data indicated that healthy geriatric subjects treated with ITI-007 for approximately one week experienced an improvement in verbal learning and memory relative to placebo-treated subjects. Dementia patients treated with ITI-007 showed enhanced recognition memory, making fewer false positive errors (i.e., responding 'yes' to non-target words) than patients treated with placebo. Other secondary endpoints in the ITI-007-200 clinical trial included the assessment of agitation. However, none of the study participants experienced agitation at baseline or during the study, and therefore no signals on this behavioral endpoint could be assessed. The completion of this study marks an important milestone in our strategy to develop low doses of ITI-007 for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results to date indicate that ITI-007 is safe and well-tolerated across a range of low doses, has

linear- and dose-related pharmacokinetics and improves cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position ITI-007 as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions. We plan to initiate additional clinical programs evaluating ITI-007 in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer's disease, in 2015.

ITI-007 for the treatment of bipolar disorder

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 Phase 2 trial in patients with acutely exacerbated schizophrenia will be used to advance ITI-007 directly into well-controlled clinical trials for the treatment of bipolar disorder. In June 2014, we had discussions with the FDA regarding our plans to initiate our Phase 3 clinical program of ITI-007 in schizophrenia. Following this meeting with the FDA, we are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and we intend to initiate a second Phase 3 clinical trial in the first half of 2015. Subject to discussions with the FDA, we intend 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. Additional meetings may be requested, as needed, to discuss in greater detail our plans for bipolar disorder and other elements of our regulatory strategy, including additional therapeutic indications, as the program progresses.

The FDA may not agree with our clinical development plans to conduct well-controlled clinical trials in bipolar disorder that overlap in time with our Phase 3 clinical trials in schizophrenia. Our clinical plans may change 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.

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

A Phase 2 double-blind, placebo controlled cross-over clinical trial conducted in 19 patients with primary insomnia with disturbed sleep maintenance at low doses of ITI-007 was completed in 2008 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-HT2A receptor antagonists increase deep, slow wave sleep in both humans and animals. We believe, however, that other neuropharmacological mechanisms, in addition to 5-HT2A 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-HT2A 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 sleep and behavioral disturbances associated with autism spectrum disorder

Sleep problems are common in patients with 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-HT2A receptor antagonism is predicted to increase slow wave sleep, improve sleep maintenance and reduce aggression. D2 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-HT2A 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 MDD, PTSD, and 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. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) entered into a license and collaboration agreement with Takeda, or the Takeda License Agreement, 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. 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. 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. On October 31, 2014, we entered into an agreement with Takeda terminating the Takeda License Agreement, or the Termination Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding obligations in connection with the development program. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. Over approximately the next 12 months, we will refine our strategy for the PDE1 inhibitor program. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE1 program to include the later stage portfolio. We do not anticipate a

significant increase in our operating expenses related to our PDE development programs over the next twelve months. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

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 March 1, 2015, we owned or controlled approximately 70 patent families filed in the United States and other major markets worldwide, including approximately 41 issued or allowed U.S. patents, 53 pending U.S. patent applications, 155 issued foreign patents, and 180 pending 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, we expect to have data exclusivity in the European Union for up to 11 years from commercial 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 molecule, ITI-214, as well as a wide range of filings on other proprietary compounds and indications. Prior to October 31, 2014, when we entered into the Termination Agreement with Takeda, certain PDE1 inhibitors were being developed under a joint development agreement with Takeda. Pursuant to the Termination Agreement, all rights granted under the Takeda License Agreement were returned to us. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding

obligations in connection with the development program. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. We are in the process of refining our strategy for the PDE1 inhibitor program. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE program to include the later stage portfolio. 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 worldwide, 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, a milestone payment of $1.25 million in December 2013, and a milestone payment of $1.5 million in December 2014 following the initiation of our first Phase 3 clinical trial for ITI-007 for patients with exacerbated schizophrenia. Possible milestone payments remaining total $12.0 million. Under the agreement, we may be obliged to make other milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 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.

Collaboration Agreement

The Takeda Pharmaceutical License and Collaboration Agreement and Termination 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 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. Upon execution of the agreement, Takeda made a nonrefundable payment to us.

Under the terms of the agreement, we conducted 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. This research program ended in February 2014. We were responsible for our expenses incurred in the conduct of certain research activities specified in the research plan. Takeda agreed to reimburse us for expenses we incurred in conducting additional research activities.

On October 31, 2014, we entered into an agreement with Takeda terminating the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding obligations in connection with the development program. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. We are in the process of refining our strategy for the PDE1 inhibitor program over the next 12 months. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE1 program to include the later stage portfolio. We do not anticipate a significant increase in our operating expenses related to our PDE development programs over the next twelve months. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

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 third-party contract manufacturers 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 3 trials for ITI-007 for the treatment of schizophrenia. We believe that we would be able to contract with other third-party contract manufacturers to obtain API if our existing sources of API were no longer available, but there is no assurance that API would be available from other third-party manufacturers 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 manufacturers. 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.

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.

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 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 API and finished drug product are produced and tested to assess compliance with 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.

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.

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.

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.

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 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 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.

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).

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.

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, which, among other things, potentially reduce Medicare payments to providers by up to 2% per fiscal year.

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, the absence of guidance in the form of regulations, and very few court decisions addressing industry practices, it is possible that 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.

Description of the Merger and Private Placement in August 2013

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.

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.

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 that were approximately $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.

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 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.

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.

The Merger was 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. Hineline, 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 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. In addition, in January 2014, Rory B. Riggs and Robert L. Van Nostrand joined our board of directors. Sir Michael resigned from our board of directors in November 2014.

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 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 in the discussion in our Proxy Statement for the 2015 Annual Meeting of Stockholders under "Certain Relationships and Related Party Transactions – Agreements with Stockholders – Registration Rights Agreement" that is incorporated by reference into Item 13 of this report. 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.

Employees

As of March 1, 2015, we employed 26 employees, 25 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.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. Our initial registration statement under the Securities Act, providing for the resale of up to 21,961,496 shares of our common stock by the selling stockholders named therein, became effective on December 18, 2013. However, if certain events occur prior to the end of such five year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three year period, we would cease to be an emerging growth company prior to the end of such five year period.

We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of certain of the reduced disclosure obligations, which include reduced executive compensation disclosure in this report, and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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.

Item 1A. RISK FACTORS

Except for the historical information contained herein, this report contains forward-looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this report.

You should consider carefully the following risk factors, together with all of the other information included or incorporated by reference in this report. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

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, has just commenced its first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In addition, all rights with respect to ITI-214, which has advanced into Phase 1 clinical trials that we previously granted to Takeda were recently returned to us in connection with the termination of the Takeda License Agreement. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders, and we are in the process of refining our strategy for the PDE1 inhibitor program. 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 planned clinical trials for ITI-007 in schizophrenia or in other indications will be successful.

In our Phase 1 and Phase 2 clinical trials, our lead product candidate, ITI-007, has demonstrated improved sleep maintenance, antipsychotic efficacy, and clinical signals consistent with reduction in negative symptoms associated with schizophrenia, depression and anxiety, and other symptoms associated with impaired social function. ITI-007 exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled Phase 2 clinical trial in patients with an acutely exacerbated episode of schizophrenia. 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, ITI-007 was shown effective at a dose that did 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 planning confirmatory later-stage clinical trials and recently initiated our first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014.

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we plan to conduct further clinical studies in patients with schizophrenia and other indications, including two Phase 3 clinical trials of ITI-007 in schizophrenia, one of which we commenced in the fourth quarter of 2014, 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.

In addition, although we believe that ITI-007 and follow-on compounds may also have clinical utility in indications other than schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, IED, 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, except for ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease, for which we announced topline data in the fourth quarter of 2014.

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 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.

We are advancing ITI-007 into Phase 3 clinical trials for the treatment of schizophrenia. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if successfully completed, are not sufficient for regulatory approval. If we are required to conduct additional clinical trials and non-clinical studies, our development of ITI-007 for schizophrenia will be more time-consuming and costly than we presently anticipate, which would have a material adverse effect on our business, results of operations and financial condition.

In June 2014, we held our end-of-Phase 2 meeting with the FDA to discuss our plans for initiating Phase 3 clinical trials of ITI-007 in schizophrenia. Following this meeting, we are proceeding with our Phase 3 development program, in which we plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Even though we believe that our planned Phase 3 clinical trials and non-clinical studies for ITI-007 in schizophrenia, if successful, will be sufficient to support our NDA, the FDA may not agree with one or more aspects of our clinical trial designs, including the duration of the trials, clinical endpoints, controls, dose ranges, collection of safety data, or adequacy of our non-clinical studies. If we submit an NDA and the FDA does not agree with our clinical and non-clinical designs, our development of ITI-007 in schizophrenia and other indications may be delayed, and we may incur additional costs and devote additional resources to address any concerns the FDA

may have with our trial designs. In addition, we may be required to conduct additional clinical trials or studies, which could result in additional delays and costs. There is no assurance that we will complete the Phase 3 trials and non-clinical studies within the timeframes and the costs that we currently expect, or at all, or in a manner that is acceptable to the FDA. Any delays or unplanned costs resulting from our Phase 3 clinical trials of ITI-007 in schizophrenia may have a material adverse effect on our business, results of operations and financial condition. Even if we eventually complete Phase 3 clinical testing, submit an NDA and receive approval of ITI-007, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve ITI-007 for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of ITI-007 or our other product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for ITI-007 would delay or prevent commercialization of ITI-007 and would materially adversely impact our business, results of operations and financial condition.

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 for the treatment of bipolar disorder may be delayed and the costs of our development of ITI-007 would increase.

In June 2014, we had discussions with the FDA regarding our plans to initiate our Phase 3 clinical program of ITI-007 in schizophrenia. Following this meeting with the FDA, we are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia by conducting two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia. Subject to further discussions with the FDA, we 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. The FDA may not agree with our clinical development plans for advancing ITI-007 for the treatment of bipolar disorder, including our plans to conduct separate well-controlled clinical trials of ITI-007 for the treatment of bipolar disorder that overlap with our Phase 3 clinical trials of ITI-007 for the treatment of schizophrenia. Our clinical plans for ITI-007 for the treatment of bipolar disorder may change based on any discussions with the FDA, the relative success and cost of our research, preclinical and clinical development programs, whether we are able to enter into future collaborations, and any unforeseen delays or cash needs. If the FDA does not agree with our clinical development plans for ITI-007 for the treatment of bipolar disorder, our development of ITI-007 in this indication may take longer and be more costly than we currently expect, which would have a material adverse effect on our business, financial condition and results of operations.

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 December 31, 2014, we had an accumulated deficit of approximately $88.3 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 to date 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. In October 2014, we entered into the Takeda Termination Agreement, which terminated our license and collaboration agreement with Takeda, pursuant to which all rights with respect to ITI-214 that we previously granted to Takeda were returned to us. We will not, therefore, receive any further milestone payments from Takeda and we cannot be certain 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.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We have consumed substantial amounts of capital since our inception. Our cash, cash equivalents and investment securities totaled $129.6 million at December 31, 2014. In addition, we received net proceeds of approximately $121.4 million from the public offering of shares of our common stock in March 2015. While we believe that our existing cash, cash equivalents and investment securities, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2016, the amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status of our planned Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, the process of refining our strategy for the PDE1 inhibitor program and the continued development of ITI-214 for the treatment of CNS and other disorders, and our other planned clinical and non-clinical trials. Furthermore, we anticipate that we will need to secure additional funding to complete additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with acute exacerbated schizophrenia, for further development of ITI-007 for other indications, and for development of our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials, or we experience delays or other setbacks in our clinical trials, our expenses would further increase beyond what we currently expect and the anticipated timing of any potential NDA would likely be delayed.

We intend to use substantially all of the remaining net proceeds from our public offering completed in February 2014 to fund the completion of two proposed Phase 3 clinical trials of ITI-007 in patients with acute exacerbated schizophrenia, one of which we initiated in the fourth quarter of 2014; to fund the initiation of other planned clinical and non-clinical trials, including manufacturing, needed for anticipated regulatory approval of ITI-007 in patients with acute exacerbated schizophrenia and other potential additional indications; and to fund research and preclinical development of our other product candidates. We intend to use substantially all of the net proceeds from our public offering completed in March 2015 to fund a clinical trial of ITI-007 for the treatment of behavioral disturbances in dementia; to fund one or more clinical trials of ITI-007 in bipolar disorder; to fund our ITI-007 long acting injectable development program through pre-clinical and early clinical development; to fund one or more clinical trials of ITI-007 for the treatment of depression; and to fund research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of ITI-007. The remaining proceeds, if any, will be used to fund new and ongoing research and development activities, general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from the offerings to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

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 any future collaborators and us to reach the milestones, and other events or developments, triggering payments under any future collaboration agreements or to otherwise make payments under such agreements;
- our ability to enter into new, and to maintain any existing, collaboration and license agreements;

- the extent to which any future collaborators are obligated to reimburse us for clinical trial costs under any future 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 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. 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, or at all. If we do obtain additional funding through equity offerings, the ownership of our existing stockholders and purchasers of shares of our common stock in any such offering will be diluted, and the terms of any financing may adversely affect the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline. 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. We also could be required to seek funds through arrangements with collaboration partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

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, including the net proceeds from our public offerings completed in February 2014 and March 2015, 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.

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, our costs will increase, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

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;
- 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. On October 31, 2014, we entered into the Termination Agreement with Takeda, which terminated the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. 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.

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.

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.

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. 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.

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 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, 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:

- our 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;
- 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 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 contracts with our current manufacturers or contract with other third parties 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 a long-term agreement 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.

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 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 manage our operations and facilities effectively in order to advance our drug development programs (including ITI-007 and ITI-214), facilitate any future 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.

Third-party payors, whether foreign or domestic, 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 product 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 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, 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;
- 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 will have on our business. 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.

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.

There are possible limitations on our use of net operating losses.

As of December 31, 2014, we had net operating loss carryforwards of approximately $78.2 million to reduce any future federal and state taxable income through 2034. Since we had net operating loss carryforwards as of December 31, 2014 and 2013, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. The net operating loss carryforwards of approximately $78.2 million as of December 31, 2014 will begin to expire in the year 2030 if unused. The use of our net operating loss carryforwards may be restricted due to changes in our ownership, including as a result of our recent public offering in March 2015.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we, our clinical research organizations and other third parties on which we rely collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business critical information including research and development information and business and financial information.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information

technology and infrastructure may be vulnerable to attacks by hackers, viruses, breaches, interruptions due to employee error, malfeasance or other disruptions, lapses in compliance with privacy and security mandates, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business and damage our reputation, any of which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

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;
- 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; and
- 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 and 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 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 any 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.

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 U.S. Patent and Trademark Office's, or 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.

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.

For example, our potential products for the treatment of 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 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, and 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 $30 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 Related to Owning Our Common Stock

Our stock price may fluctuate significantly and you may have difficulty selling your shares based on current trading volumes of our stock. In addition, numerous other factors could result in substantial volatility in the trading price of our stock.

Since January 31, 2014, our common stock has been listed on the NASDAQ Global Select Market, and from December 20, 2013 to January 30, 2014, was quoted for trading on the OTC Markets—OTCQB tier, or OTCQB, in very limited volume. In the 12 months preceding March 1, 2015, the price per share of our common stock has ranged from a high of $30.72 to a low of $12.67. Prior to December 20, 2013, our common stock was not publicly-traded. We cannot predict the extent to which investor interest in our company will result in an active trading market on the NASDAQ Global Select Market or any other exchange in the future. We have several stockholders, including affiliated stockholders, who hold substantial blocks of our stock. Sales of large numbers of shares by any of our large stockholders could adversely affect our trading price, particularly given our small historic trading volumes. If stockholders holding shares of our common stock sell, indicate an intention to sell, or if it is perceived that they will sell, substantial amounts of their common stock in the public market, the trading price of our common stock could decline.

In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of medical innovations or new products by our competitors;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the biopharmaceutical industry;
- timing and announcement of regulatory approvals;
- any future sales of our common stock or other securities in connection with raising additional capital or otherwise;
- any major change to the composition of our board of directors or management; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of biotechnology companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We will need to satisfy our future cash needs through public or private sales of our equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. We filed a universal shelf

registration statement on Form S-3 with the SEC, which was declared effective on September 15, 2014, on which we registered for sale up to $150 million of securities of any combination of common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that we may determine. On March 11, 2015, we completed our public offering of $129.9 million of shares of our common stock registered on the universal shelf registration statement and received net proceeds of approximately $121.4 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or grant licenses on terms that are not favorable to us.

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

The market price of our common stock 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.

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 our outstanding equity securities. 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 our charter, other fundamental corporate transactions, such as mergers, asset sales and the sale of the company, and otherwise will be able to direct our 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 have incurred and will incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with current corporate governance requirements, including requirements under Section 404 and other provisions of the Sarbanes-Oxley Act, as well as rules implemented by the SEC or the NASDAQ Global Select Market or any other 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.

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 are 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, for public companies that are not emerging growth companies, 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 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.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an emerging growth company under 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 take advantage of these exemptions, 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 of 1933, as amended, or the Securities Act. Our first registration statement filed under the Securities Act was declared effective on December 18, 2013. 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.

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.

The trading market for our common stock is and will be influenced by whether industry or securities analysts publish or continue to publish research and reports about us, our business, our market or our competitors and, to the extent analysts do publish such reports, what they publish in those reports. We may not continue to have or to 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 covers us or 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.

Provisions of the Delaware law, our restated certificate of incorporation and our restated bylaws may delay or prevent a takeover which may not be in the best interests of our stockholders.

The provisions of Delaware law and our 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.

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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements within the meaning of Section 27A of 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 description of our Business set forth in Item 1, the Risk Factors set forth in this Item 1A and our Management’s Discussion and Analysis of Financial Condition and Results of Operations set forth in Item 7 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 accuracy of our estimates regarding expenses, future revenues and capital requirements and the need for additional financing;
- 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 current and future product candidates;
- our collaborators’ election to pursue research, development and commercialization activities;

- our ability to obtain future reimbursement and/or milestone payments from our collaborators;
- 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;
- 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 public offerings in March 2015 and February 2014 and our private placement in August 2013;
- any restrictions on our ability to use our net operating loss carryforwards;
- our exposure to investment risk, interest rate risk and capital market risk;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- 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 set forth in Item 1A of this Annual Report on Form 10-K, 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our headquarters are located at 430 East 29th Street, New York, New York 10016, where we occupy approximately 14,678 square feet of useable office and laboratory space. The term of the lease expires January 31, 2026. We also lease office space in Towson, Maryland on a month to month basis.

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Item 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

From December 20, 2013 through January 30, 2014, our common stock was quoted on the OTC Markets—OTCQB tier, or OTCQB, under the symbol "ITCI." On January 31, 2014, our common stock commenced trading on the NASDAQ Global Select Market under the symbol "ITCI" and ceased being quoted on the OTCQB. The high and low bid quotations per share of our common stock as reported by the OTCQB and the high and low sales prices per share of our common stock as reported by NASDAQ for the applicable periods when the common stock was quoted on the OTCBB or listed on the NASDAQ Global Select Market, as applicable, since the common stock commenced public trading are set forth below:

Year Ended December 31, 2014	High	Low
First Quarter	$21.26	$10.00
Second Quarter	$19.60	$14.53
Third Quarter	$19.77	$12.67
Fourth Quarter	$19.00	$13.37

Year Ended December 31, 2013	High	Low
Fourth Quarter	$20.00	$10.00

Stockholders

As of March 11, 2015, we had 34,928,424 outstanding shares of common stock and no outstanding shares of preferred stock. As of March 11, 2015, there were approximately 167 holders of record of our common stock.

Dividends

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.

Unregistered Sales of Securities

Not applicable.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the fourth quarter of 2014.

Use of Proceeds from Registered Securities

On February 5, 2014, we completed our initial public offering of 7,063,300 shares of our common stock at a price of $17.50 per share for aggregate gross proceeds of approximately $123.6 million. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form S-1, which was declared effective on January 30, 2014 (File No. 333-193313), and a registration statement on Form S-1 filed pursuant to Rule 462(b) promulgated under the Securities Act (File No. 333-193676). Leerink Partners LLC and Cowen and Company, LLC acted as joint book-running managers for the offering and as representatives of the underwriters. Guggenheim Securities, LLC and JMP Securities LLC acted as co-managers for the offering. The offering commenced on January 24, 2014 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of approximately $115.4 million, after deducting approximately $7.4 million of underwriting discounts and commissions, and approximately $0.8 million of offering expenses payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates.

We have invested the net proceeds from the offering in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as commercial paper and corporate debt securities, U.S. government securities, certificates of deposit and institutional money market funds. As of December 31, 2014, $23.2 million of the net proceeds of the offering had been used primarily for working capital purposes, including recurring expenses and preclinical and clinical trial costs related to the development of ITI-007. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus dated January 30, 2014 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act on January 31, 2014. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our stock.

Item 6. SELECTED FINANCIAL DATA

The selected financial data set forth below have been derived from our consolidated financial statements, which financial statements have been audited by Ernst & Young LLP, independent registered public accounting firm. The consolidated financial statements for 2014 and 2013 and the report thereon are included elsewhere in this Annual Report on Form 10-K. The information below should be read in conjunction with the consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in Item 7.

	2014 (Audited)	2013 (Audited)	2012 (Audited)	2011 (Audited)
Statements of Operations:				
Revenues:				
License and collaboration revenue	$ 547,546	$ 2,737,002	$ 3,117,991	$ 22,327,464
Grant revenue	29,755	—	—	1,034,495
Total Revenues	577,301	2,737,002	3,117,991	23,361,959
Costs and expenses:				
Research and development	21,226,345	23,027,578	15,486,476	7,654,546
General and administrative	10,337,679	5,976,276	4,034,925	4,612,450
Total costs and expenses	31,564,024	29,003,854	19,521,401	12,266,996
Loss from operations	(30,698,223)	(26,266,852)	(16,403,410)	11,094,963
Interest expense	(7,073)	(612,963)	(193,498)	(15)
Interest income	303,936	29,617	39,002	62,315
Income taxes	(1,600)	(18,000)	(32,921)	(64,834)
Net loss	$ (30,691,460)	$(26,868,198)	$(16,590,827)	$ 11,092,429
Net earnings (loss) per common share:				
Basic	$ (1.07)	$ (1.56)	$ (2.96)	$ 1.98
Diluted	$ (1.07)	$ (1.56)	$ (2.96)	$ 1.47
Weighted average number of common shares:				
Basic	28,650,067	17,260,768	5,607,539	5,601,495
Diluted	28,650,067	17,260,768	5,607,539	7,558,150

	December 31,			
	2014 (Audited)	2013 (Audited)	2012 (Audited)	2011 (Audited)
Balance Sheet data:				
Cash and cash equivalents	$ 61,325,044	$ 35,150,924	$ 15,645,528	$ 13,693,215
Total assets	131,111,769	38,449,312	19,823,680	23,594,725
Total liabilities	10,557,064	6,834,037	2,839,595	5,702,422
Accumulated deficit	(88,255,957)	(57,564,497)	(30,696,299)	(14,105,472)
Total stockholders' equity	120,554,705	31,615,275	16,984,085	17,892,303

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of our operations and our wholly-owned subsidiary should be read in conjunction with the financial statements and the notes to those statements appearing elsewhere in this Annual Report on Form 10-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 set forth in Item 1A of this Annual Report on Form 10-K 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

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 drug candidate, ITI-007, is in Phase 3 clinical development as a first-in-class treatment for schizophrenia. Results from our Phase 2 trial are included in "Business—Our Clinical Programs—ITI-007 Program —ITI-007 for the treatment of exacerbated and residual schizophrenia—Phase 2 Clinical Trial (ITI-007-005)" under Item 1 of this Annual Report on Form 10-K. We are proceeding with Phase 3 development of ITI-007 for the treatment of schizophrenia. We plan to conduct two randomized, double-blind, placebo-controlled Phase 3 clinical trials of ITI-007 in patients with acutely exacerbated schizophrenia, with over 400 patients in each trial. We initiated the first Phase 3 clinical trial in schizophrenia in the fourth quarter of 2014 and, subject to finalizing the trial protocols and arrangements with clinical trial sites, we intend to initiate a second Phase 3 clinical trial in the first half of 2015. In the first Phase 3 trial, we are randomizing patients to two doses of ITI-007 (60mg or 40mg) or placebo over a 4-week treatment duration, and the primary outcome measure is change from baseline to Day 28 on the PANSS total score. We currently expect that the second Phase 3 trial will be conducted for a 6-week treatment duration. Subject to timely enrollment, we anticipate that the results of the first Phase 3 clinical trial of ITI-007 in patients with schizophrenia could be available as early as the fourth quarter of 2015. Subject to further discussions with the FDA, we also plan to initiate separate additional trials in bipolar disorder in 2015. We have not yet discussed our plans to develop ITI-007 for the treatment of bipolar disorder with the FDA. We expect that the planned trials in bipolar disorder will overlap in time with the clinical conduct of the planned trials in schizophrenia. In addition to our Phase 3 clinical trials, we will need to complete other clinical and non-clinical trials and manufacturing and pre-commercialization activities necessary to support the submission of a planned New Drug Application, or NDA, for ITI-007 in schizophrenia, which we currently expect could occur at the end of 2016 or the beginning of 2017.

In addition, in the fourth quarter of 2014, we announced the topline data from ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer's disease. The completion of this study marks an important milestone in our strategy to develop low doses of ITI-007 for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results to date indicate that ITI-007 is safe and well-tolerated across a range of low doses, has linear- and dose-related pharmacokinetics and improves cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position ITI-007 as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions. We plan to initiate additional clinical programs evaluating ITI-007 in patients with behavioral disturbances associated with dementia and related disorders, including Alzheimer's disease, in 2015.

We are currently conducting an open-label positron emission tomography, or PET, study of ITI-007 examining brain receptor occupancy and assessing occupancy of striatal D2 receptors. In this study, patients with

stable schizophrenia will be treated with ITI-007 for 14 days. We expect topline data from this study in 2015. We believe this study will further characterize ITI-007 and provide additional insight into the molecule's unique mechanism and clinical profile.

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-HT2A 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-HT2A antagonism for treating agitation, aggression and sleep disturbances in diseases that include dementia, Alzheimer's disease, Huntington'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-HT2A serotonin receptors. At a dose of 60 mg, ITI-007 has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range will be useful for the treatment of 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 additional diseases that include 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.

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibits the enzyme PDE1. PDE1 helps regulate brain activity related to cognition, memory processes and movement/coordination. On February 25, 2011, we (through our wholly owned operating subsidiary, ITI) entered into the Takeda License Agreement with Takeda, 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. On October 31, 2014, we entered into the Termination Agreement with Takeda terminating the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to us. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to us but will not have any other ongoing involvement or funding obligations in connection with the development program. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to continue the development of ITI-214 for the treatment of CNS and other disorders. Over approximately the next 12 months, we will refine our strategy for the PDE1 inhibitor program. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, we can now integrate the efforts of our internal PDE1 program to include the later stage portfolio. We do not anticipate a significant increase in our operating expenses related to our PDE development programs over the next twelve months. Other compounds in the PDE1 portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

Our pipeline also includes pre-clinical 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 substantially all of our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of December 31, 2014, our accumulated deficit was $88.3 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.

Our corporate headquarters and laboratory are located in New York, New York.

Public Offering in March 2015

On March 11, 2015, we completed a public offering of 5,411,481 shares of our common stock at a price of $24.00 per share for aggregate gross proceeds of approximately $129.9 million, and net proceeds of approximately $121.4 million.

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 year ended December 31, 2014 have been from the recently terminated license and collaboration agreement with Takeda and to a much lesser extent from a government grant. For the year ended December 31, 2013, revenues were entirely from the agreement with Takeda. We will not receive any further revenue under the Takeda License Agreement, which was terminated on October 31, 2014. We have received and may continue to receive grants from U.S. government agencies and foundations.

We do not expect any revenues that we may generate in the next several years to be significant enough to fund our operations.

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 portion of our current, as well as projected, resources. In addition, in the third quarter of 2014 we completed a Phase 1/2 clinical trial of ITI-007-200, which was designed to evaluate the safety, tolerability and pharmacokinetics of low doses of ITI-007 in healthy geriatric subjects and in patients with dementia, including Alzheimer’s disease. 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 ITI-002 program has a compound, ITI-214, in Phase 1 development. We intend to pursue the development of this and the other compounds in our PDE1 portfolio for the treatment of central nervous system, cardiovascular and other disorders. Over approximately the next twelve months, we will refine our strategy for the PDE1 inhibitor program that was returned to us from Takeda. We do not anticipate a significant increase in our operating expenses related to our PDE development programs over the next twelve months. Our other projects are still in the pre-clinical stages, and will require extensive funding not only to complete pre-clinical 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 results of 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 pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments.

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.

We expect that research and development expenses will increase substantially as we proceed with our Phase 3 clinical trials for ITI-007 in patients with exacerbated schizophrenia. We also expect that our general and administrative costs will increase substantially from prior periods primarily due to the increased costs associated with being a public reporting entity, which would include adding additional personnel. We granted options to purchase 1,108,000 shares of our common stock in 2014 and have granted options to purchase an additional 636,902 shares of our common stock in January 2015. We will recognize expense associated with these options over the next three years in both research and development expenses and general and administrative expenses. We expect this non-cash expense to be material and affect quarter to quarter and year to date comparisons in the upcoming year. We expect to continue to grant stock options and other stock-based awards in the future, which will increase our stock-based compensation expense in future periods.

The following table sets forth our revenues, operating expenses, interest income (expense) and income taxes expenses for the years ended December 31, 2014, 2013 and 2012:

	For the Year Ended December 31,		
	2014	**2013**	**2012**
Revenues	**$ 577**	$ 2,737	$ 3,118
Expenses			
Research and Development	**21,226**	23,028	15,486
General and Administrative	**10,338**	5,976	4,035
	31,564	29,004	19,521
Interest Income (Expense)	**298**	(583)	(155)
Income Taxes	**(2)**	(18)	(33)
Net Loss	**$(30,691)**	$(26,868)	$(16,591)

Comparison of Years Ended December 31, 2014 and December 31, 2013

Revenues

Revenue decreased for the year ended December 31, 2014 as compared to the year ended December 31, 2013 by approximately $2.2 million, or 79%, due primarily to the recognition in 2013 of previously deferred revenue relating to the Takeda License Agreement and lower reimbursable costs payable to us by Takeda in 2014 under the Takeda License Agreement, offset to a much lesser extent by revenue from a government grant in 2014.

Research and Development Expenses

Research and development expenses decreased for the year ended December 31, 2014 as compared to the year ended December 31, 2013 by approximately $1.8 million, or 8%. This decrease is due primarily to costs associated with outside clinical testing for our ITI-007 Phase 2 clinical trial that was completed in late 2013 as compared to costs incurred in conducting our ITI-007 Phase 3 clinical trial, which began in the fourth quarter of

2014. Partially offsetting this decrease were expenses of approximately $6.6 million incurred in 2014 as compared to $1.9 million in 2013 related to the manufacturing and other clinical and non-clinical testing of our ITI-007 product candidate and expenses of approximately $1.9 million related to our ITI-007-200 Phase 1/2 clinical trial in healthy geriatric and dementia patients incurred only in 2014. In addition, stock option expense increased by $1.7 million for the year ended December 31, 2014 due primarily to stock options granted in 2014.

The research and development expenses incurred for amounts payable to external parties comprised a significant portion of our research and development expenses during the years ended December 31, 2014 and 2013. We incurred expenses of approximately $14.8 million and $18.8 million for the years ended December 31, 2014 and 2013, respectively, for amounts payable to external parties who manufactured, tested and performed clinical trial activities for all of our projects. We spent approximately $14.4 million and $18.3 million, on external costs for the development of ITI-007 for the years ended December 31, 2014 and 2013, respectively. During the same periods, our internal research and development expenses for all projects were approximately $5.0 million and $3.0 million, respectively. The clinical development work related to ITI-007 requires the largest portion of our resources and, consequently, comprises the majority of our spending. For the years ended December 31, 2014 and 2013, we incurred total expenses of $18.8 million and $20.8 million, respectively, for all ITI-007 related projects and $2.4 million and $2.2 million, respectively, for all of our other projects. Total research and development expenses were approximately $21.2 million for the year ended December 31, 2014 as compared to $23.0 million for 2013. As development of ITI-007 progresses, we anticipate costs for ITI-007 to increase considerably in 2015 and in the next several years as we conduct Phase 3 and 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. As of December 31, 2014, we employed 16 full time personnel in our research and development group as compared to 13 at December 31, 2013. We expect to hire additional staff as we increase our development efforts in the upcoming years.

We currently have several projects, in addition to ITI-007, that are in the research and development stages, including 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 also in connection with these additional projects as well. We have not, however, reported these costs on a project by project basis, as these costs 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 2014 and in previous years, we also incurred costs that were both reimbursable and non-reimbursable under the Takeda License Agreement. For the year ended December 31, 2014, we incurred approximately $14,000 on direct costs that were billable to Takeda as compared to $97,000 for the year ended December 31, 2013. As we refine our strategy for the PDE1 inhibitor program that was returned to us from Takeda, we do not expect a significant increase in our operating expenses related to our PDE development programs over the next twelve months.

The research and development process necessary to develop a pharmaceutical product for commercialization is subject to extensive regulation by numerous governmental authorities in the United States and other countries. This process typically takes years to complete and requires the expenditure of substantial resources. 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 Investigational New Drug application, or 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 a New Drug Application, or 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 successful development of our product candidates and the approval process requires substantial time, effort and financial resources, and is uncertain and subject to a number of risks. We cannot be certain that any of our product candidates will prove to be safe and effective, will meet all of the applicable regulatory requirements needed to receive and maintain marketing approval, or will be granted marketing approval on a timely basis, if at all. Data from pre-clinical studies and clinical trials are susceptible to varying interpretations that could delay, limit or prevent regulatory approval or could result in label warnings related to or recalls of approved products. We, the FDA, or other regulatory authorities may suspend clinical trials at any time if we or they believe that the subjects participating in such trials are being exposed to unacceptable risks or if such regulatory agencies find deficiencies in the conduct of the trials or other problems with our product candidates. Other risks associated with our product candidates are described in the section entitled “Risk Factors” in Item IA of this Annual Report on Form 10-K.

General and Administrative Expenses

General and administrative expenses increased for the year ended December 31, 2014 as compared to the year ended December 31, 2013 by approximately $4.4 million or 73%. This increase was primarily due to increased stock option expense of $1.7 million in 2014 related to options granted in 2014, and increased labor and related benefit costs of approximately $0.6 million, with the remainder comprised of higher professional fees, directors’ and officers’ insurance costs, and board of directors compensation fees, which are due to the activities associated with being a public company. We expect these costs to increase significantly as we expand our operations, including hiring of additional personnel, continue to be subject to the reporting requirements of being a public company and issue additional equity incentive awards.

Comparison of Years Ended December 31, 2013 and December 31, 2012

Revenues

Revenue decreased for the year ended December 31, 2013 as compared to the year ended December 31, 2012 by approximately $0.4 million, due primarily to lower reimbursable costs from Takeda in 2013 as compared to 2012.

Research and Development Expenses

Total research and development expenses were approximately $23.0 million for the fiscal year ended December 31, 2013, as compared to $15.5 million for the fiscal year ended December 31, 2012. This increase of $7.5 million in total research and development expenses is due primarily to an increase of $6.3 million in direct costs for clinical trials, which is primarily the result of an increase in the number of clinical trial subjects for our Phase 2 trial of ITI-007 in patients with acutely exacerbated schizophrenia and $1.25 million for a milestone payment we made related to our license agreement with BMS. Clinical trial costs for the fiscal year ended December 31, 2013 were $16.9 million as compared to $10.6 million for the fiscal year ended December 31, 2012 due to more patients screened and tested in 2013 versus 2012 and the costs associated with the non-patent related data, statistical and other testing needed to complete the study.

The research and development expenses incurred for amounts payable to external parties comprised a significant portion of our research and development expenses during the years ended December 31, 2013 and 2012, due primarily to the preparation for and commencement of our Phase 2 clinical trial for ITI-007 in patients with acutely exacerbated schizophrenia. We incurred expenses of approximately $18.8 million and $12.6 million for the years ended December 31, 2013 and 2012, 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 for all projects were approximately $3.0 million and $2.9 million, respectively. The clinical development work related to ITI-007 required the largest portion of our resources and, consequently, comprised the majority of our spending. We spent approximately $21.0 million and $11.3 million on direct costs for the development of ITI-007 during the periods ended December 31, 2013 and 2012, respectively. During the years ended December 31, 2013 and 2012, we also incurred costs that were both reimbursable and non-reimbursable under the Takeda License Agreement. We incurred approximately $97,000 and $700,000 on direct costs that were billable to Takeda for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we employed 13 full time personnel in our research and development group as compared to 15 at December 31, 2012.

General and Administrative Expenses

General and administrative expenses increased by approximately $2.0 million, or 50%, to $6.0 million for the fiscal year ended December 31, 2013 compared to $4.0 million for the fiscal year ended December 31, 2012. The increase is the result of higher personnel costs, legal, accounting, patent and public company reporting-related costs, including costs related to the reverse merger and private placement in August 2013.

Liquidity and Capital Resources

Through December 31, 2014, we have provided funds for our operations by obtaining approximately $266.3 million of cash primarily through public and private offerings of our common stock and other securities, grants from government agencies and foundations and payments received under the recently terminated Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future, and Takeda has no ongoing funding obligations following the termination of the Takeda License Agreement on October 31, 2014.

As of December 31, 2014, we had a total of $129.6 million in cash and cash equivalents and available-for-sale investment securities, and approximately $10.6 million of short-term liabilities consisting entirely of short-term liabilities from operations. Excluding the increase in net cash of approximately $115.4 million from the public offering which closed on February 5, 2014, we spent approximately $22.9 million in cash and reduced working capital by approximately $26.4 million for the year ended December 31, 2014. This use of working capital is due primarily to funding recurring operating expenses and the preparation and initiation of additional clinical trials and non-clinical testing, including manufacturing related activities.

On March 11, 2015 we completed our public offering of 5,411,481 shares of our common stock for aggregate gross proceeds of approximately $129.9 million, and net proceeds of approximately $121.4 million.

We expect to use cash of up to $43 million during the first half of 2015, which we expect to be due primarily to expenses associated with our clinical and non-clinical development of ITI-007 in patients with schizophrenia and recurring expenses and costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to ITI-007 as well as incurring expenses associated with our other development programs and general operations. Cash expenditures will increase significantly after the first half of 2015 as we incur costs to fund our development of ITI-007 in patients with schizophrenia, behavioral disturbances in dementia, bipolar disorder and depression, our ITI-007 long acting injectable development program through pre-clinical and early clinical development, research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of ITI-007. We believe that our existing cash and cash equivalents, along with the net proceeds from our public offering that was completed in March 2015, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2016.

We will require significant additional financing in the future to continue to fund our operations. In particular, we anticipate that we will need to secure funding to complete the additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of ITI-007 in patients with schizophrenia, continuing clinical trials of ITI-007 in patients with dementia, including Alzheimer's disease, for further development of ITI-007 in patients with bipolar disorder, depression and other indications, and for development of our other product candidates.

We have incurred losses in every year since inception with the exception of 2011, when we received an up-front fee and a milestone payment related to the Takeda License Agreement. These losses have resulted in significant cash used in operations. During the years ended December 31, 2014 and 2013, our net cash used in operating activities was approximately $22.8 million and $22.6 million, respectively. 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 amount of cash needed to fund operations to increase significantly in 2015 and over the next several years.

With the termination of the Takeda License Agreement in October 2014, we will not be eligible to receive milestone payments and expense reimbursements, including patent filing costs, from Takeda and will be responsible for the costs of developing ITI-214. Over approximately the next twelve months we will refine our strategy for our PDE1 inhibitor program. We do not anticipate a significant increase in our operating expenses related to our PDE development programs during the next twelve months.

We seek to balance the level of cash, cash equivalents and investments on hand with our projected needs and to allow us to withstand periods of uncertainty relative to the availability of funding on favorable terms. 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, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of our product candidates and technology and, to a lesser extent, grant funding. On August 29, 2014, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 15, 2014, to register $150 million of our common stock, preferred stock, various series of debt securities, warrants, rights and purchase contracts to purchase any of such securities, either individually or in units, for issuance from time to time at prices and on terms to be determined at the time of any such offering. We sold approximately $129.9 million of our common stock that is registered on the universal shelf registration statement in our public offering which was completed on March 11, 2015. This registration statement will remain in effect for up to three years from the date it was declared effective. We cannot be sure that future funding will be available to us when we need it on terms that are acceptable to us, or at all. We sell securities and incur debt when the terms of such transactions are deemed favorable to us and as necessary to fund our current and projected cash needs. The amount of funding we raise through sales of our common stock or other securities depends on many factors, including, but not limited to, the status and progress of our product development programs, projected cash needs, availability of funding from other sources, our stock price and the status of the capital markets. Due to the volatile nature of the financial markets, equity and debt financing may be difficult to obtain. In addition, any unfavorable development or delay in the progress of our ITI-007 program could have a material adverse impact on our ability to raise additional capital.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends.

If adequate funds are not available to us on a timely basis, we may be required to: (1) delay, limit, reduce or terminate pre-clinical studies, clinical trials or other clinical development activities for one or more of our product candidates, including our lead product candidate ITI-007, ITI-214, and our other pre-clinical stage product

candidates; (2) delay, limit, reduce or terminate our discovery research or pre-clinical development activities; or (3) enter into licenses or other arrangements with third parties on terms that may be unfavorable to us or sell, license or relinquish rights to develop or commercialize our product candidates, technologies or intellectual property at an earlier stage of development and on less favorable terms than we would otherwise agree.

Our cash is maintained in checking accounts, money market accounts, money market funds, certificates of deposit, commercial paper, corporate notes and corporate bonds 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.

Contractual Obligations and Commitments

Total contractual obligations as of December 31, 2014 are summarized in the following table (in thousands):

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations	$13,125	$ 11	$3,435	$3,854	$ 5,825

The table of Contractual Obligations and Commitments does not reflect that, under the License Agreement with BMS, we may be obligated to make future milestone payments to BMS totaling $12 million; to make other future milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million; to make tiered single digit percentage royalty payments on sales of licensed products; and to pay BMS a percentage of non-royalty payments made in consideration of any sublicense.

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 that persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the 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 Topic 605-45, *Revenue Recognition/Principal Agent Considerations* . We are the primary obligor with respect to 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.

We have entered into arrangements involving the delivery of more than one element. 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 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.

The adoption of this accounting standard did not have a material impact on our results of operations for the years ended December 31, 2014, 2013 and 2012, or on our financial positions as of those dates.

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 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 Topic 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 awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. For awards that contain a performance-based vesting condition, expense is amortized using the accelerated attribution method. As stock-based compensation expense recognized in the statements of

operations for the years ended December 31, 2014, 2013 and 2012 is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC Topic 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 for the fiscal years ended December 31, 2014, 2013 and 2012 were estimated based on our historical experience and have not been material.

We utilize the Black-Scholes model for estimating fair value of our stock options granted. Option valuation models, including the 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 options is the period of time for which the stock 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 our stockholders since our inception and do not plan to pay cash dividends in the foreseeable future. Therefore, we have assumed an expected dividend rate of zero.

Given the absence of an active market for our common stock during 2012 and 2013, the exercise prices of the stock options on the dates of grant were 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 Topic 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 Topic 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 carryforwards as of December 31, 2014, 2013 and 2012, 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 Topic 718 and ASC Topic 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.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize

revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early application is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Presently, we are assessing what effect the adoption of ASU 2014-09 will have on our consolidated financial statements and accompanying notes.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity. As of December 31, 2014, we had cash, cash equivalents and marketable securities of $129.6 million consisting of cash deposited in a highly rated financial institution in the United States and in a short-term U.S. Treasury money market fund, as well as high-grade corporate bonds and commercial paper. The primary objective of our investment activities is to preserve our capital for the purpose of funding operations and we do not enter into investments for trading or speculative purposes. We believe that we do not have material exposure to high-risk investments such as mortgage-backed securities, auction rate securities or other special investment vehicles within our money-market fund investments. We believe that we do not have any material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, would reduce future investment income.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INTRA-CELLULAR THERAPIES, INC.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (1992).

Based on our assessment, management believes that, as of December 31, 2014, the company's internal control over financial reporting is effective based on those criteria **.**

Changes in Internal Controls

There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the fourth quarter of our last fiscal year that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Management and Corporate Governance,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “Code of Conduct and Ethics” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Executive Officer and Director Compensation” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Certain Relationships and Related Person Transactions” and “Management and Corporate Governance” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The response to this item is incorporated by reference from the discussion responsive thereto under the caption “Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2015 Annual Meeting of Stockholders.

PART IV

Item 15. **EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

Item 15(a). The following documents are filed as part of this annual report on Form 10-K:

Item 15(a)(1) and (2) See "Index to Consolidated Financial Statements and Financial Statement Schedules" at Item 8 to this Annual Report on Form 10-K. Other financial statement schedules have not been included because they are not applicable or the information is included in the financial statements or notes thereto.

Item 15(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number		Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
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.		8-K (Exhibit 2.1)	8/29/2013	000-54896
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.		8-K (Exhibit 2.2)	9/5/2013	000-54896
3.1		Restated Certificate of Incorporation of the Registrant, filed with the Secretary of State of the State of Delaware on November 7, 2013.		S-1/A (Exhibit 3.1)	11/26/13	333-191238
3.2		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.		8-K (Exhibit 3.3)	9/5/2013	000-54896
3.3		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.		8-K (Exhibit 3.4)	9/5/2013	000-54896
3.4		Restated Bylaws of the Registrant.		8-K (Exhibit 3.5)	9/5/2013	000-54896
4.1		Form of common stock certificate.		8-K (Exhibit 4.1)	9/5/2013	000-54896
4.2	.1	Warrant to Purchase Common Stock dated April 19, 2013 issued to Alzheimer Drug Discovery Foundation, Inc.		8-K (Exhibit 4.2.1)	9/5/2013	000-54896

Exhibit Number		Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
	.2	Amendment dated August 29, 2013 to Warrant to Purchase Common Stock dated April 19, 2013 issued to Alzheimer Drug Discovery Foundation, Inc.		8-K (Exhibit 4.2.2)	9/5/2013	000-54896
10.1	.1	License Agreement dated as of May 31, 2005 by and between Bristol-Meyers Squibb Company and Intra-Cellular Therapies, Inc.**		8-K/A (Exhibit 10.1.1)	10/31/2013	000-54896
	.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.		8-K (Exhibit 10.1.2)	9/5/2013	000-54896
10.2	.1	License and Collaboration Agreement dated as of February 25, 2011 by and between Takeda Pharmaceutical Company Limited and Intra-Cellular Therapies, Inc.**		8-K/A (Exhibit 10.2)	10/31/2013	000-54896
	.2	Termination Agreement dated as of October 31, 2014 by and between Takeda Pharmaceutical Company Limited and Intra-Cellular Therapies, Inc.†	X			
10.3		Employment Agreement effective as of February 26, 2008 by and between Sharon Mates, Ph.D. and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.3)	9/5/2013	000-54896
10.4		Offer Letter dated July 28, 2014 by Intra-Cellular Therapies, Inc. to Michael Halstead.*		10-Q (Exhibit 10.1)	11/3/2014	001-36274
10.5		Employment Agreement effective as of February 26, 2008 by and between Lawrence J. Hineline and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.4)	9/5/2013	000-54896
10.6		Employment Agreement effective as of February 26, 2008 by and between Allen Fienberg, Ph.D. and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.5)	9/5/2013	000-54896
10.7		Employment Agreement effective as of February 26, 2008 by and between Lawrence Wennogle, Ph.D. and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.6)	9/5/2013	000-54896
10.8		Offer Letter dated February 2, 2007 by Intra-Cellular Therapies, Inc. to Kimberly Vanover.*		8-K (Exhibit 10.7)	9/5/2013	000-54896

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.9	Offer Letter dated February 21, 2014 by Intra-Cellular Therapies, Inc. to Juan Sanchez, M.D.*		10-K (Exhibit 10.8)	3/25/2014	001-36274
10.10	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.*		8-K (Exhibit 10.8)	9/5/2013	000-54896
10.11	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of July 29, 2014 by and between Michael Halstead and Intra-Cellular Therapies, Inc.*	X			
10.12	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of December 1, 2003 by and between Lawrence J. Hineline and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.9)	9/5/2013	000-54896
10.13	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.*		8-K (Exhibit 10.10)	9/5/2013	000-54896
10.14	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.*		8-K (Exhibit 10.11)	9/5/2013	000-54896
10.15	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.*		8-K (Exhibit 10.12)	9/5/2013	000-54896
10.16	Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of March 7, 2014 by and between Juan Sanchez, M.D. and Intra-Cellular Therapies, Inc.*		10-K (Exhibit 10.14)	3/25/2014	001-36274
10.17	Form of Indemnification Agreement by and between the Company and its directors and executive officers.*		8-K (Exhibit 10.13)	9/5/2013	000-54896
10.18	2003 Equity Incentive Plan, as amended.*		8-K (Exhibit 10.14)	9/5/2013	000-54896

Exhibit Number		Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.19		Form of Stock Option Agreement under the 2003 Equity Incentive Plan, as amended.*		8-K (Exhibit 10.15)	9/5/2013	000-54896
10.20		2013 Equity Incentive Plan.*		8-K (Exhibit 10.16)	9/5/2013	000-54896
10.21		Form of Stock Option Agreement under the 2013 Equity Incentive Plan.*		10-K (Exhibit 10.19)	3/25/2014	001-36274
10.22		Non-Employee Director Compensation Policy.*		10-Q (Exhibit 10.1)	8/12/2014	001-36274
10.23		Redemption Agreement dated as of August 29, 2013 by and between the Registrant and NLBDIT 2010 Services, LLC.		8-K (Exhibit 10.17)	9/5/2013	000-54896
10.24		Indemnity Agreement dated as of August 29, 2013 by and among the Registrant, Intra-Cellular Therapies, Inc. and Samir N. Masri.		8-K (Exhibit 10.18)	9/5/2013	000-54896
10.25		Registration Rights Agreement dated as of August 29, 2013 by and among Intra-Cellular Therapies, Inc., the stockholders named therein and the Registrant.		8-K (Exhibit 10.19)	9/5/2013	000-54896
14.1		Corporate Code of Conduct and Ethics and Whistleblower Policy.		8-K (Exhibit 14.1)	1/7/2014	000-54896
21.1		Subsidiaries.		S-1 (Exhibit 21.1)	9/18/13	333-191238
23.1		Consent of Ernst & Young LLP.	X			
31.1		Certification of the Chief Executive Officer.	X			
31.2		Certification of the Chief Financial Officer.	X			
32.1		Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101	.INS	XBRL Instance Document.	X			
	.SCH	XBRL Taxonomy Extension Schema Document.	X			
	.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X			
	.DEF	XBRL Taxonomy Extension Definition.	X			
	.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X			
	.PRE	XBRL Taxonomy Presentation Linkbase Document.	X			

* Management contract or compensatory plan or arrangement.
** Confidential treatment has been granted for portions of this Exhibit. Redacted portions filed separately with the Securities and Exchange Commission.
† Confidential treatment is being requested for portions of this Exhibit. Redacted portions filed separately with the Securities and Exchange Commission.

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SIGN ATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INTRA-CELLULAR THERAPIES, INC.

Date: March 12, 2015

By: /s/ Sharon Mates, Ph.D.
Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signatures	Title	Date
By: /s/ Sharon Mates, Ph.D. Sharon Mates, Ph.D.	Chairman, President and Chief Executive Officer (principal executive officer)	March 12, 2015
By: /s/ Lawrence J. Hineline Lawrence J. Hineline	Vice President of Finance and Chief Financial Officer (principal financial officer and principal accounting officer)	March 12, 2015
By: /s/ Christopher Alafi, Ph.D. Christopher Alafi, Ph.D.	Director	March 12, 2015
By: /s/ Richard Lerner, M.D. Richard Lerner, M.D.	Director	March 12, 2015
By: /s/ Joel S. Marcus Joel S. Marcus	Director	March 12, 2015
By: /s/ Rory B. Riggs Rory B. Riggs	Director	March 12, 2015
By: /s/ Robert L. Van Nostrand Robert L. Van Nostrand	Director	March 12, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of
Intra-Cellular Therapies, Inc.

We have audited the accompanying consolidated balance sheets of Intra-Cellular Therapies, Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Intra-Cellular Therapies, Inc. at December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young
McLean, VA
March 12, 2015

Intra-Cellular Therapies, Inc.

Consolidated Balance Sheets

	December 31, 2014	2013
Assets		
Current assets:		
Cash and cash equivalents	**$ 61,325,044**	$ 35,150,924
Investment securities, available-for-sale	**68,320,672**	2,000,000
Accounts receivable	**51,603**	336,318
Prepaid expenses and other current assets	**1,288,953**	762,243
Total current assets	**130,986,272**	38,249,485
Property and equipment, net	**54,553**	68,272
Other assets	**70,944**	131,555
Total assets	**$131,111,769**	$ 38,449,312
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 2,052,765**	$ 3,395,067
Accrued and other current liabilities	**7,529,241**	2,611,091
Accrued employee benefits	**975,058**	827,879
Total current liabilities	**10,557,064**	6,834,037
Stockholders' equity:		
Common stock, $.0001 par value: 100,000,000 shares authorized; 29,499,059 and 22,159,446 shares issued and outstanding at December 31, 2014 and 2013, respectively	**2,950**	2,216
Additional paid-in capital	**208,912,345**	89,177,556
Accumulated deficit	**(88,255,957)**	(57,564,497)
Accumulated comprehensive loss	**(104,633)**	—
Total stockholders' equity	**120,554,705**	31,615,275
Total liabilities and stockholders' equity	**$131,111,769**	$ 38,449,312

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc.

Consolidated Statements of Operations

	Years Ended December 31,		
	2014	**2013**	**2012**
Revenues:			
License and collaboration revenue	**$ 547,546**	$ 2,737,002	$ 3,117,991
Grant Revenue	**29,755**	—	—
Total revenues	**577,301**	2,737,002	3,117,991
Costs and expenses:			
Research and development	**21,226,345**	23,027,578	15,486,476
General and administrative	**10,337,679**	5,976,276	4,034,925
Total costs and expenses	**31,564,024**	29,003,854	19,521,401
Loss from operations	**(30,986,723)**	(26,266,852)	(16,403,410)
Interest income	**303,936**	29,617	39,002
Interest expense	**(7,073)**	(612,963)	(193,498)
Income taxes	**(1,600)**	(18,000)	(32,921)
Net loss	**$(30,691,460)**	$(26,868,198)	$(16,590,827)
Net loss per common share:			
Basic & Diluted	**$ (1.07)**	$ (1.56)	$ (2.96)
Weighted average number of common shares:			
Basic & Diluted	**28,650,067**	17,260,768	5,607,539

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc.

Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		
	2014	2013	2012
Net loss	**$(30,691,460)**	$(26,868,198)	$(16,590,827)
Other comprehensive loss:			
Unrealized loss on investment securities	**(104,633)**	—	—
Comprehensive loss	**$(30,796,093)**	$(26,868,198)	$(16,590,827)

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2011	12,149,061	1,215	31,996,560	(14,105,472)	—	17,892,303
Exercise of stock options	33,270	3	31,078	—	—	31,081
Share-based compensation	—	—	295,106	—	—	295,106
Conversion of convertible notes	2,417,281	242	15,356,180	—	—	15,356,422
Net loss	—	—	—	(16,590,827)	—	(16,590,827)
Balance at December 31, 2012	14,599,612	1,460	$ 47,678,924	$(30,696,299)	$ —	$ 16,984,085
Conversion of convertible notes	110,446	11	701,712	—	—	701,723
Private placement of common stock	6,916,697	692	39,962,808	—	—	39,963,500
Exercise of stock options	514,466	51	332,887	—	—	332,938
Stock subscription	18,225	2	109,832	—	—	109,834
Share-based compensation	—	—	391,393	—	—	391,393
Net loss	—	—	—	(26,868,198)	—	(26,868,198)
Balance at December 31, 2013	22,159,446	$2,216	$ 89,177,556	$(57,564,497)	$ —	$ 31,615,275
Common shares issued February 5, 2014	**7,063,300**	**706**	**115,442,041**	**—**		**115,442,747**
Exercise of stock options	**247,165**	**25**	**162,955**	**—**		**162,980**
Stock issued for services	**10,923**	**1**	**176,084**			**176,085**
Stock subscription	**18,225**	**2**	**109,831**			**109,833**
Share-based compensation	**—**	**—**	**3,843,878**	**—**		**3,843,878**
Net loss	**—**	**—**	**—**	**(30,691,460)**		**(30,691,460)**
Other comprehensive loss					**(104,633)**	**(104,633)**
Balance at December 31, 2014	**29,499,059**	**$2,950**	**$208,912,345**	**$(88,255,957)**	**$ (104,633)**	**$120,554,705**

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc.

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2014	2013	2012
Operating activities			
Net loss	**$ (30,691,460)**	$(26,868,198)	$(16,590,827)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation expense	**25,481**	23,249	47,747
Share-based compensation expense	**3,843,878**	391,393	295,106
Issuance of stock for services	**176,085**	—	—
Amortization of premiums on investment activities	**297,223**	—	—
Changes in operating assets and liabilities:			
Accounts receivable	**284,715**	(35,889)	48,634
Prepaid expenses and other assets	**(466,099)**	(574,341)	(34,189)
Accounts payable	**(1,342,302)**	3,353,459	(554,256)
Accrued liabilities and employee benefits	**5,065,329**	2,785,736	(448,493)
Deferred revenue	**—**	(1,666,674)	(1,666,659)
Net cash used in operating activities	**(22,807,150)**	(22,591,265)	(18,902,937)
Investing activities			
Purchases of investments	**(103,601,836)**	—	(12,000,000)
Maturities of investments	**36,879,308**	1,500,000	17,700,122
Purchase of property and equipment	**(11,762)**	(33,255)	(38,957)
Net cash (used in) provided by investing activities	**(66,734,290)**	1,466,745	5,661,165
Financing activities			
Proceeds from issuance of convertible promissory notes, net	**—**	100,000	15,163,004
Proceeds from stock option exercises	**162,980**	332,938	31,081
Proceeds from stock subscription	**109,833**	109,834	—
Gross proceeds of public and private offerings	**116,191,285**	43,841,850	—
Payment of costs of public and private offerings	**(748,538)**	(3,754,706)	—
Net cash provided by financing activities	**115,715,560**	40,629,916	15,194,085
Net increase in cash and cash equivalents	**26,174,120**	19,505,396	1,952,313
Cash and cash equivalents at beginning of period	**35,150,924**	15,645,528	13,693,215
Cash and cash equivalents at end of period	**$ 61,325,044**	$ 35,150,924	$ 15,645,528
Cash paid for interest	**$ 7,073**	$ 11,320	$ —
Cash paid for taxes	**$ 44,998**	$ 31,437	$ 13,857
Unrealized loss on investment securities	**$ (104,633)**	$ —	$ —

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc.

Notes to Consolidated Financial Statements

December 31, 2014

1. Organization

Intra-Cellular Therapies, Inc. (the "Company"), through its wholly-owned operating subsidiary, ITI, Inc. ("ITI"), is 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 ("CNS"). The Company's lead product candidate, ITI-007, is in Phase 3 clinical development as a first-in-class treatment for schizophrenia.

ITI was incorporated in the State of Delaware on May 22, 2001 under the name "Intra-Cellular Therapies, Inc." and commenced operations in June 2002. ITI was founded to discover and develop drugs for the treatment of neurological and psychiatric disorders.

On August 29, 2013, ITI completed a reverse merger (the "Merger") with a public shell company named Oneida Resources Corp. ("Oneida"). Oneida was formed in August 2012 as a vehicle to investigate and, if such investigation warranted, acquire a target company or business seeking the perceived advantages of being a publicly held corporation. In the Merger, each outstanding share of capital stock of ITI was exchanged for 0.5 shares of common stock of Oneida, and each outstanding option to purchase one share of ITI common stock and each outstanding warrant to purchase one share of ITI common stock was assumed by Oneida and became exercisable for 0.5 shares of Oneida common stock. As a result of the Merger and related transactions, ITI survived as a wholly-owned subsidiary of Oneida, Oneida changed its fiscal year end from March 31 to December 31, and Oneida changed its name to Intra-Cellular Therapies, Inc. (the "Company"). In addition, the Company began operating ITI and its business, and therefore ceased being a shell company. Following the Merger and the redemption of all then outstanding shares of Oneida at the closing of the Merger, the former shareholders of ITI owned 100% of the shares of the Company's outstanding capital stock.

In accordance with Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") Topic 805, *Business Combinations* , ITI is considered the acquirer for accounting purposes, and has accounted 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 represented all of the senior management of the combined entity. Consequently, the assets and liabilities and the historical operations that are reflected in the Company's consolidated financial statements are those of ITI and have been recorded at the historical cost basis of the Company. All share and per share amounts in the consolidated financial statements and related notes have been retrospectively adjusted to reflect the one-for-0.5 shares of capital stock exchange as well as the conversion of the Notes (defined below) and the Series A, B, and C redeemable convertible preferred stock of ITI.

Immediately prior to the Merger, on August 29, 2013, 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 (the "Private Placement"), 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 (the "Notes").

On February 5, 2014, the Company completed a public offering of common stock in which the Company sold 7,063,300 shares of common stock, which included the exercise of the underwriters' option to purchase an additional 921,300 shares, at an offering price of $17.50 per share. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $115.4 million.

On October 31, 2014, the Company entered into a termination agreement with Takeda Pharmaceutical Company Limited ("Takeda") terminating the worldwide license and collaboration agreement under which the Company

1. Organization (continued)

and Takeda were jointly developing the Company's proprietary compound ITI-214 and other selected compounds that selectively inhibit phosphodiesterase type 1 ("PDE1") for use in the prevention and treatment of human diseases. Through December 31, 2014, the Company had received $28.9 million in total payments under the agreement and was eligible to receive milestone payments and royalties based on net sales. The Company is in the process of refining its strategy for the PDE1 inhibitor program.

In order to further its research projects and support its collaborations, the Company will require additional financing until such time, if ever, that revenue streams are sufficient to generate consistent positive cash flow from operations. Possible sources of funds include public or private sales of the Company's equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of the Company's product candidates and technology and, to a lesser extent, grant funding. On August 29, 2014, the Company filed a universal shelf registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission (the "SEC") on September 15, 2014, to register $150 million of the Company's common stock, preferred stock, various series of debt securities, warrants, rights and purchase contracts to purchase any of such securities, either individually or in units, for issuance from time to time at prices and on terms to be determined at the time of any such offering. This registration statement will remain in effect for up to three years from the initial effective date.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Although actual results could differ from those estimates, management does not believe that such differences would be material.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist of checking accounts, money market accounts, money market funds, and certificates of deposit with a maturity date of three months or less. Certificates of deposit, commercial paper, corporate notes and corporate bonds with a maturity date of more than three months are classified separately on the balance sheet. Their carrying values approximate the fair market value.

Marketable Securities

Marketable securities may consist of investments in U.S. Treasuries, various U.S. governmental agency debt securities, corporate bonds, certificates of deposit, and other fixed income securities with an average maturity of twelve months or less. Management classifies the Company's investments as available-for-sale. Such securities are carried at estimated fair value, with any unrealized holding gains or losses reported, net of any tax effects reported, as accumulated other comprehensive income, which is a separate component of stockholders' equity. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are included in consolidated results of operations. A decline in the market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in fair value, which is charged to earnings in that period, and a new cost basis for the security is established. Dividend and interest income is recognized as interest income when earned. The cost of securities sold is calculated using the specific identification method.

2. Summary of Significant Accounting Policies (continued)

Investment Securities

Investment securities consisted of the following (in thousands):

	December 31, 2014			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
		(unaudited)		
U.S. Government Agency Securities	$ 4,316	$ —	$ (3)	$ 4,313
FDIC Certificates of Deposit	16,374	—	(14)	16,360
Certificates of Deposit	2,000	—	—	2,000
Commercial Paper	9,743	1	—	9,744
Corporate Notes/Bonds	35,992	—	(89)	35,903
	$ 68,425	$ 1	$ (106)	$ 68,320

	December 31, 2013			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
Certificates of Deposit	$ 2,000	—	—	$ 2,000
	$ 2,000	$ —	$ —	$ 2,000

The Company has classified all of its investment securities available-for-sale, including those with maturities beyond one year, as current assets on the consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations. As of December 31, 2014 and December 31, 2013, the Company held $31.8 million and $0, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

Fair Value Measurements

The Company applies the fair value method under ASC Topic 820, *Fair Value Measurements and Disclosures* . ASC Topic 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The ASC Topic 820 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following categories based on the lowest level input used that is significant to a particular fair value measurement:

- Level 1—Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.
- Level 2—Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.
- Level 3—Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity—e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC Topic 820 hierarchy.

2. Summary of Significant Accounting Policies (continued)

The Company has no assets or liabilities that were measured using quoted prices for significant unobservable inputs (Level 3 assets and liabilities) as of December 31, 2014 and December 31, 2013. The carrying value of cash held in money market funds of approximately $8.5 million as of December 31, 2014 and $0.0 million as of December 31, 2013, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs.

The fair value measurements of the Company's cash equivalents and available-for-sale investment securities are identified in the following tables (in thousands):

	December 31, 2014	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 8,495	$ 8,495	$ —	$ —
U.S. Government Agency Securities	4,313	—	4,313	—
FDIC certificates of deposit	16,360	—	16,360	—
Certificates of deposit	41,000	—	41,000	—
Commercial paper	9,744	—	9,744	—
Corporate Bonds/Notes	35,903	—	35,903	—
	$ 115,815	$ 8,495	$ 107,320	$ —

	December 31, 2013	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Certificates of deposit	6,000	—	6,000	—
	$ 6,000	$ —	$ 6,000	$ —

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, investment securities available-for-sale, accounts receivable, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at December 31, 2014 and December 31, 2013. Management believes that the risks associated with its financial instruments are minimal as the counterparties are various corporations, financial institutions and government agencies of high credit standing.

Concentration of Credit Risk

Cash equivalents are held with major financial institutions in the United States. Certificates of deposit held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

2. Summary of Significant Accounting Policies (continued)

Accounts Receivable

Accounts receivable that management has the intent and ability to collect are reported in the balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of December 31, 2014 and 2013, as the Company has a history of collecting on all its accounts including government agencies and collaborations funding its research.

Property and Equipment

Property and equipment is stated at cost and depreciated on a straight-line basis over estimated useful lives ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the assets or the term of the related lease. Expenditures for maintenance and repairs are charged to operations as incurred.

When indicators of possible impairment are identified, the Company evaluates the recoverability of the carrying value of its long-lived assets based on the criteria established in ASC 360, *Property, Plant and Equipment* . The Company considers historical performance and anticipated future results in its evaluation of potential impairment. The Company evaluates the carrying value of those assets in relation to the operating performance of the business and undiscounted cash flows expected to result from the use of those assets. Impairment losses are recognized when carrying value exceeds the undiscounted cash flows, in which case management must determine the fair value of the underlying asset. No such impairment losses have been recognized to date.

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. The Company is reimbursed for certain costs incurred on specified research projects under the terms and conditions of grants, collaboration agreements, and awards. The Company records the amount of reimbursement as revenues on a gross basis in accordance with ASC Topic 605-45, *Revenue Recognition/Principal Agent Considerations* . The Company is the primary obligor with respect to purchasing goods and services from third-party suppliers, is obligated to compensate the service provider for the work performed, and has 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.

The Company has entered into arrangements involving the delivery of more than one element. Each required deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. For the Company, this determination is generally based on whether the deliverable has “stand-alone value” to the customer. The Company adopted this accounting standard on a prospective basis for all Multiple-Deliverable Revenue Arrangements (“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.

The Company adopted ASC Topic 605-28, *Milestone Method* . Under this guidance, the Company recognizes 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;

2. Summary of Significant Accounting Policies (continued)

- Achievement of the milestone involves a degree of risk and was not reasonably assured at the inception of the arrangement;
- Substantive effort on the Company's 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 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 in accordance with the revenue models described above. In addition, the determination that one such payment was not a substantive milestone could prevent the Company 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 **.**

Deferred Revenue

Cash received as prepayment on future services is deferred and recognized as revenue as the services are performed. The Company must remit interest on any deferred revenue related to a governmental agency. As of December 31, 2014 and 2013, no interest was due as the Company did not have any deferred revenue from a government agency.

Research and Development

Except for payments made in advance of services, the Company expenses its research and development costs as incurred. For payments made in advance, the Company recognizes research and development expense as the services are rendered. Research and development costs primarily consist of salaries and related expenses for personnel and resources and the costs of clinical trials. Other research and development expenses include preclinical analytical testing, outside services, providers, materials and consulting fees.

Income Taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and its respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled.

The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when necessary to reduce net deferred tax assets to the amount expected to be realized. Income tax expense is the tax payable for the period and the change during the period in deferred tax assets and liabilities.

The Company accounts for uncertain tax positions pursuant to ASC Topic 740 (previously included in FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*). Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more-likely-than-not threshold of that position being sustained. If the tax position meets

2. Summary of Significant Accounting Policies (continued)

this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Comprehensive Income (Loss)

All components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are incurred. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. In accordance with accounting guidance, the Company presents the impact of any unrealized gains or (losses) on its investment securities in a separate statement of comprehensive income (loss) for each period.

Share-Based Compensation

Share-based payments are accounted for in accordance with the provisions of ASC Topic 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 (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 awards granted with time-based vesting conditions, expense is amortized using the straight-line attribution method. For awards that contain a performance-based vesting condition, expense is amortized using the accelerated attribution method. As share-based compensation expense recognized in the statements of operations for the years ended December 31, 2014, 2013 and 2012 is based on share-based awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC Topic 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 the Company's historical experience for the years ended December 31, 2014, 2013 and 2012, and have not been material.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the 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 the Company's common stock. The expected life of stock options is the period of time for which the stock 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. The Company has not paid dividends to its stockholders since its inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

For the years ended December 31, 2013 and 2012, given that there was no active market for the Company's common stock, the exercise prices of the stock options on the dates of grant were determined and approved by the board of directors using several factors, including progress and milestones achieved in the Company's business development and performance, the price per share of its convertible preferred stock offerings and general industry and economic trends. In establishing the estimated fair value of the common stock, the Company

2. Summary of Significant Accounting Policies (continued)

considered the guidance set forth in American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* . For the year ended December 31, 2014, the exercise price was determined by using the closing market price of the Company's common stock on the date of grant.

Under ASC Topic 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 temporary difference in applying ASC Topic 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 the Company, as all the deferred tax assets have a full valuation allowance.

Since the Company had net operating loss carryforwards as of December 31, 2014, 2013 and 2012, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations.

Equity instruments issued to consultants are accounted for under the provisions of ASC Topic 718 and ASC Topic 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.

Loss Per Share

Basic net loss per common share is determined by dividing the net loss allocable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted-average number of common stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants.

The following common stock equivalents were excluded in the calculation of diluted loss per share because their effect would be anti-dilutive as applied to the loss from operations as of December 31, 2014, 2013 and 2012:

	Years Ended December 31,		
	2014	2013	2012
Stock Equivalents	958,712	898,982	905,284

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction-specific and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early application is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Presently, the Company is assessing what effect the adoption of ASU 2014-09 will have on our consolidated financial statements and accompanying notes.

3. Property and Equipment

Property and equipment consist of the following:

	December 31, 2014	2013
Computer equipment	$ 39,160	$ 82,252
Furniture and fixtures	35,958	46,523
Scientific equipment	2,207,848	2,851,947
Leasehold improvements	—	319,553
	2,282,966	3,300,275
Less accumulated depreciation	(2,228,413)	(3,232,003)
	$ 54,553	$ 68,272

Depreciation expense for the years ended December 31, 2014, 2013 and 2012 was $25,481, $23,249 and $47,747 respectively. During 2014, in conjunction with its move in February 2015 to its new headquarters, the Company retired $319,553 of fully depreciated leasehold improvements and disposal of $709,518 of fully depreciated property and equipment. During 2013, the Company retired $11,663 of fully depreciated property and equipment.

4. Share-Based Compensation

The Company sponsors the Intra-Cellular Therapies, Inc. 2013 Equity Incentive Plan (the “2013 Plan”) to provide for the granting of stock-based awards, such as stock options, restricted common stock and restricted stock units to employees, directors and consultants as determined by the Board of Directors. In August 2013, the Company assumed in the Merger the ITI 2003 Equity Incentive Plan , as amended (the “2003 Plan”), which expired by its terms in July 2013. As of December 31, 2014, the outstanding awards under the 2003 Plan were options to purchase 1,125,460 shares of common stock. Effective in November 2013, the Company adopted the 2013 Plan. The Company reserved 2,850,000 shares of common stock for issuance under the 2013 Plan. In January 2014, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 800,000 pursuant to the evergreen provisions of the 2013 Plan.

Stock options granted under the 2013 Plan may be either incentive stock options (“ISOs”) as defined by the Internal Revenue Code of 1986, as amended (the “Code”), or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally one to three years) and the exercise prices of such options. Options have a maximum term of 10 years. The exercise price of ISOs granted under the 2013 Plan must be at least equal to the fair market value of the common stock on the date of grant.

Total stock-based compensation expense related to all of the Company’s share-based awards to employees, directors and consultants recognized during the years ended December 31, 2014, 2013 and 2012, was comprised of the following:

	Years Ended December 31, 2014	2013	2012
Research and development	**$1,842,828**	$132,543	$111,206
General and administrative	**2,001,050**	258,850	183,900
Total share-based compensation expense	**$3,843,878**	$391,393	$295,106

4. Share-Based Compensation (continued)

The following table describes the weighted-average assumptions used for calculating the value of options granted during the years ended December 31, 2014, 2013 and 2012:

	2014	2013	2012
Dividend yield	**0%**	0%	0%
Expected volatility	**80.0%**	80.0%	79.7%
Weighted-average risk-free interest rate	**2.0%**	2.2%	1.2%
Expected term (in years)	**6.3**	6.2	6.3

Information regarding the stock options activity including with respect to grants to employees, directors and consultants as of December 31, 2014, and changes during the period then ended, are summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Contractual Life
Outstanding at December 31, 2013 (audited)	1,400,125	$ 1.98	$ —	5.3 years
Options granted	1,108,000	$ 16.50	$ —	9.5 years
Options exercised	(247,165)	$ 0.66	$ —	0.5 year
Options canceled or expired	(27,500)	$ 12.34	$ —	6.9 year
Outstanding at December 31, 2014	2,233,460	$ 9.20	$18,867,087	7.3 years
Vested or expected to vest at December 31, 2014	2,233,460	$ 9.20	$ —	
Exercisable at December 31, 2014	1,324,552	$ 5.10	$16,625,120	5.9 years

The weighted-average grant date fair value for awards granted during the year ended December 31, 2014, was $16.50 per share. Total intrinsic value of the options exercised was approximately $3,696,775 in the year ended December 31, 2014. The total fair value of shares vested in the years ended December 31, 2014, 2013 and 2012, was approximately $3,703,000, $278,000 and $332,000, respectively.

During 2014, 2013 and 2012, the Company granted options to certain scientific advisory board members of the Company to purchase 95,000, 19,000 and 19,500 shares of common stock at an average exercise price per share of $16.86, $3.26, and $2.84 respectively. The options vest ratably over a period of 12 to 24 months. Stock compensation related to these grants will fluctuate with any changes in the underlying value of the Company's common stock, as the performance period is not fixed.

The unrecognized share-based compensation expense related to stock option awards at December 31, 2014, is $9,240,467 and will be recognized over a weighted-average period of 2.0 years.

5. Income Taxes

Total income tax expense for the years ended December 31 is allocated as follows:

	December 31, 2014	2013
Current	**$ 1,600**	$ 18,000
Deferred	**(14,655,320)**	(13,229,355)
Valuation allowance	**14,655,320**	13,229,355
Provision for income taxes	**$ 1,600**	$ 18,000

5. Income Taxes (continued)

A reconciliation of the difference between the statutory federal income tax rate and the effective income tax rate for the years ended December 31 is as follows:

	December 31, 2014	2013
Income tax benefit at statutory federal rate	**35.00%**	35.00%
Permanent differences	**0.12**	(1.20)
Return-to-provision—R&D Credit	**(0.05)**	2.61
R&D Credit—current year	**2.32**	3.72
Reserve for uncertain tax positions	**(0.01)**	(6.53)
Change in effective state tax rates	**(0.14)**	6.58
State income tax expense	**10.50**	10.12
Change in valuation allowance	**(47.75)**	(50.37)
Provision for income taxes	**(0.01)%**	(0.07)%

Deferred income taxes reflect the net tax effect of temporary differences that exist between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, using enacted tax rates in effect for the year in which the differences are expected to reverse. As of December 31, 2014, the Company had $78.2 million of federal net operating loss carryforwards, which expire at various dates through 2034. The gross amount of the state net operating loss carryforwards is equal to or less than the federal net operating loss carryforwards and expires over various periods based on individual state tax law. In general, businesses with U.S. net operating losses (“NOLs”) are considered loss corporations for U.S. federal income tax purposes. Pursuant to Section 382 of the Code, loss corporations that undergo an ownership change, as defined under the Code, may be subject to an annual limitation on the amount of NOLs (and certain other tax attributes) available to offset taxable income earned after such ownership change. The Company has performed an analysis and has determined that it has not triggered any ownership changes pursuant to the rules prescribed under U.S. tax law and accordingly, the Company believes that the use of the Company’s net operating loss carryforwards will not be restricted due to changes in Company ownership as of December 31, 2014.

At December 31, 2014, the Company had $1.5 million in excess tax benefits related to stock-based compensation deductions, the benefit of which will be recorded to additional paid-in-capital once the benefit is realized through a reduction of income taxes payable.

The following summarizes the significant components of the Company’s deferred tax assets and liabilities as of December 31, 2014 and 2013, respectively:

	December 31, 2014	2013
Deferred tax assets:		
Net operating loss carryforwards	**$ 34,870,169**	$ 22,346,862
Accrued employee benefits	**443,371**	377,049
Capitalized research and development costs	**—**	31,891
Research and development credit	**2,570,540**	1,874,939
Nonqualified stock options	**1,563,785**	53,686
Deferred tax liabilities:		
Depreciation	**(5,204)**	102,916
Net deferred tax asset	**39,442,661**	24,787,343
Valuation allowance	**(39,442,661)**	(24,787,343)
Net deferred tax asset	**$ —**	$ —

5. Income Taxes (continued)

Based upon the Company's historical operating performance and the reported cumulative net losses to date, the Company presently does not have sufficient objective evidence to support the recovery of its net deferred tax assets. Accordingly, the Company has established a valuation allowance against its net deferred tax assets for financial reporting purposes because it is not more likely than not that these deferred tax assets will be realized.

The following summarizes the significant components of gross unrecognized tax benefits as of December 31, 2014 and 2013, respectively:

	December 31, 2014	December 31, 2013
Balance at January1,	**$1,715,904**	**$ —**
Current Year Uncertain Tax Positions:		
Gross Increases	**1,731**	**6,649**
Prior Year Uncertain Tax Positions:		
Gross Increases	**—**	**1,709,255**
Balance at December 31,	**$1,717,635**	**$1,715,904**

6. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

On May 31, 2005, the Company entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company ("BMS"), pursuant to which the Company holds 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. The Company has the right to grant sublicenses of the rights conveyed by BMS. The Company is obliged under the license to use commercially reasonable efforts to develop and commercialize the licensed technology. The Company is also prohibited from engaging in the clinical development or commercialization of specified competitive compounds.

Under the agreement, the Company made an upfront payment of $1.0 million to BMS, a milestone payment of $1.25 million in December 2013, and a milestone payment of $1.5 million in December 2014 following the initiation of the Company's first Phase 3 clinical trial for ITI-007 for patients with exacerbated schizophrenia. Possible milestone payments remaining total $12.0 million. Under the agreement, the Company may be obliged to make other milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million. The Company is also obliged to make tiered single digit percentage royalty payments on sales of licensed products. The Company is 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, the Company 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.

The Takeda Pharmaceutical License and Collaboration Agreement and Termination Agreement

On February 25, 2011, the Company entered into a license and collaboration agreement with Takeda Pharmaceutical Company Limited under which the Company agreed to collaborate to research, develop and

6. Collaborations and License Agreements (continued)

commercialize its 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, the Company assigned to Takeda certain patents owned by the Company 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, the Company retained rights to all compounds that do not meet the specified criteria and the Company continues to develop PDE1 inhibitors outside the scope of the agreement.

Under the terms of the agreement, the Company conducted 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. This research program ended in February 2014. The Company was responsible for its expenses incurred in the conduct of certain research activities specified in the research plan. Takeda agreed to reimburse the Company for expenses the Company incurred in conducting additional research activities.

Upon execution of the agreement, Takeda made a nonrefundable payment to the Company. The Company was eligible to receive payments of approximately $500 million in the aggregate upon achievement of certain development milestones and up to an additional $250 million 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.

On October 31, 2014, the Company entered into an agreement with Takeda terminating the Takeda License Agreement, pursuant to which all rights granted under the Takeda License Agreement were returned to the Company. Takeda will complete certain ongoing activities relating to non-clinical studies and will transfer product inventory and materials to the Company but will not have any other ongoing involvement or funding obligations in connection with the development program. ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. The Company intends to continue the development of ITI-214 for the treatment of CNS and other disorders. The Company is in the process of refining its strategy for the PDE1 inhibitor program. By regaining unrestricted access to ITI-214, backups and the proprietary chemistry, the Company can now integrate the efforts of its internal PDE program to include the later stage portfolio. The Company does not anticipate a significant increase in its operating expenses related to its PDE development programs over the next twelve months. Other compounds in the PDE portfolio are also being advanced for the treatment of various indications, including non-CNS therapeutic areas.

Other License Agreement

In May 2002, ITI entered into a license agreement (the “License”) and research agreement with a university. Under the provisions of the License, ITI is entitled to use this organization’s patented technology and other intellectual property relating to diagnosis and treatment of central nervous system disorders.

The License expires upon expiration of the patent rights or 15 years subsequent to the first sale of products developed through this License. ITI is required to make future milestone payments for initiation of clinical trials and approval of a New Drug Application (“NDA”). Should ITI commercialize the technology related to this License, ITI would be required to make royalty payments, and would also be required to pay fees under any sublicense agreements with third parties.

In addition, ITI is required to use at least $1.0 million annually of its resources for the development and commercialization of the technology until ITI submits an NDA. ITI met its spending requirements in 2014. There were no other payments made or required under the License for the years ended December 31, 2014 and 2013.

7. Commitments and Contingencies

The Company currently has operating lease agreements with commitments for $13,125,243 for laboratory and office facilities through 2020.

At December 31, 2014, future minimum lease payments under leases having an initial or remaining non-cancellable lease term in excess of one year are set forth in the table below:

Year	
2015	$ 10,630
2016	1,048,661
2017	1,175,454
2018	1,210,718
2019	1,247,039
2020	8,432,741
	$13,125,243

Rent expense for the years ended December 31, 2014, 2013 and 2012 was $853,504, $827,479 and $809,332, respectively.

8. Employee Benefit Plan

The Company sponsors a defined contribution 401(k) plan covering all full-time employees. Participants may elect to contribute their annual pre-tax earnings up to the federally allowed maximum limits. The Company makes a matching contribution of 50% on the first 6% of contributions made by participants. Participant and Company contributions vest immediately. During the years ended December 31, 2014, 2013 and 2012, the Company recorded matching contribution expense of $84,757, $77,138 and $79,656, respectively.

9. Subsequent Events

In the first quarter of 2015, the Company moved its headquarters to 430 East 29th Street, New York, New York 10016. The Company has entered into a long-term lease for approximately 14,678 square feet of useable laboratory and office space. The lease has a term of 11 years. The Company expects that its facility related costs will increase moderately beginning in 2015 due to this new facility.

On March 11, 2015, the Company completed its public offering of 5,411,481 shares of its common stock at a price of $24.00 per share for aggregate gross proceeds of approximately $129.9 million, and net proceeds of approximately $121.4 million.

10. Unaudited Quarterly Financial Information

The tables herein set forth the Company's unaudited condensed consolidated 2014 and 2013 quarterly statements of operations.

The following table sets for the Company's unaudited condensed consolidated statements of operations for the 2014 quarters ended:

2014 Quarter Ended	December 31,	September 31,	June 30,	March 31,
Revenue	$ 65,862	$ 124,414	$ 219,238	$ 167,787
Net loss	(15,199,130)	(6,415,507)	(4,533,539)	(4,543,284)
Basic and diluted net loss per share	$ (0.52)	$ (0.22)	$ (0.15)	$ (0.17)

10. Unaudited Quarterly Financial Information (continued)

The following table sets for the Company's unaudited condensed consolidated statements of operations for the 2013 quarters ended:

2013 Quarter Ended	December 31,	September 31,	June 30,	March 31,
Revenue	$ 827,531	$ 667,955	$ 643,264	$ 598,252
Net loss	(8,040,810)	(4,911,620)	(8,277,391)	(5,638,377)
Basic and diluted net loss per share	$ (0.36)	$ (0.28)	$ (0.56)	$ (0.39)

TERMINATION AGREEMENT

THIS TERMINATION AGREEMENT (the "***Termination Agreement***") is entered into as of October 31, 2014 by and between **TAKEDA PHARMACEUTICAL COMPANY LIMITED**, a company organized under the laws of Japan ("***Takeda***"), having a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645 Japan, and **INTRA-CELLULAR THERAPIES, INC.**, a Delaware Corporation ("***ITI***"), having a place of business at Audubon Biomedical Science and Technology Park, 3960 Broadway, New York, NY 10032 U.S.A. Takeda and ITI may be referred to herein individually as a "***Party***" or collectively as the "***Parties***."

RECITALS

WHEREAS, Takeda and ITI are parties to that certain License and Collaboration Agreement, dated February 25, 2011 (the "***License Agreement***"); and

WHEREAS, the Parties desire to terminate the License Agreement in its entirety by mutual written agreement in accordance with the terms and conditions set forth in this Termination Agreement; and

WHEREAS, the Parties desire to terminate certain agreements relating to the License Agreement;

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

1.1 Except as set forth herein, any and all capitalized terms used and not otherwise defined in this Termination Agreement shall have the meanings ascribed to such terms in the License Agreement.

1.2 "**Transition Completion Date**" shall mean [***].

1.3 "**Termination Date**" shall be the date set forth at the start of this Agreement.

2. TERMINATION OF LICENSE AGREEMENT

2.1 Termination. As of the Termination Date, the License Agreement shall terminate in its entirety and any and all agreements by and between ITI, and any of its Affiliates, and Takeda, and any of its Affiliates, relating to the License Agreement, including the Quality Agreement between Takeda, Takeda Global Research & Development Center, Inc., BASF Pharma Evionnaz SA ("***BASF***") and ITI, the letter agreement between Takeda, ITI and BASF,

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.

dated October 12, 2012, and the Memorandum of Understanding between ITI and Takeda, dated May 7, 2014 (" ***Ancillary Agreements*** "), shall terminate as of the Termination Date; provided that certain rights and obligations of the Parties under such agreements shall survive in accordance with the survival provisions set forth in such agreements, as may be modified herein.

2.2 Close-Out Activities. The Parties, through the oversight of the JSC, shall complete the activities set forth in this Termination Agreement and Exhibit 1 hereto in accordance with a written transition plan to be approved within [***] ([***]) days of the Termination Date (unless otherwise agreed by the Parties) by the JSC, along with other such activities as agreed upon by the Parties at the JSC in writing necessary to complete the activities set forth in this Termination Agreement and Exhibit 1 hereto (collectively, the " ***Close-Out Activities*** "). Except as set forth herein, [***]. The JSC shall appoint a working group to create such written transition plan and work closely with the Parties to complete the Close-Out Activities (the " ***Transition Working Group*** "). Notwithstanding anything to the contrary in Section 3.2 of the License Agreement, should the Executive Officers be unable to resolve a dispute or disagreement with respect to the scope of the Close-Out Activities or the transition plan, then such dispute shall be referred to a neutral arbitrator reasonably acceptable to both Parties for resolution. For the avoidance of doubt, subject to the diligence obligations set forth in this Termination Agreement, each Party shall have final decision making authority with respect to its performance of Close-Out Activities.

2.3 Diligence. Each Party will exercise the level of effort and resources reasonably necessary to perform its respective obligations in completion of the Close-Out Activities with the goal of completing the Close-Out Activities no later than the Transition Completion Date. The efforts and resources committed by Takeda to complete the Close-Out Activities assigned to it prior to the Transition Completion Date shall be no less than the level Takeda would typically commit in the performance of research programs for its other compounds currently under development. For the avoidance of doubt, in performance of the Close-Out Activities and its other obligations hereunder, Takeda shall act in good faith and shall not take any action that could reasonably be expected to have a material adverse impact on the further Development and Commercialization of any Product. In the event that, despite applying the foregoing level of diligence, Takeda does not complete one or more of the Close-Out Activities assigned to it prior to the Transition Completion Date, then Takeda shall use [***] to complete such activities as quickly as possible, and the obligation for Takeda to complete such activities shall survive the Transition Completion Date and shall continue until such activities have been completed, including, for the avoidance of doubt, the transfer of any Information generated from such Close-Out Activities to ITI. In the event Takada is required to use [***] to complete such activities as provided in the prior sentence, then ITI shall also use [***] to facilitate the completion of such activities.

2.4 Transition Assistance . As part of the Close-Out Activities, Takeda, in accordance with this Section 2.4, shall assist ITI, with ITI's cooperation, as may be reasonably necessary for ITI to continue Developing, Manufacturing and/or Commercializing the Products throughout the Territory. Notwithstanding the other provisions set forth in this Section 2.4, to the extent that any contract between Takeda and a Third Party is not assignable to ITI, Takeda shall reasonably cooperate and assist with and assist ITI to arrange for ITI to receive the services contemplated under such contract either from the Third Party with whom Takeda had contracted

or a different Third Party; provided, however, in no circumstance shall Takeda be required to complete (either directly or indirectly through its vendor) any activity beyond those activities set forth in this Termination Agreement and Exhibit 1 as of the Termination Date, unless mutually agreed in writing by the Parties at the JSC. For the avoidance of doubt, such assistance by Takeda shall include the following.

(a) **Materials, Data and Information Transfer.** Unless otherwise prohibited by applicable Law or contract, Takeda will, in accordance with the timing agreed upon by the Parties, promptly return, transfer and assign to ITI or its designee the agreed upon materials, including biological materials and samples, Information (including without limitation case report forms, study databases and other study records), Regulatory Materials, Regulatory Approvals, licenses, third party agreements and other items (including, without limitation, any Drug Master File(s), INDs, and NDAs, together with the material correspondence with Regulatory Authorities) related to the Compounds and Products and related data and Information relating to the Products and Compounds, all of which shall be deemed Confidential Information of ITI (and not of Takeda) (provided that Takeda will be allowed to retain (or if available, ask ITI to share in the future) any such materials that a Regulatory Authority requires Takeda to retain or submit under applicable Laws). For any of the foregoing documentation, data and information that is to be transferred to ITI and is not in English, Takeda will, upon the request of ITI, translate the foregoing into English and deliver true and accurate, in all material respects, translations thereof to ITI. All such information shall be transferred to ITI or its designee in an organized and clear manner, with all documents and files clearly labeled.

(b) **Intellectual Property Transfer.** Takeda hereby assigns to ITI, effective on the Termination Date, Takeda's 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 reassignments 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 [***] ([***]) days of the Termination Date. 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 2.4(b).

(c) **Clinical Study Transfer.** [***] .

(d) **Toxicology Studies Transfer.** Upon completion of the Close Out Activities related to the [***] toxicology studies assigned to it under Exhibit 1 hereto, Takeda shall, in accordance with the timing set forth in Exhibit 1 hereto or otherwise as agreed upon by the Parties, transfer to ITI the management and continued performance of the [***] week toxicology studies for the Product ongoing as of the Termination Date and shall promptly deliver the agreed upon biological materials and information relevant to such toxicology studies to ITI or its designee.

(e) **Manufacturing Process Transfer.** Pursuant to Section 13.6(e) of the License Agreement, Takeda shall transfer the current manufacturing process for ITI-214 to ITI or its designee (as instructed by ITI in writing), commencing upon the Termination Date, and shall complete such transfer within [***] ([***]) months of the Termination Date; provided, however, that the failure to timely complete such transfer due to matters outside Takeda's reasonable control shall not be deemed a breach of this Termination Agreement by Takeda. Takeda shall be required to provide, at its own cost and expense, no more than [***] ([***]) [***] (exclusive of any travel time) in support of the transfer of the manufacturing process to ITI or its designee, as applicable. In the event ITI requests Takeda provide manufacture transfer support in excess of [***] ([***]) [***], Takeda and ITI shall enter into good faith negotiations on a consulting agreement, pursuant to which Takeda would provide such continued support and ITI would reimburse Takeda for its FTE costs at the rate of $[***] (USD) per hour, along with reasonable travel and lodging expenses. Notwithstanding Section 13.6(e) of the License Agreement, the Parties agree that Takeda need not supply additional quantities of Products to ITI, and that the Returned Product (as defined below) is sufficient for ITI's requirements, such that Takeda shall not be required to supply additional quantities to ITI. For clarity, Takeda's obligation to support the transfer of manufacturing process, as described herein, shall survive the Transition Completion Date.

(f) **Inventories Transfer.** Prior to the Transition Completion Date, Takeda shall ship to ITI or its designee, the inventories of the Compound and the Product as set forth in Exhibit 2 (the " ***Returned Product*** "). The Parties acknowledge that to the extent Takeda is required to use Compound or Product to complete the Close-Out Activities assigned to it or that Takeda is required to retain such Compound or Product under applicable Law, the actual amounts of the Compound and Product delivered to ITI may vary from the amounts set forth in Exhibit 2. The Parties will agree on the terms of such shipment, provided that ITI shall have no obligation to reimburse or otherwise compensate Takeda for its costs to manufacture such Returned Product. This Section (f) supersedes Section 13.6(h) of the License Agreement.

2.5 Intellectual Property Licenses .

(a) Takeda hereby grants to ITI, effective upon the Termination Date, an exclusive, fully paid, worldwide, fully transferrable, irrevocable license (with the right to grant sublicenses through multiple tiers) under [***].

(b) [***]

(c) [***].

2.6 Survival Provisions. Notwithstanding Section 13.7 of the License Agreement, the Parties agree that the following Sections within the License Agreement shall terminate upon the Termination Date: Sections 8.2 (ITI Development and Manufacturing Activities), 8.7 (Foreign Exchange), 8.8 (Payment Method; Late Payments), 8.9 (Records and Audit), and 9.2 (Disclosure of Inventions).

2.7 Mutual Releases; Indemnification for Future Activities.

(a) In consideration for the terms set forth in this Termination Agreement, ITI, on behalf of itself and its Affiliates, and the directors, officers, stockholders and employees of such entities and the successors and assigns of the foregoing (the " ***ITI Releasors*** "), hereby

fully releases Takeda and its Affiliates and the directors, officers and employees of such entities (the " ***Takeda Releasees*** ") from any and all claims, actions, causes of action, liabilities, damages, judgments and demands of any kind, whether known or unknown that the ITI Releasors had, has, may have or ever claim to have against Takeda Releasees, under or directly or indirectly related to the License Agreement, except to the extent of existing rights and obligations of the Parties under the License Agreement that survive as provided in Section 13.7 of the License Agreement or as otherwise provided herein. For clarity, the foregoing provision shall not release Takeda Releasees with respect to (i) Takeda's gross negligence or violation of laws; or (ii) a Claim by any Third Party to the extent that indemnification is owed to an ITI Indemnitee in accordance with Article 11 of the License Agreement and otherwise to the extent that a Claim by a Third Party is caused by or arises from the conduct of a Takeda Releasee.

(b) In consideration for the terms set forth in this Termination Agreement, Takeda, on behalf of itself and its Affiliates, and the directors, officers, stockholders and employees of such entities and the successors and assigns of the foregoing (the " ***Takeda Releasors*** "), hereby fully releases ITI and its Affiliates and the directors, officers and employees of such entities (the " ***ITI Releasees*** ") from any and all claims, actions, causes of action, liabilities, damages, judgments and demands of any kind, whether known or unknown that the Takeda Releasors had, has, may have or ever claim to have against ITI Releasees, under or directly or indirectly related to the License Agreement, except to the extent of existing rights and obligations of the Parties under the License Agreement that survive as provided in Section 13.7 of the License Agreement or as otherwise provided herein. For clarity, the foregoing provision shall not release ITI Releasees with respect to (i) ITI's gross negligence or violation of laws; or (ii) a Claim by any Third Party to the extent that indemnification is owed to a Takeda Indemnitee in accordance with Article 11 of the License Agreement and otherwise to the extent that a Claim by a Third Party is caused by or arises from the conduct of an ITI Releasee.

(c) Without limiting the obligations of either Party under Article 11 of the License Agreement or under this Agreement, ITI further agrees that it shall defend, indemnify and hold the Takeda Indemnitees harmless from and against any and all Third Party Claims to the extent that such Claim arises out of, is based on, or results from the manufacture, use, handling, storage, sale or other disposition of the Compound or a Back-Up Compound, including any Variant thereof, as well as any Product, by ITI, its Affiliate or any Third Party on behalf of ITI after the Termination Date. The foregoing indemnity obligation shall not apply to the extent that the Takeda Indemnitees fail to comply with the indemnification procedures set forth in Section 11.3 of the License Agreement and ITI's defense of the Claim is prejudiced by such failure.

(d) Nothing in this Termination Agreement shall be deemed to release, acquit or discharge either Party, or its Affiliates, its agents, representative, employees, officers, directors, attorneys, successors and assigns, from its obligations under this Termination Agreement or any claim arising from any breach of such obligations.

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.

3. REPRESENTATIONS AND WARRANTIES

3.1 By Takeda . Takeda represents and warrants to ITI that, as of the Termination Date:

(a) Takeda has disclosed all Sole Inventions to ITI as required under Section 9.2 of the License Agreement.

(b) Takeda has not sublicensed, assigned, encumbered or transferred any ITI Technology.

(c) Takeda has not licensed, assigned, encumbered or transferred any Assigned Patents.

(d) Takeda has kept ITI informed of major regulatory developments relating to Compounds and Products as required in Section 5.2 of the License Agreement.

(e) Takeda has not terminated any Clinical Trials for Products without ITI's prior written consent.

(f) Exhibit 1 constitutes the complete list of Takeda's material activities related to the Compound or the Product ongoing as of the date hereof.

3.2 By ITI . ITI represents and warrants to Takeda that, as of the Termination Date, ITI has not sublicensed, assigned, encumbered or transferred any Takeda Technology.

4. GENERAL

4.1 Confidential Information . All information furnished by one Party or any of its Affiliates to the other Party or any of its Affiliates pursuant to this Termination Agreement shall be Confidential Information as defined in and subject to the provisions of Article 10 of the License Agreement. Each Party may use Confidential Information only as permitted by the License Agreement or this Termination Agreement. All Information received, developed and/or authored by Takeda in respect of the Products and Compounds, and Clinical Trials and other studies conducted pursuant to the License Agreement, constitute ITI's Confidential Information and is subject to the on-going confidentiality and non-disclosure obligations set forth in the License Agreement.

4.2 Press Release . Upon the termination date, the Parties shall issue a joint press release describing the termination of the Parties' collaboration under the License Agreement substantially in the in the form set forth in Exhibit 3 hereto.

4.3 Dispute Resolution . Article 14 of the License Agreement shall apply to any disputes as to matters arising under or relating to this Termination Agreement or either Party's rights and/or obligations hereunder.

4.4 Assignment . Neither Party shall assign or delegate its rights and obligations under this Termination Agreement either in whole or in part (including any assignment by operation of law) except with the prior written consent of the other Party, except that a Party may assign and delegate its rights and obligations under this Termination Agreement either in whole or in part (including any assignment by operation of law) without the prior written consent of the other Party (a) in connection with the transfer or sale of all or substantially all of the business of such Party to a Third Party, whether by merger, sale of stock, sale of assets or otherwise

(including through any assignment by operation of law); or (b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate. The Parties' rights and obligations under this Termination Agreement will bind and inure to the benefit of their respective successors, heirs, executors and administrators and permitted assigns. Except as expressly permitted herein, any assignment of this Termination Agreement shall be null and void.

4.5 Notices. All notices which are required or permitted hereunder shall be provided in accordance with Section 15.3 of the License Agreement.

4.6 Applicable Law. This Termination 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. The Parties agree to resolve any dispute with respect to this Termination Agreement in accordance with Article 14 of the License Agreement

4.7 Entire Agreement; Amendments. This Termination Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes and cancels all previous express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, in respect to the subject matter hereof, except for the provisions of Section 13.6 of the License Agreement and the other provisions of the License Agreement referenced herein, which shall survive in accordance with their terms. This Termination Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

4.8 Injunctive Relief . Takeda acknowledges that its failure to perform Close-Out Activities as required herein may cause irreparable harm to ITI, which harm may not be reasonably or adequately compensated in damages in an action at law. By reasons thereof, Takeda agrees that ITI shall be entitled, in addition to any other remedies it may have under this Agreement or otherwise, to seek preliminary and permanent injunctive and other equitable relief to prevent or curtail any actual or threatened breach of those Sections.

4.9 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Termination Agreement. Accordingly, the rule of construction that any ambiguity in this Termination Agreement shall be construed against the drafting Party shall not apply.

4.10 English Language. This Termination Agreement is in the English language, and the English language shall control their interpretation. In addition, all notices required or permitted to be given under this Termination Agreement, and all written, electronic, oral or other communications between the Parties regarding this Termination Agreement, shall be in the English language.

4.11 Counterparts. This Termination Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Facsimile copies of signature pages or signatures delivered by any electronic means shall be effective as original signatures.

[Remainder of this page intentionally left blank.]

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.

IN WITNESS WHEREOF, the Parties hereto have duly executed this **TERMINATION AGREEMENT** as of the date set forth above.

TAKEDA PHARMACEUTICAL COMPANY LIMITED		**INTRA-CELLULAR THERAPIES, INC.**	
By:	/s/ Christophe Weber	By:	/s/ Sharon Mates
Name:	Christophe Weber	Name:	Sharon Mates, Ph.D.
Title:	President & COO	Title:	Chief Executive Officer
Date:	October 30, 2014	Date:	October 31, 2014

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 1

Close-Out Activities

Functional Area	Study	Close-Out Activity	Estimated Completion Date	Party Responsible
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

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EXHIBIT 2

Returned Inventory

Activity	Item	Lot	Quantity (Kg)
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]		[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
	[***]	[***]	[***]
	[***]	[***]	[***]

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 3

Form of Press Release

Intra-Cellular Therapies and Takeda Announce Mutual Termination of Collaboration to Develop Phosphodiesterase (PDE1) Inhibitors for CNS Disorders

New York, NY [Date] and Osaka, Japan [Date] – Intra-Cellular Therapies, Inc. (NASDAQ: ITCI) and Takeda Pharmaceutical Company Limited announced today that they have entered into an agreement to mutually terminate the February 2011 license agreement covering Intra-Cellular Therapies' proprietary compound ITI-214 and related PDE 1 inhibitors and to return the rights for these compounds to Intra-Cellular Therapies.

Under the terms of the agreement, Intra-Cellular Therapies has regained all worldwide development and commercialization rights for the compounds previously licensed to Takeda. Takeda will be responsible for transitioning the compounds back to Intra-Cellular Therapies and will not participate in future development or commercialization activities. After transition of the program, Intra-Cellular Therapies plans to continue the clinical development of PDE1 inhibitors for the treatment of central nervous system, cardiovascular and other disorders.

"We are grateful for Takeda's substantial efforts in advancing this program into clinical development," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "This provides us with the opportunity to unify our PDE1 platform and we look forward to continuing the development of ITI-214 and our other PDE1 inhibitors."

Intra-Cellular Therapies will discuss the PDE1 program in its previously announced earnings call on Monday, November 3, 2014. To participate in the conference call, please dial _____five to ten minutes prior to the start of the call. The participant passcode is _____.

About PDE1 Inhibitors

PDE1 inhibitors are unique, orally available, investigational drug candidates being developed for the treatment of cognitive impairments accompanying schizophrenia, Alzheimer's disease and other neuropsychiatric disorders and neurological diseases and may also treat patients with Attention Deficit Hyperactivity Disorder and Parkinson's disease. These compounds may also have the potential to improve motor dysfunction associated with these conditions and may also have the potential to treat patients with multiple sclerosis and other autoimmune diseases and pulmonary arterial hypertension. 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.

About Intra-Cellular Therapies

Intra-Cellular Therapies, Inc. (the "Company") is developing novel drugs for the treatment of neuropsychiatric and neurodegenerative disease and other disorders of the central nervous system ("CNS"). The Company is developing its lead drug candidate, ITI-007, for the treatment of schizophrenia, behavioral disturbances in dementia, bipolar disorder and other

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neuropsychiatric and neurological disorders. The Company is also utilizing its phosphodiesterase platform and other proprietary chemistry platforms to develop drugs for the treatment of CNS disorders.

Forward-Looking Statements

This news release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, our proposed development plans for our portfolio of PDE1 inhibitors; our beliefs about the potential uses and benefits of PDE1 inhibitors; and our research and development efforts and plans under the caption "About Intra-Cellular Therapies, Inc." All such forward-looking statements are based on management's present expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to the following: our current and planned clinical trials for ITI-007 and our other product candidates may not be successful or may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety and/or efficacy in larger-scale or later clinical trials; our reliance on collaborative partners and other third-parties for development and commercialization of our product candidates; and the other risk factors discussed under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission, as well as any updates to those risk factors filed from time to time in our periodic and current reports. All statements contained in this press release are made only as of the date of this press release, and we do not intend to update this information unless required by law.

About Takeda Pharmaceutical Company Limited

Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.Takeda.com .

Takeda Forward-Looking Statement

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

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.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the U.S. and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

Juan Sanchez, M.D.
Vice President
Corporate Communications and Investor Relations of Intra-Cellular Therapies, Inc.
212-923-3344

Burns McClellan, Inc.
Lisa Burns/Angeli Kolhatkar (Investors)
Justin Jackson (Media)
jjackson@burnsmc.com
212-213-0006

Takeda Pharmaceuticals Company Limited
Corporate Communications Dept.
+81-3-3278-2037

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Exhibit 10.11

INTRA-CELLULAR THERAPIES, INC.

EMPLOYEE PROPRIETARY INFORMATION,
INVENTIONS, AND NON-COMPETITION AGREEMENT

In consideration of my employment or continued employment by **I NTRA - CELLULAR T HERAPIES , I NC** . (the " **Company** "), and the compensation now and hereafter paid to me, I hereby agree as follows:

1. N ONDISCLOSURE .

1.1 Recognition of Company's Rights; Nondisclosure. At all times during my employment and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon or publish any of the Company's Proprietary Information (defined below), except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such in writing. I will obtain Company's written approval before publishing or submitting for publication any material (written, verbal, or otherwise) that relates to my work at Company and/or incorporates any Proprietary Information. I hereby assign to the Company any rights I may have or acquire in such Proprietary Information and recognize that all Proprietary Information shall be the sole property of the Company and its assigns. I have been informed and acknowledge that the unauthorized taking of the Company's trade secrets may subject me to civil and/or criminal penalties.

1.2 Proprietary Information. The term " **Proprietary Information** " shall mean any and all confidential and/or proprietary knowledge, data or information of the Company. By way of illustration but not limitation, " **Proprietary Information** " includes (a) tangible and intangible information relating to antibodies and other biological materials, cell lines, samples of assay components, media and/or cell lines and procedures and formulations for producing any such assay components, media and/or cell lines, formulations, products, processes, know-how, designs, formulas, methods, developmental or experimental work, clinical data, improvements, discoveries, plans for research, new products (***"Inventions"***); (b) marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and (c) information regarding the skills and compensation of other employees of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which is generally known in the trade or industry, which is not gained as result of a breach of this Agreement, and my own, skill, knowledge, know-how and experience to whatever extent and in whichever way I wish.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties confidential or proprietary information (" **Third Party Information** ") subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing.

1.4 No Improper Use of Information of Prior Employers and Others. During my employment by the Company I will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person. I will use in the performance of my duties only information which is generally known and used by persons with training and experience comparable to my own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company.

2. ASSIGNMENT OF INVENTIONS.

2.1 Proprietary Rights. The term " **Proprietary Rights** " shall mean all trade secret, patent, copyright, mask work and other intellectual property rights or "moral rights" throughout the world. "Moral rights" refers to any rights to claim authorship of an Invention or to object to or prevent the modification of any Invention, or to withdraw from circulation or control the publication or distribution of any Invention, and any similar right, existing under judicial or statutory law of any country in the world, or under any treaty, regardless of whether or not such right is denominated or generally referred to as a "moral right."

2.2 Prior Inventions. Inventions, if any, patented or unpatented, which I made prior to the commencement of my employment with the Company are excluded from the scope of this Agreement. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Previous Inventions) attached hereto a complete list of all Inventions that I have, alone or jointly with others, conceived, developed or reduced to practice or caused to be conceived, developed or reduced to practice prior to the commencement of my employment with the Company, that I consider to be my property or the property of third parties and that I wish to have excluded from the scope of this Agreement (collectively referred to as " **Prior Inventions** "). If disclosure of any such Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to list such Prior Inventions in *Exhibit A* but am only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on *Exhibit A* for such purpose. If no such disclosure is attached, I represent that there are no Prior Inventions. If, in the course of my employment with the Company, I incorporate a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention. Notwithstanding the foregoing, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent.

2.3 Assignment of Inventions. Subject to Sections 2.4, and 2.6, I hereby assign and agree to assign in the future (when any such Inventions or Proprietary Rights are first reduced to practice or first fixed in a tangible medium, as applicable) to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto) whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to this Section 2, are hereinafter referred to as " **Company Inventions** ."

2.4 Unassigned Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that was developed entirely on my own time without using the Company's equipment, supplies, facilities, or trade secrets and neither related to the Company's actual or anticipated business, research or development, nor resulted from work performed by me for the Company.

2.5 Obligation to Keep Company Informed. During the period of my employment and for six (6) months after termination of my employment with the Company, I will promptly disclose to the Company fully and in writing all Inventions authored, conceived or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to the Company all patent applications filed by me or on my behalf within a year after termination of employment. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to the Company pursuant to this Agreement.

2.6 Government or Third Party. I also agree to assign all my right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States, as directed by the Company.

2.7 Works for Hire. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

2.8 Enforcement of Proprietary Rights. I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of my employment, but the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to the Company.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that may be required by the Company) of all Proprietary Information developed by me and all Inventions made by me during the period of my employment at the Company, which records shall be available to and remain the sole property of the Company at all times.

4. DUTY OF LOYALTY DURING EMPLOYMENT. I understand that my employment with the Company requires my full attention and effort. I agree that during the period of my employment by the Company I will not, without the Company's express written consent, engage in any employment or business activity other than for the Company, including but not limited to employment or business activity which is competitive with, or would otherwise conflict with, my employment by the Company.

5. **No Solicitation of Employees, Consultants, Contractors or Customers.** I agree that for the period of my employment by the Company and for one (1) year after the date my employment by the Company ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, either directly or through others, (i) solicit or attempt to solicit any employee of the Company to end his or her relationship with the Company; and (ii) solicit any consultant, contractor, or customer of the Company, with whom I had contact or whose identity I learned as a result of my employment with the Company to diminish or materially alter its relationship with the Company.

The parties agree that for purposes of this Agreement, a customer is any person or entity to which the Company has provided goods or services at any time during the period commencing six (6) months prior to my employment with the Company and ending on the date my employment with the Company ends.

6. **Non-Compete Provision.** I agree that for the period of my employment with the Company, and for the period of one (1) year after the later of (1) the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company; or (2) the date a court of competent jurisdiction enters an order enforcing this provision, I will not provide services, similar to those I provided to the Company, to any person or entity in competition (as defined below) with the Company. I acknowledge that this non-compete provision is limited to the types of activities and services I provided in my employment with the Company.

At the present time, the Company engages in the research and discovery of genes and their function, and therefore entities and individuals which provide similar products or services are defined as in competition with the Company. The parties understand that the scope and nature of my activities and services, and the Company's business, products or services, may change as the Company develops. The parties agree that the scope of this provision will change to cover any changes in my activities or services, as well as any changes in the Company's business, products or services, during my employment.

7. **No Conflicting Agreement or Obligation.** I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement or obligation of any kind made prior to my employment by the Company, including agreements or obligations I may have with prior employers or entities for which I have provided services. I have not entered into, and I agree I will not enter into, any agreement or obligation either written or oral in conflict herewith.

8. **Return of Company Documents.** When I leave the employ of the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas, and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Proprietary Information of the Company. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice. Prior to leaving, I will cooperate with the Company in completing and signing the Company's termination statement.

9. **Legal and Equitable Remedies.** I recognize that in the course of employment with the Company, I will have access to Proprietary Information, to Third Party Information, and to employees, consultants, contractors, clients, and customers of the Company. I also recognize that the services I will be employed to provide are personal and unique. I understand that because of this the Company may sustain irreparable injury if I violate this Agreement. In order to limit or prevent such irreparable injury, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement.

10. NOTICES. Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery to the appropriate address or if sent by certified or registered mail, three (3) days after the date of mailing.

11. NOTIFICATION OF NEW EMPLOYER. In the event that I leave the employ of the Company, I authorize the Company to provide notice of my rights and obligations under this Agreement to my subsequent employer and to any other entity or person to whom I provide services.

12. GENERAL PROVISIONS.

12.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of New York, as such laws are applied to agreements entered into and to be performed entirely within New York between New York residents. I hereby expressly consent to the personal jurisdiction of the state and federal courts for New York County, New York in any lawsuit filed there against me by Company arising from or related to this Agreement.

12.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. Moreover, if any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

12.3 Successors and Assigns. This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns.

12.4 Survival. The provisions of this Agreement shall survive the termination of my employment and the assignment of this Agreement by the Company to any successor in interest or other assignee.

12.5 Employment At-Will. I agree and understand that I am employed at-will, and that nothing in this Agreement shall change this at-will status or confer any right with respect to continuation of employment by the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.

12.6 Waiver. No waiver by the Company of any breach of this Agreement shall be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement shall be construed as a waiver of any other right. The Company shall not be required to give notice to enforce strict adherence to all terms of this Agreement.

12.7 Entire Agreement. The obligations pursuant to Sections 1 and 2 of this Agreement shall apply to any time during which I was previously employed, or am in the future employed, by the Company as a consultant if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes and merges all prior discussions between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

This Agreement shall be effective as of the first day of my employment with the Company, namely: July 29, 2014.

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS . I HAVE COMPLETELY FILLED OUT E XHIBIT A TO THIS A GREEMENT .

Dated: 7/29/14

/s/ Michael Halstead
(Signature)

Michael Halstead
(Printed Name)

A CCEPTED A ND A GREED T O :

I NTRA - CELLULAR T HERAPIES , I NC .

By: /s/ Allen Fienberg

Title: VP, Business Development

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-198496) of Intra-Cellular Therapies, Inc.,

(2) Registration Statement (Form S-3 No. 333-191238) of Intra-Cellular Therapies, Inc., and

(3) Registration Statement (Form S-8 No. 333-193310) pertaining to the ITI, Inc. 2003 Equity Incentive Plan, as amended, and the Intra-Cellular Therapies, Inc. 2013 Equity Incentive Plan of Intra-Cellular Therapies, Inc.;

of our report dated March 12, 2015, with respect to the consolidated financial statements of Intra-Cellular Therapies, Inc. included in this Annual Report (Form 10-K) of Intra-Cellular Therapies, Inc. for the year ended December 31, 2014.

/s/ Ernst & Young LLP
McLean, VA
March 12, 2015

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Sharon Mates, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Intra-Cellular Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2015

/s/ Sharon Mates, Ph.D.
Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Lawrence J. Hineline, certify that:

1. I have reviewed this annual report on Form 10-K of Intra-Cellular Therapies, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2015

/s/ Lawrence J. Hineline
Lawrence J. Hineline
Vice President of Finance and Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Intra-Cellular Therapies, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2014 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 12, 2015

/s/ Sharon Mates, Ph.D.
Sharon Mates, Ph.D.
Chairman, President and Chief Executive Officer
(principal executive officer)

Dated: March 12, 2015

/s/ Lawrence J. Hineline
Lawrence J. Hineline
Vice President of Finance and Chief Financial Officer
(principal financial officer and principal accounting officer)