# 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, 2017**

**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 (646) 440-9333**

**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. ☐[1]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and emerging growth 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 | ☐ |
| | | Emerging growth company | ☐ |

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

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 approximately $443 million.

As of February 28, 2018, the registrant had 54,680,452 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 2018 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission.

# 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 subsidiaries, ITI, Inc. and ITI Limited.*

## 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. Lumateperone (also known as ITI-007) is our lead product candidate with mechanisms of action that, we believe, may represent an effective treatment across multiple therapeutic indications. In our preclinical and clinical trials to date, lumateperone 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 and for the treatment of bipolar disorder, including bipolar depression. At dopamine D2 receptors, lumateperone has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. Lumateperone has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA 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 efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for major depressive disorder ("MDD"). We believe lumateperone may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases. Lumateperone is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer's disease, or AD.

*Lumateperone for the Treatment of Schizophrenia*

In September 2015, we announced top-line clinical results from our first Phase 3 clinical trial of lumateperone for the treatment of patients with schizophrenia. This randomized, double-blind, placebo-controlled Phase 3 clinical trial was conducted at 12 sites in the United States with 450 patients randomized (1:1:1) to receive either 60 mg of ITI-007, 40 mg of ITI-007 or placebo once daily in the morning for 28 days. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (4 weeks) on the centrally rated Positive and Negative Syndrome Scale, or PANSS, total score. In this trial, the once-daily dose of 60 mg of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint) with additional improvements observed in social function. Moreover, the 60 mg dose of ITI-007 showed significant antipsychotic efficacy as early as week 1, which was maintained at every time point throughout the entire study. ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint. In addition, the 60 mg dose of ITI-007 met the key secondary endpoint of statistically significant improvement on the Clinical Global Impression Scale for Severity of Illness, or CGI-S. The 40 mg dose of ITI-007 also demonstrated a statistically significant improvement versus placebo on the CGI-S, though not formally tested against placebo as a key secondary endpoint since it did not separate on the primary endpoint. A high treatment completion rate was observed with ITI-007 (87% of patients completed treatment on ITI-007 60 mg, 82% completed on ITI-007 40 mg, and 75% completed on placebo). Patients randomized to ITI-007 60 mg demonstrated a statistically significant longer time to treatment discontinuation due to any reason compared to placebo (p=0.006) and a statistically significant longer time to treatment discontinuation due to lack of efficacy (p=0.01). Consistent with previous studies, lumateperone had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids. The number of patients who discontinued treatment in this study due to an adverse event was low and the time to treatment discontinuation due to an adverse event was not statistically significantly different from placebo for either dose of lumateperone.

In September 2015, we also announced top-line data from an open-label positron emission tomography, or PET, study of lumateperone examining brain occupancy of striatal D2 receptors. This study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily lumateperone oral administration. In this trial, the 60 mg dose of ITI-007 was associated with a mean of approximately 40% striatal dopamine D2 receptor occupancy. As predicted by preclinical and earlier clinical data, lumateperone demonstrated antipsychotic effect at relatively low striatal D2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism likely contributes to the favorable safety profile of lumateperone, with reduced risk for hyperprolactinemia, akathisia, extrapyramidal symptoms, and other motoric side effects.

The top-line results from our first Phase 3 clinical trial of lumateperone confirmed the earlier Phase 2 results that we announced in December 2013, in which lumateperone exhibited antipsychotic efficacy in a randomized, double-blind, placebo and active controlled clinical trial in patients with schizophrenia. In this Phase 2 trial (ITI-007-005), 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 PANSS total score. In this study, lumateperone (ITI-007 60 mg) 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.

In September 2016, we announced top-line results from the second Phase 3 clinical trial (ITI-007-302) of lumateperone for the treatment of patients with schizophrenia. In this trial, neither dose of lumateperone separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, lumateperone was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of our Phase 2 study (ITI-007-005) in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe lumateperone did not separate from placebo on the pre-specified primary endpoint in the ITI-007-302 study in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. In addition, we believe other confounding factors may have played a role in the efficacy outcome of ITI-007-302, including an expectation bias and the potential for functional unblinding. We believe the lumateperone late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia. Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same trajectory and magnitude of change from baseline in the primary endpoint, the PANSS total score.

As part of our ongoing dialogue with the U.S. Food and Drug Administration, or FDA, regarding our lumateperone development program in schizophrenia, we requested guidance from the FDA on the acceptability of the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of a new drug application, or NDA, for the treatment of schizophrenia. In connection with this request we provided extensive information and data analyses to the FDA relating to the three studies. The FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. We believe our schizophrenia clinical development program collectively provides evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia.

In addition, the FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. The data we presented supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA's agreement that we presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, we have proceeded with our long-term safety study of lumateperone in patients with schizophrenia. We have completed patient enrollment in our long-term safety study and clinical conduct is ongoing. Further, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in our nonclinical studies. With over 2,000 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo.

In September 2017, we announced positive topline data from the first part of an open-label safety switching study in which 302 patients with stable symptoms of schizophrenia were switched from standard-of-care antipsychotic medications to lumateperone (ITI-007 60 mg) with no dose titration of lumateperone required for a six-week treatment duration, then switched back to standard-of-care. Many currently available antipsychotic agents are associated with motor side effects and/or weight gain, cardiovascular liabilities, dyslipidemia, and hyperglycemia. In this study, lumateperone was generally well tolerated with a favorable safety profile. Statistically significant improvements from standard-of-care baseline were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone and worsened again when switched back to standard-of-care medication. Additionally, treatment with lumateperone was not associated with the motor or cardiovascular disturbances often associated with other antipsychotic medications. These data are consistent with previous study results reflecting a safety profile similar to placebo in placebo-controlled trials with lumateperone in patients with acutely exacerbated schizophrenia and extend this favorable safety profile to this stable patient population. Symptoms of schizophrenia did not worsen upon switch to lumateperone from standard-of-care. Rather, statistically significant improvement from baseline was observed in the PANSS mean total score. Notably, greater improvements were observed in subgroups of patients with elevated symptomatology such as those with comorbid symptoms of depression and those with prominent negative symptoms.

In November 2017, we announced that the FDA has granted Fast Track designation for lumateperone for the treatment of schizophrenia. We requested Fast Track designation for lumateperone based on clinical evidence that lumateperone has the potential to address the unmet medical need for the treatment of schizophrenia with significant improvements on several clinically significant safety parameters, including with respect to metabolic, motor and cardiovascular issues associated with many currently available antipsychotic agents. The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drug candidates to treat serious and life-threatening conditions. Fast Track designation may allow for more frequent meetings and communications with the FDA to discuss a drug candidate's development plans and review process. Drug candidates with Fast Track designation may also qualify for priority review to expedite the FDA review process, if relevant criteria are met.

We intend to submit an NDA for lumateperone for the treatment of schizophrenia by mid-2018. We have a pre-NDA meeting scheduled to be held in March of 2018 with the FDA to discuss this submission.

*Lumateperone for the Treatment of Depressive Episodes Associated with Bipolar Disorder (Bipolar Depression)*

Our bipolar depression program consists of three Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials. In the ITI-007-401 and the ITI-007-404 trials, lumateperone is being evaluated as a monotherapy and in the ITI-007-402 trial, lumateperone is being evaluated as an adjunctive therapy with lithium or valproate. All three trials are evaluating lumateperone in patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode. In the ITI-007-401 and the ITI-007-402 trials, patients are randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007, or placebo in a 1:1:1 ratio orally once daily for 6 weeks. In the ITI-007-404 trial, patients are randomized to receive 60 mg ITI-007 or placebo in a 1:1 ratio orally once daily for 6 weeks. In the ITI-007-401 and the ITI-007-404 trials, patients receive lumateperone or placebo as a monotherapy. In the ITI-007-402 trial, patients receive lumateperone or placebo adjunctive to their existing mood stabilizer lithium or valproate. In each of these trials, we are employing a number of strategies designed to ensure we recruit appropriately diagnosed patients in an effort to reduce the risk of a high placebo response. We anticipate top-line results from the ITI-007-401 trial will be available in the second half of 2018 and top-line results from the ITI-007-004 trial will be available in 2019. Subject to the outcomes of these trials, we expect to file an NDA for bipolar depression in the second half of 2019. In connection with the global strategy of this program we are adding sites outside the U.S. to the ITI-007-402 trial and we expect to provide anticipated timelines for this trial after completing the expansion.

The primary endpoint for these clinical trials is change from baseline at Day 42 on the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score versus placebo. The MADRS is a well-validated 10-item checklist that measures the ability of a drug to reduce overall severity of depressive symptoms. Individual items are rated by an expert clinician on a scale of 0 to 6 in which a score of 6 represents the most depressed evaluation for each item assessed. The total score ranges from 0 to 60. Secondary endpoints include measures of social function and quality of life that may illustrate the differentiated clinical profile of lumateperone. Safety and tolerability are also assessed in these clinical trials.

*Lumateperone for the Treatment of Behavioral Disturbances Associated with Dementia, Including Alzheimer's Disease*

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

In the second quarter of 2016, we initiated Phase 3 development of lumateperone for the treatment of agitation in patients with dementia, including AD. Our ITI-007-201 trial is a Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation. In this trial, approximately 360 patients are planned to be randomized to receive 9 mg ITI-007 or placebo in a 1:1 ratio orally once daily for four weeks. This study includes a single interim analysis reviewed by an independent data monitoring committee, which will be used to assess the assumptions of variability and effect size. The primary efficacy measure is the Cohen-Mansfield Agitation Inventory—Community version, or CMAI-C. The CMAI-C is a well-validated 37-item scale that measures the ability of a drug to reduce overall frequency of agitation symptoms, including aggressive behaviors. Individual items are rated by an expert clinician on a scale of 1 to 7 in which a score of 7 represents the most frequent for each item assessed. The key secondary efficacy measure is CGI-S. Other exploratory secondary endpoints include measures of other behavioral disturbances associated with dementia. Safety and tolerability are also assessed in the trial. Subject to timely patient enrollment, we expect that the outcome of the interim analysis for this trial will be available in the second half of 2018.

*Other Indications for Lumateperone*

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At the lowest doses, lumateperone 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, AD, 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 lumateperone 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, depressive disorders and other neuropsychiatric diseases.

We are advancing our development program to evaluate lumateperone for the treatment of MDD, including the evaluation of a rapid onset of action. In previous studies schizophrenia patients with co-morbid depression experienced improvements in depressive symptoms. Additionally, recent preclinical data support the potential for rapid-acting antidepressant effects. We plan to initiate a late stage clinical program of lumateperone in depressive disorders in 2018.

Within the lumateperone portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. Given the encouraging tolerability data to date with oral lumateperone, we believe that a long-acting injectable ("LAI") option, in particular, may lend itself to being an important formulation choice for patients.

Given the potential utility for lumateperone 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, 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 lumateperone and a family of compounds from Bristol-Myers Squibb Company pursuant to an exclusive license.

*Other Product Candidates*

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. 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. On September 15, 2015, Takeda completed the transfer of the Investigational New Drug application, or IND, for ITI-214 to us. We believe ITI-214 is the first compound in its class to successfully advance through Phase 1 clinical trials. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, including cardiovascular disease. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. We anticipate top-line results from this trial will be available in the second half of 2018. In addition, we plan to initiate a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure in the first quarter of 2018.

Our pipeline also includes preclinical programs that are focused on advancing drugs for the treatment of schizophrenia, Parkinson's disease, AD and other neuropsychiatric and neurodegenerative disorders. We are also investigating the development of treatments for disease modification of neurodegenerative disorders and non-CNS diseases, including our ITI-333 development program. ITI-333 is designed as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. We believe the potential exists for ITI-333 to address these challenges. In preclinical studies, ITI-333 functions as a partial agonist at mu opiate receptors, attenuating the behavioral effects of morphine while displaying full analgesic efficacy that is reversible by the mu opiate antagonist, naloxone. ITI-333 also acts as a 5-HT2A antagonist with interactions at D1 receptors. Preclinical safety studies are currently ongoing. If successfully translated to humans, this unique pharmacological profile may yield clinical utility for the treatment of substance use disorders and pain.

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 and ITI's business continues as the business of the Company. As used herein, the words the "Company," "we," "us," and "our" refer to the current Delaware Corporation and its wholly owned subsidiaries, ITI, Inc. and ITI Limited.

Our corporate headquarters and laboratory are located at 430 East 29th Street, New York, New York 10016, and our telephone number is (646) 440-9333. 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 Investors section of our 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 and other 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 and other 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 diseases and other diseases 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 lumateperone for its lead indication, treatment of schizophrenia, and for additional neuropsychiatric indications, such as bipolar disorder, behavioral disturbances in dementia, including AD, and residual symptoms in schizophrenia;
- expand the commercial potential of lumateperone by investigating its usefulness in additional neurological areas, such as 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, such as ITI-333, for substance use disorders, pain and psychiatric comorbidities including depression and anxiety.

**Our Drug Discovery Platform and Capabilities**

Based on the pioneering efforts of our 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, 2017 and 2016, we incurred approximately $79.4 million and $93.8 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 and other 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 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 hallucinations, 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 exceeded $20 billion in 2015. 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.

***Bipolar Disorder***

Bipolar disorder, sometimes 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 approximately 5.7 million adults in the United States in any given year, or about 2.6 percent of the adult U.S. population. 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.

***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 AD 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 AD 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 AD. In view of the potential multiple effects of lumateperone on aggression, agitation, sleep disorders and depression, and its safety profile to date, we believe that lumateperone may provide a novel therapy for treating the behavioral disturbances accompanying dementia, including AD.

The FDA has not approved any drug to treat the behavioral symptoms of dementia, including AD. 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 AD.

***Alzheimer's Disease***

AD 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. AD primarily affects older people and, in most cases, symptoms first appear after age 60. AD gets worse over time and is fatal.

The market for AD therapeutics is categorized into two segments: acetylcholinesterase inhibitors and NMDA receptor antagonists, which include Aricept®, Namenda® / Ebixa® and Exelon®. Therapeutics used to treat AD had global sales of $4.9 billion in 2015.

While the diagnostic criteria for AD 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 AD 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 AD patients may develop psychosis at some point in the disease process, commonly consisting of hallucinations and delusions. The diagnosis of AD psychosis is associated with more rapid cognitive and functional decline and institutionalization. Sleep disturbances increase the likelihood of day-night reversal, 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 AD. 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 AD. In addition, antipsychotic drugs may exacerbate the cognitive disturbances associated with AD. 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 AD.

***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 AD. According to the National Parkinson Foundation, about 1 million people in the United States and approximately 10 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 7% of adults experience MDD each year. Worldwide sales of antidepressant drugs reached $9.5 billion in 2015. 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.

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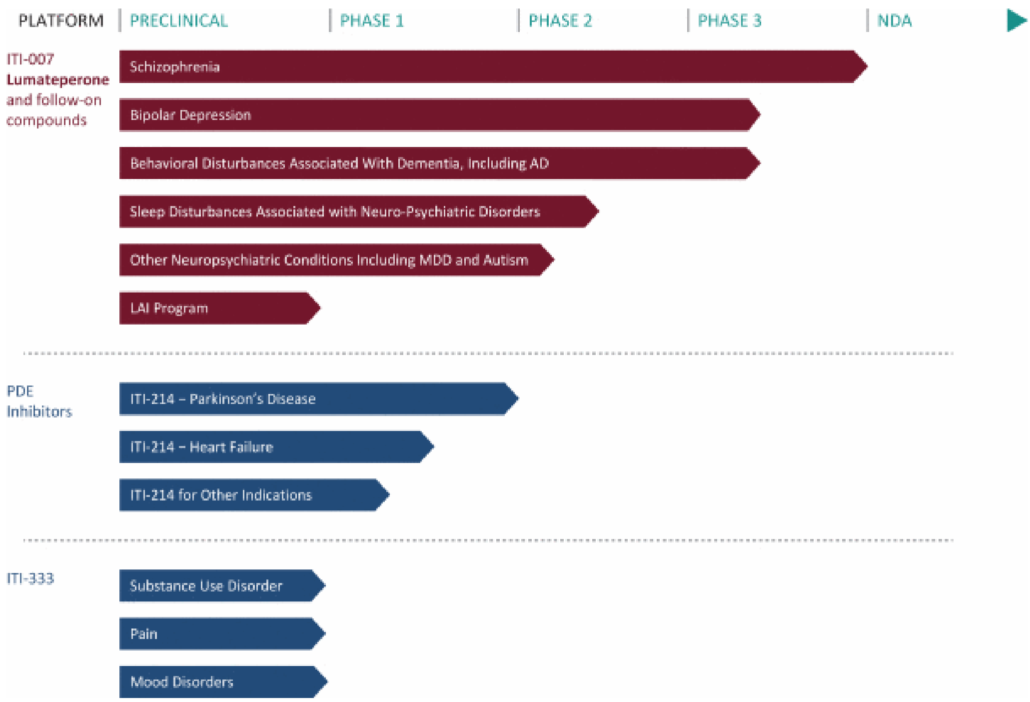
**Our Clinical Programs**

Our pipeline includes two product candidates in clinical development and product candidates in preclinical 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:

**OUR THERAPEUTIC PIPELINE**




***Lumateperone Program***

Our lead product candidate, lumateperone, possesses mechanisms of action that, we believe, may represent an effective treatment across multiple therapeutic indications. In the third quarter of 2016, we completed the second Phase 3 trial for the treatment of schizophrenia. In our preclinical and clinical trials to date, lumateperone 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, lumateperone has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. Lumateperone has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA NR2B, or GluN2B, receptors in a mesolimbic specific manner, resulting in enhanced glutamatergic function through both NDMA and AMPA current. 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 efficacy for a broad array of symptoms associated with schizophrenia. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for MDD. We believe lumateperone 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 lumateperone 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, lumateperone 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).

*Lumateperone for the treatment of exacerbated and residual schizophrenia*

In multiple clinical trials of lumateperone 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. Lumateperone 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, lumateperone 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)

Lumateperone 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 lumateperone (ITI-007 60 mg) 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, lumateperone 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 lumateperone was well-tolerated at the tested doses. Lumateperone 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. Lumateperone 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, lumateperone was well-tolerated. The most frequent AE was sedation, as described above. There were no serious adverse events related to lumateperone. There were no clinically meaningful changes in safety measures with lumateperone. Notably, lumateperone 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. Lumateperone 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 lumateperone.

Phase 3 Clinical Trials and Regulatory Plans

We have conducted two randomized, double-blind, placebo-controlled Phase 3 clinical trials of lumateperone in patients with acutely exacerbated schizophrenia. In September 2015, we announced top-line clinical results from our first Phase 3 clinical trial of lumateperone for the treatment of patients with schizophrenia. This randomized, double-blind, placebo-controlled Phase 3 clinical trial was conducted at 12 sites in the United States with 450 patients randomized (1:1:1) to receive either 60 mg of ITI-007, 40 mg of ITI-007 or placebo once daily in the morning for 28 days. The pre-specified primary efficacy measure was change from baseline versus placebo at study endpoint (4 weeks) on the centrally rated Positive and Negative Syndrome Scale, or PANSS, total score. In this trial, the once-daily dose of 60 mg of ITI-007 met the primary endpoint and demonstrated antipsychotic efficacy with statistically significant superiority over placebo at week 4 (study endpoint) with additional improvements observed in social function. Moreover, the 60 mg dose of ITI-007 showed significant antipsychotic efficacy as early as week 1, which was maintained at every time point throughout the entire study. ITI-007 showed a dose-related improvement in symptoms of schizophrenia with the 40 mg dose approximating the trajectory of improvement seen with the 60 mg dose, but the effect with 40 mg did not reach statistical significance on the primary endpoint. In addition, the 60 mg dose of ITI-007 met the key secondary endpoint of statistically significant improvement on the Clinical Global Impression Scale for Severity of Illness, or CGI-S. The 40 mg dose of ITI-007 also demonstrated a statistically significant improvement versus placebo on the CGI-S, though not formally tested against placebo as a key secondary endpoint since it did not separate on the primary endpoint. A high treatment completion rate was observed with ITI-007 (87% of patients completed treatment on ITI-007 60 mg, 82% completed on ITI-007 40 mg, and 75% completed on placebo). Patients randomized to ITI-007 60 mg demonstrated a statistically significant longer time to treatment discontinuation due to any reason compared to placebo (p=0.006) and a statistically significant longer time to treatment discontinuation due to lack of efficacy (p=0.01). Consistent with previous studies, lumateperone had a favorable safety and tolerability profile as evidenced by motoric, metabolic, and cardiovascular characteristics similar to placebo, and no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, or lipids. The number of patients who discontinued treatment in this study due to an adverse event was low and the time to treatment discontinuation due to an adverse event was not statistically significantly different from placebo for either dose of lumateperone.

In September 2016, we announced top-line results from the second Phase 3 clinical trial (ITI-007-302) of lumateperone for the treatment of patients with schizophrenia. In this trial, neither dose of lumateperone separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. In this trial, lumateperone was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of our Phase 2 study (ITI-007-005) in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar. We believe lumateperone did not separate from placebo on the pre-specified primary endpoint in the ITI-007-302 study in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. In addition, we believe other confounding factors may have played a role in the efficacy outcome of ITI-007-302, including an expectation bias and the potential for functional unblinding. We believe the lumateperone late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this second Phase 3 study, collectively provide evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia. Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same trajectory and magnitude of change from baseline in the primary endpoint, the PANSS total score.

As part of our ongoing dialogue with the FDA regarding our lumateperone development program in schizophrenia, we requested guidance from the FDA on the acceptability of the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of an NDA, for the treatment of schizophrenia. In connection with this request we provided extensive information and data analyses to the FDA relating to the three studies. The FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. We believe our schizophrenia clinical development program collectively provides evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia.

In addition, the FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. The data we presented supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA’s agreement that we presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, we have proceeded with our long-term safety study of lumateperone in patients with schizophrenia. We have completed patient enrollment in our long-term safety study and clinical conduct is ongoing. Further, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in our nonclinical studies. With over 2,000 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo.

In November 2017, we announced that the FDA has granted Fast Track designation for lumateperone for the treatment of schizophrenia. We requested Fast Track designation for lumateperone based on clinical evidence that lumateperone has the potential to address the unmet medical need for the treatment of schizophrenia with significant improvements on several clinically significant safety parameters, including with respect to metabolic, motor and cardiovascular issues associated with many currently available antipsychotic agents. The FDA's Fast Track designation is designed to facilitate the development and expedite the review of drug candidates to treat serious and life-threatening conditions. Fast Track designation may allow for more frequent meetings and communications with the FDA to discuss a drug candidate's development plans and review process. Drug candidates with Fast Track designation may also qualify for priority review to expedite the FDA review process, if relevant criteria are met.

We intend to submit an NDA for lumateperone for the treatment of schizophrenia by mid-2018. We have a pre-NDA meeting scheduled to be held in March of 2018 with the FDA to discuss this submission. In addition to our pre-NDA meeting, additional meetings with the FDA may be requested, as needed, to discuss in greater detail our plans for schizophrenia, 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 lumateperone, our development of lumateperone may be delayed and the costs of our development of lumateperone could increase, which would have a material adverse effect on our business, financial condition and results of operations.

We are also developing long acting injectable formulations of ITI-007 for the treatment of schizophrenia. This is a preclinical stage development program.

PET study of lumateperone in patients with stable schizophrenia

On September 16, 2015, we announced top line data from an open-label PET study of lumateperone examining brain occupancy of striatal D2 receptors. This study was conducted in patients diagnosed with schizophrenia who were otherwise healthy and stable with respect to their psychosis. After washout from their previous antipsychotic medication for at least two weeks, PET was used to determine target occupancy in brain regions at baseline (drug-free) and again after two weeks of once daily lumateperone oral administration. In this trial, the 60 mg dose of ITI-007 was associated with a mean of approximately 40% striatal dopamine D2 receptor occupancy. As predicted by preclinical and earlier clinical data, lumateperone demonstrated antipsychotic effect at relatively low striatal D2 receptor occupancy, lower than the occupancy range required by most other antipsychotic drugs. Unlike any existing schizophrenia treatment, this dopamine receptor phosphoprotein modulator, or DPPM, acts as a pre-synaptic partial agonist and post-synaptic antagonist at D2 receptors. We believe this mechanism likely contributes to the favorable safety profile of lumateperone, with reduced risk for hyperprolactinemia, akathisia, extrapyramidal symptoms, and other motoric side effects.

Open-label safety switching study

In September 2017, we announced positive topline data from the first part of an open-label safety switching study in which 302 patients with stable symptoms of schizophrenia were switched from standard-of-care antipsychotic medications to lumateperone (ITI-007 60 mg) with no dose titration of lumateperone required for a six-week treatment duration, then switched back to standard-of-care. Many currently available antipsychotic agents are associated with motor side effects and/or weight gain, cardiovascular liabilities, dyslipidemia, and hyperglycemia. In this study, lumateperone was generally well tolerated with a favorable safety profile. Statistically significant improvements from standard-of-care baseline were observed in body weight, cardiometabolic and endocrine parameters in patients with stable symptoms of schizophrenia when switched to lumateperone and worsened again when switched back to standard-of-care medication. Additionally, treatment with lumateperone was not associated with the motor or cardiovascular disturbances often associated with other antipsychotic medications. These data are consistent with previous study results reflecting a safety profile similar to placebo in placebo-controlled trials with lumateperone in patients with acutely exacerbated schizophrenia and extend this favorable safety profile to this stable patient population. Symptoms of schizophrenia did not worsen upon switch to lumateperone from standard-of-care. Rather, statistically significant improvement from baseline was observed in the PANSS mean total score. Notably, greater improvements were observed in subgroups of patients with elevated symptomatology such as those with comorbid symptoms of depression and those with prominent negative symptoms.

*Lumateperone for the treatment of depressive episodes associated with bipolar disorder (bipolar depression)*

The pharmacological profile of lumateperone 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 lumateperone 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 lumateperone may treat a wide array of symptoms in patients with bipolar disorder, including improvement of cognition and sleep.

Our bipolar depression program consists of three Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials. In the ITI-007-401 and the ITI-007-404 trials, lumateperone is being evaluated as a monotherapy and in the ITI-007-402 trial, lumateperone is being evaluated as an adjunctive therapy with lithium or valproate. All three trials are evaluating lumateperone in patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode. In the ITI-007-401 and the ITI-007-402 trials, patients are randomized to receive one of three treatments: 60 mg ITI-007, 40 mg ITI-007, or placebo in a 1:1:1 ratio orally once daily for 6 weeks. In the ITI-007-404 trial, patients are randomized to receive 60 mg ITI-007 or placebo in a 1:1 ratio orally once daily for 6 weeks. In the ITI-007-401 and the ITI-007-404 trials, patients receive lumateperone or placebo as a monotherapy. In the ITI-007-402 trial, patients receive lumateperone or placebo adjunctive to their existing mood stabilizer lithium or valproate. In each of these trials, we are employing a number of strategies designed to ensure we recruit appropriately diagnosed patients in an effort to reduce the risk of a high placebo response. We anticipate top-line results from the ITI-007-401 trial will be available in the second half of 2018 and top-line results from the ITI-007-004 trial will be available in 2019. Subject to the outcomes of these trials, we expect to file an NDA for bipolar depression in the second half of 2019. In connection with the global strategy of this program we are adding sites outside the U.S. to the ITI-007-402 trial and we expect to provide anticipated timelines for this trial after completing the expansion.

The primary endpoint for these clinical trials is change from baseline at Day 42 on the Montgomery-Åsberg Depression Rating Scale (MADRS) total score versus placebo. The MADRS is a well-validated 10-item checklist that measures the ability of a drug to reduce overall severity of depressive symptoms. Individual items are rated by an expert clinician on a scale of 0 to 6 in which a score of 6 represents the most depressed evaluation for each item assessed. The total score ranges from 0 to 60. Secondary endpoints include measures of social function and quality of life that may illustrate the differentiated clinical profile of lumateperone. Safety and tolerability are also assessed in these clinical trials.

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

Behavioral disturbances are common in dementia and AD. 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 AD. In the fourth quarter of 2014, we announced the top-line data from ITI-007-200, a Phase 1/2 clinical trial designed to evaluate the safety, tolerability and pharmacokinetics of low doses of lumateperone in healthy geriatric subjects and in patients with dementia, including AD. 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 lumateperone in healthy geriatric subjects. In each of three cohorts in Part 1, approximately 10 subjects were randomized to receive lumateperone (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 lumateperone in the elderly and in the target dementia patient population. Secondary measures were included to explore the effects of lumateperone on cognition and agitation. The Hopkins Verbal Learning Test-R, or 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 lumateperone for approximately one week experienced an improvement in verbal learning and memory relative to placebo-treated subjects. Dementia patients treated with lumateperone 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 marked an important milestone in our strategy to develop low doses of lumateperone for the treatment of behavioral disturbances associated with dementia and related disorders. The ITI-007-200 trial results indicate that lumateperone is safe and well-tolerated across a range of low doses, has linear- and dose-related pharmacokinetics and may improve cognition in the elderly. The most frequent adverse event was mild sedation at the higher doses. We believe these results further position lumateperone as a development candidate for the treatment of behavioral disturbances in patients with dementia and other neuropsychiatric and neurological conditions.

In the second quarter of 2016, we initiated Phase 3 development of lumateperone for the treatment of agitation in patients with dementia, including AD. Our ITI-007-201 trial is a Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation. In this trial, approximately 360 patients are planned to be randomized to receive 9 mg ITI-007 or placebo in a 1:1 ratio orally once daily for four weeks. This study includes a single interim analysis reviewed by an independent data monitoring committee, which will be used to assess the assumptions of variability and effect size. The primary efficacy measure is the Cohen-Mansfield Agitation Inventory—Community version, or CMAI-C. The CMAI-C is a well-validated 37-item scale that measures the ability of a drug to reduce overall frequency of agitation symptoms, including aggressive behaviors. Individual items are rated by an expert clinician on a scale of 1 to 7 in which a score of 7 represents the most frequent for each item assessed. The key secondary efficacy measure is the CGI-S. Other exploratory secondary endpoints include measures of other behavioral disturbances associated with dementia. Safety and tolerability are also assessed in the trial. Subject to timely patient enrollment, we expect that the outcome of the interim analysis for this trial will be available in the second half of 2018.

*Lumateperone 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 lumateperone was completed in 2008 in Europe. The primary outcome measure was slow wave sleep as determined by polysomnography. Lumateperone 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, lumateperone did not induce sleep, but rather helped maintain sleep once sleep had been initiated. In addition, lumateperone was not associated with next day cognitive impairment, or “hang-over” effects. We believe that lumateperone 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 lumateperone 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 lumateperone 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.

*Lumateperone 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 lumateperone 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 lumateperone 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 lumateperone into Phase 2 trials in this patient population, and we are presently exploring the feasibility of such trials.

*Lumateperone for the treatment of depression and other mood disorders*

As a potent 5-HT2A receptor antagonist and serotonin reuptake inhibitor, we believe that lumateperone could improve symptoms of depression with fewer side effects than selective serotonin reuptake inhibitors, or SSRIs. Dopamine modulation by lumateperone may reduce irritability and aggression that can accompany many mood disorders. Lumateperone, as a standalone agent, indirectly enhances glutamatergic neurotransmission through both AMPA and NMDA channels in the prefrontal cortex via lumateperone’s dopamine D1 receptor activation. Lumateperone also activates key proteins in the mTOR pathway similar to ketamine which has shown rapid antidepressant effects, yet lumateperone has not been associated with ketamine-like safety concerns. As such, lumateperone may be effective for the treatment of mood disorders including MDD, posttraumatic stress disorder and intermittent explosive disorder and we are currently advancing our development program to evaluate lumateperone for the treatment of MDD, including the evaluation of a rapid onset of action. We plan to initiate a late stage clinical program of lumateperone in depressive disorders in 2018.

***ITI-002 (PDE1) Program***

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. In addition, PDE1 inhibitors may have utility in treating non-CNS disorders. 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. Takeda conducted four Phase 1 studies. A single rising dose study was conducted in the U.S. in healthy male and female, Japanese and non-Japanese volunteers. In a second U.S. study, ITI-214 was administered once daily over 14 days to healthy volunteers and patients with stable schizophrenia. In a third study, conducted in Japan, ITI-214 was administered for seven days at multiple rising oral doses in both male and female healthy volunteers. A fourth study compared the relative bioavailability of oral formulations of ITI-214 used in all previous studies to an immediate-release tablet, either with or without food in healthy volunteers. In these studies, ITI-214 demonstrated a favorable safety profile and was generally well-tolerated across a broad range of doses both in healthy volunteers and in patients with schizophrenia with a pharmacokinetic profile that supports once daily dosing. We believe ITI-214 is the first compound in its class to successfully advance through Phase 1 clinical trials. 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. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to pursue the development of our PDE program, including ITI-214, for the treatment of several CNS and non-CNS conditions, including cardiovascular disease. Following the positive safety and tolerability results in our Phase 1 program, we initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. We anticipate top-line results from this trial will be available in the second half of 2018. In addition, we plan to initiate a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure in the first quarter of 2018.

***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.

***ITI-333 Program***

ITI-333 is a pre-clinical stage development program. ITI-333 is designed as a potential treatment for substance use disorders, pain and psychiatric comorbidities including depression and anxiety. There is a pressing need to develop new drugs to treat opioid addiction and safe, effective, non-addictive treatments to manage pain. We believe the potential exists for ITI-333 to address these challenges. In preclinical studies, ITI-333 functions as a partial agonist at mu opiate receptors, attenuating the behavioral effects of morphine while displaying full analgesic efficacy that is reversible by the mu opiate antagonist, naloxone. ITI-333 also acts as a 5-HT2A antagonist with interactions at D1 receptors. Preclinical safety studies are currently ongoing. If successfully translated to humans, this unique pharmacological profile may yield clinical utility for the treatment of substance use disorders and pain.

**Intellectual Property**

***Our Patent Portfolio***

As of February 1, 2018, we owned or controlled approximately 105 patent families filed in the United States and other major markets worldwide, including approximately 83 issued or allowed U.S. patents, 27 pending U.S. patent applications, 216 issued or allowed foreign patents and 184 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, pharmaceutical formulations, new indications, improved methods of manufacture, metabolites, derivatives, and structurally related novel compounds. As of February 1, 2018, our ITI-007 program consisted of approximately 30 patent families that we own or control, filed in the United States and other major markets, including 27 issued or allowed U.S. patents, 10 pending U.S. patent applications, 116 issued or allowed foreign patents and 63 pending foreign patent applications. Patent protection for ITI-007 thus includes:

| Summary Description of Patent or Patent Application | United States or Foreign Jurisdiction | Expiration Date |
|---|---|---|
| Base ITI-007 Patent | **Granted:** United States, JP, EP (AT, BE, CH, DE, ES, FR, GB, IE, IT, LU, MC) | June 15, 2025 (including regulatory extensions; additional Orange Book-listable protection to 2034; does not include expected 6 month extension in US for pediatric studies) |
| Supplemental ITI-007 Patent | **Granted:** US, EP (AT, BE, BG, CH, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IT, LT, LU, LV, NL, NO, PL, PT, RO, SE, SI, SK, TR), AU, CA, CN, KR, JP and MX;<br><br>Pending in IL, IN | December 1, 2029 (US; does not include expected 6 month extension for pediatric studies);<br>March 12, 2029 (ex-US) |
| ITI-007 Dosage Patents | **Granted:** US, AU, CN, JP, MX<br>Pending: US (continuation), CA, CN (divisional), EP, IN, KR, MX (divisional) | December 28, 2029 (US);<br>May 27, 2029 (ex-US) |
| Patents for Additional Indications | Granted or pending in US, EP, JP, and other countries | 2033-2034 |

Our program on PDE1 inhibitors for cognition, dopamine-mediated and other disorders, includes patent protection for the lead molecule, ITI-214, as well as a wide range of filings on other proprietary compounds and indications. 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 AD, 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 lumateperone 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 lumateperone 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 lumateperone 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.

**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 lumateperone for the treatment of schizophrenia, bipolar depression and behavioral disturbances associated with dementia, including AD. 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.

On January 4, 2017, we entered into a supply agreement, or the Siegfried Agreement, with Siegfried Evionnaz SA, or Siegfried. Under the Siegfried Agreement, Siegfried has agreed to manufacture and supply the API for lumateperone in commercial quantities. Each month, we will provide Siegfried with a rolling forecast of our anticipated requirements for supply of the API, with the first 12 months of each forecast being binding on us. Under the agreement, our purchase prices for supply of the API from Siegfried are specified prices based on the volume of API produced. The term of the Siegfried Agreement extends for five years. Either party may terminate the agreement prior to its expiration upon an uncured material breach by the other party, the liquidation or dissolution of the other party, the commencement of insolvency procedures or other bankruptcy-related proceedings that are not dismissed within a certain period of time, the appointment of any receiver, trustee or assignee to take possession of the properties of the other party, the cessation of all or substantially all of the other party’s business operations, a continuing force majeure event affecting the other party, or the debarment or certain other events involving the other party’s employees, affiliates or agents. Under the Siegfried Agreement, we have the right to and may purchase the API for lumateperone from other suppliers, including if Siegfried cannot fulfill our requirements.

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 including, Latuda®, marketed by Sunovion, Rexulti® marketed by Otsuka Pharmaceutical, VRAYLAR®, marketed by Allergan, Saphris® marketed by Allergan and Fanapt®, marketed by Vanda Pharmaceuticals. In addition, our product candidates, if approved, will compete with, among other generic antipsychotic products, aripiprazole, haloperidol, paliperidone, risperidone, quetiapine/XR, olanzapine and clozapine.

In addition, the companies described above and other competitors may have a variety of drugs in development or be 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 studies 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 preclinical 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 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.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical 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. The FDA, sponsor or an Institutional Review Board, or IRB, may place a study on hold at any time during development.

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 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.

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. 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 preclinical 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 NDA is subject to a sixty day acceptance period, and if sufficiently complete to permit substantive review, will be filed by FDA at the end of that period. For NDAs that are assigned a standard review designation, the FDA's goal is to complete its review ten months from the date the FDA files the NDA and, for priority review of those NDAs, six months from the date FDA files the NDA. These goals can be extended by the FDA through requests for additional information from the sponsor.

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, preclinical 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 trials. 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 through the submission and approval of a supplemental NDA. Obtaining approval for a new indication generally requires that additional clinical trials 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. Also, the approval must be the first permitted commercial marketing or use of the active ingredient under the relevant provision of law. 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 preclinical studies, adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. The FDCA also provides seven years of market exclusivity for a drug designated for a rare disease or condition (e.g., a disease or condition that affects less than 200,000 people in the U.S.). The exclusivity prohibits the approval of the same drug for the same disease or condition, unless there is a showing of clinical superiority.

### *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.

### *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 of 2010, or collectively, the ACA, enacted in March 2010, substantially changed the way health care is financed by both governmental and private insurers. Certain legislative changes to and regulatory changes under the ACA have occurred in the 115th United States Congress and under the Trump Administration. For instance, the Bipartisan Budget Act of 2018 increased the ACA required manufacturer point-of-sale discount from 50% to 70% off the negotiated price for Medicare Part D beneficiaries during their coverage gap period beginning in 2019. Further legislative changes to and regulatory changes under the ACA remain possible. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

### *Sales and Marketing*

The FDA, in conjunction with the U.S. Federal Trade Commission, or FTC, regulates all advertising and promotion activities for products under FDA's 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 preclinical 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.

At such time as we market, sell and distribute any products for which we obtain marketing approval, it is possible that our business activities could be subject to scrutiny and enforcement under one or more federal or state health care fraud and abuse laws and regulations. These fraud and abuse laws include:

- The federal Anti-Kickback Law, which prohibits, among other things, knowingly or willingly offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward the purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any health care items or service for which payment may be made, in whole or in part, by federal health care programs such as Medicare and Medicaid;

- The federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;

- The federal Physician Payment Sunshine Act, being implemented as the Open Payments Program, requires certain pharmaceutical manufacturers to engage in extensive tracking of payments and other transfers of value to physicians and teaching hospitals, and to submit such data to the Centers for Medicare and Medicaid Studies ("CMS"), which will then make all of this data publicly available on the CMS website; and

- Analogous state laws and regulations, including state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the payer, as well as other state laws that require pharmaceutical companies to report expenses related to the marketing and promotion of pharmaceutical products, prohibit certain gifts or payments to health care providers in the state, and/or require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

Violations of fraud and abuse laws may be punishable by significant 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, employees or consultants of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions under some of the fraud and abuse laws described above. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and extensive enforcement of them by law enforcement authorities. Further, federal and state laws that require manufacturers to make reports on pricing and marketing information could subject us to penalty provisions.

**Description of the Merger**

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. In connection with the Merger, ITI changed its name to ITI, Inc. and Oneida Resources Corp. assumed the name Intra-Cellular Therapies, Inc. 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.

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. Immediately following the Effective Time, 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, which 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.

**Employees**

As of February 15, 2018, we employed 49 employees all of whom were full-time. We consider our relations with our employees to be good. 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, general and administrative and commercial related 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.

## 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 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 have never generated revenue from product sales and do not expect to do so until at least 2019, if ever.***

Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully complete the development of and obtain regulatory approvals necessary to commercialize lumateperone and our other product candidates. 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 product 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.

Our lead product candidate, lumateperone, is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including AD. In September 2016, we announced top-line results from the second Phase 3 clinical trial (ITI-007-302) of lumateperone for the treatment of patients with schizophrenia. In this trial, neither dose of lumateperone separated from placebo on the primary endpoint, change from baseline on the PANSS total score, in the pre-defined patient population. While the FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date, including the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, there can be no assurance that any NDA that we submit to the FDA will be acceptable to or approved by the FDA or that, if approved, we will be able to successfully commercialize lumateperone for the treatment of patients with schizophrenia. In addition, in response to questions raised by the FDA relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in our nonclinical studies. If we are unable to complete our long-term safety study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we may not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia.

Our bipolar depression program consists of three Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials. In the ITI-007-401 and the ITI-007-404 trials, lumateperone is being evaluated as a monotherapy and in the ITI-007-402 trial, lumateperone is being evaluated as an adjunctive therapy with lithium or valproate. All three trials are evaluating lumateperone in patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode. We have also initiated Phase 3 development of lumateperone for the treatment of agitation in patients with dementia, including AD. Our ITI-007-201 trial is a Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation.

In addition, we intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, including cardiovascular disease. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson's disease.

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 until at least 2019, if at all.

***There is no guarantee that our planned clinical trials for lumateperone will be successful.***

The historical rate of failures for product candidates in clinical development and late-stage clinical trials is high. While we will need to successfully complete our long-term safety study and we may be required to conduct further clinical trials in patients with schizophrenia, and we plan to conduct further clinical trials in other indications beyond schizophrenia, there is no guarantee that we will have the same level of success in these trials as we have had in certain of our earlier clinical trials, or be successful at all.

In addition, although we believe that lumateperone and follow-on compounds may also have clinical utility in indications other than schizophrenia, such as behavioral disturbances in dementia, bipolar disorder, intermittent explosive disorder, non-motor disorders associated with Parkinson's disease, obsessive compulsive disorder and anxiety disorders and post-traumatic stress disorder, we have never tested lumateperone 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 lumateperone in healthy geriatric subjects and in patients with dementia, including AD, for which we announced top-line data in the fourth quarter of 2014.

If we do not successfully complete clinical development of lumateperone, we will be unable to market and sell products derived from it and to generate product revenues. Even though we have successfully completed certain clinical trials for lumateperone in patients with schizophrenia, those results are not necessarily predictive of results of future 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.

***The FDA may ultimately determine that our Phase 3 clinical trials and non-clinical studies, even if certain of the trials are successfully completed, are not sufficient for regulatory approval. If we are required to conduct additional clinical trials and non-clinical studies, our development of lumateperone 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, financial condition and cash flows.***

The FDA may not agree with our belief that the lumateperone late-stage clinical development program, including two large, well-controlled positive studies (a Phase 2 and a Phase 3) and supportive evidence from a second Phase 3 study, collectively provide evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia. In addition, 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, or our interpretations of the data from such studies, our development of lumateperone 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. 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 other clinical 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 lumateperone in schizophrenia may have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we eventually submit an NDA and receive approval of lumateperone, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve lumateperone 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 lumateperone or our other product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for lumateperone would delay or prevent commercialization of lumateperone and would materially adversely impact our business, results of operations, financial condition and cash flows.

***If we are unable to complete our long-term safety study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we may not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia.***

The FDA had raised questions relating to certain findings observed in nonclinical toxicology studies of lumateperone in an animal species and requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans. The data we presented supports the position that there are significant species differences in the metabolism of lumateperone. Based on the FDA's agreement that we presented adequate data indicating that the toxicity seen in the animal species is not relevant to humans, we have proceeded with our long-term safety study of lumateperone in patients with schizophrenia. We have completed patient enrollment in our long-term safety study and clinical conduct is ongoing. Further, based on feedback from the FDA, we have incorporated additional monitoring in our long-term safety study for metabolites seen in animal species but not seen to date in humans, and also will continue to monitor for toxicities in our nonclinical studies. The results of the long-term safety study will be required to support an NDA approval for a chronic condition such as schizophrenia. If we are unable to complete our long-term study or the results of our long-term safety study do not demonstrate the safety and tolerability of long-term use of lumateperone, we may not be able to file an NDA for lumateperone for a chronic condition such as schizophrenia. Any failure to complete our long-term safety study or to file an NDA for lumateperone for schizophrenia or any other chronic condition would have a significant adverse effect on our business.

***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, 2017, we had an accumulated deficit of approximately $407.2 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 until at least 2019, 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 $464.3 million at December 31, 2017. 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 middle of 2020, the amount and timing of our actual expenditures will depend upon numerous factors, including the ongoing status of our planned NDA submission for lumateperone in patients with schizophrenia and the results of our long-term safety study of lumateperone in patients with schizophrenia; the ongoing status of our Phase 3 clinical trials of lumateperone in patients with bipolar depression and dementia, including AD; the continued development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions; and our other planned clinical and non-clinical trials. We may require additional funds to obtain regulatory approval for lumateperone for patients with behavioral disturbances associated with dementia, including AD. Furthermore, we anticipate that we will need to secure additional funding to obtain regulatory approval for lumateperone in patients with dementia, including AD, for further development of lumateperone in other programs including in patients with depressive disorders and 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.

With the remaining proceeds from our public offerings in September 2015 and October 2017, we intend to fund the following: the initiation of other planned clinical and non-clinical trials, including manufacturing, in connection anticipated regulatory approval of lumateperone in patients with schizophrenia and other potential additional indications; pre-launch activities for lumateperone for the treatment of schizophrenia and, if it receives regulatory approval, to fund our initial commercialization efforts; the completion of our clinical trials of lumateperone in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate; clinical trials of lumateperone for the treatment of behavioral disturbances in dementia, including AD; preclinical and clinical development of our ITI-007 long acting injectable development program; other clinical trials of lumateperone; the continued clinical development of our PDE1 program, including ITI-214; and research and preclinical development of our other product candidates and the continuation of manufacturing activities in connection with the development of lumateperone. The remaining proceeds, if any, will be used to fund new and ongoing research and development activities, new business opportunities, general corporate purposes, including general and administrative expenses, capital expenditures and working capital. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from these 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:

- whether the FDA ultimately determines that our Phase 3 clinical trials and non-clinical studies of lumateperone are or are not sufficient for regulatory approval of lumateperone for the treatment of schizophrenia;
- 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 preparing for and 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, March 2015, September 2015 and October 2017, 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.

***We may encounter substantial delays in our clinical trials for lumateperone or we may fail to demonstrate safety and efficacy to the satisfaction of the FDA.***

Before obtaining marketing approval from the FDA for the sale of lumateperone, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug candidate for its proposed indications. Clinical trials are time-consuming, 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.

Additionally, the FDA may not agree with our belief that the lumateperone late-stage clinical development program collectively provide evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia, which may require us to conduct additional trials, which would be expensive and time-consuming, would delay our ability to file an NDA with the FDA, and may have a material adverse effect on our business, results of operations, financial condition and cash flows.

***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 PDE 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, none of our product candidates have experienced any serious and unexpected suspected adverse reactions that resulted in the submission of an IND safety report to the FDA; 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 significant safety issues. As we continue the development and clinical trials of our product candidates, there can be no assurance that our product candidates will not experience significant safety issues.

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 or following approval;
- regulatory authorities may not approve our product candidates or, as a condition of approval, may 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, results of operations, financial condition and cash flows.

***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, cash flows 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 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.

***Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. In particular, we will need to develop a larger scale manufacturing process that is more efficient and cost-effective to commercialize lumateperone and other product candidates, which may not be successful, and we plan to transfer our production to one or more other third-party manufacturers in addition to our current third-party manufacturer, potentially delaying regulatory approval and commercialization.***

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. On January 4, 2017, we entered into a supply agreement with Siegfried. Under the Siegfried Agreement, Siegfried has agreed to manufacture and supply the API for lumateperone in commercial quantities. There is no assurance that Siegfried or other manufacturers will be successful in establishing a larger-scale commercial manufacturing process for lumateperone which achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

***We rely on third-party manufacturers to manufacture and supply our product candidates for us. If one of our suppliers or manufacturers fails to perform adequately or fulfill our needs, we may be required to incur significant costs and devote significant efforts to find new suppliers or manufacturers. We may also face significant delays in our clinical trials, regulatory approvals and product introductions and commercialization.***

We have no manufacturing facilities and have limited 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 lumateperone, for clinical trials. For example, on January 4, 2017, we entered into a supply agreement with Siegfried under which Siegfried has agreed to manufacture and supply the API for lumateperone in commercial quantities. Each month, we will provide Siegfried with a rolling forecast of our anticipated requirements for supply of the API, with the first 12 months of each forecast being binding on us. Under the Siegfried Agreement, we have the right to and may purchase the API for lumateperone from other suppliers, including if Siegfried cannot fulfill our requirements. In addition, we expect to have an additional third party source of supply of the API for lumateperone in commercial 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. If our existing or planned third party manufacturing arrangements are terminated or if the sources of supply from such arrangements are inadequate and we must seek supply agreements from alternative sources, 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. The manufacture of pharmaceutical products in compliance with the cGMPs requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, including difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced cGMP requirements, other federal and state regulatory requirements and foreign regulations. If our manufacturers were to encounter any of these difficulties or otherwise fail to comply with their obligations to us or under applicable regulations, our ability to provide product candidates in our clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial materials could delay the completion of our clinical trials, increase the costs associated with maintaining our clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or terminate the clinical trials completely.

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. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. 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. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our products and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical studies, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or impair our reputation.

***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 lumateperone 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 information technology systems and 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 of 2010, or collectively, ACA, became law in the United States. The ACA 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 ACA 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 Medicare Part D coverage gap discount program, in which manufacturers agreed 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;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- 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 requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the details regarding the implementation of the ACA are yet to be determined and, at this time, it remains unclear what the full effect that the ACA will have on our business. Moreover, certain legislative changes to and regulatory changes under the ACA have occurred in the 115th United States Congress and under the Trump Administration. For instance, the Bipartisan Budget Act of 2018 increased the ACA required manufacturer point-of-sale discount from 50% to 70% off the negotiated price for Medicare Part D beneficiaries during their coverage gap period beginning in 2019. Further legislative changes to and regulatory changes under the ACA remain possible. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

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 the ACA, in its current form or as it may be amended, 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. There are risks involved with both establishing our own sales, marketing, managerial and related capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively, which could damage our reputation. If we do not establish adequate sales, marketing, and distribution capabilities, whether independently or in collaboration with third parties, we will not be successful in commercializing our product candidates, 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, 2017, we had net operating loss carryforwards, or NOLs, of approximately $131.1 million, which are available to reduce any future federal and state taxable income and will begin to expire in the year 2034. The use of our NOLs may be restricted due to changes in our ownership, including as a result of our public offerings.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in our ownership may limit the amount of NOLs and tax credit carryforwards that could be utilized annually in the future to offset taxable income.

For the year ended December 31, 2017, we performed a Section 382 ownership analysis and determined that no ownership change occurred (within the meaning of Section 382 of the Code) as a result of our public offering in 2017. Our previous ownership analysis, through December 31, 2015, reflected an ownership change occurred as a result of our 2015 public offerings. Based on the analysis performed, however, we do not believe that the Section 382 annual limitation will impact our ability to utilize the tax attributes that existed as of the date of the ownership change in a material manner. If we experience an ownership change in the future, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

In September 2016, we licensed certain intellectual property rights to our wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. The costs to develop, test, manufacture and perform other activities related to the ITI-007 program will be the responsibility of ITI Limited and will be incurred outside of the United States. Therefore, the majority of expected losses that we incur during the next several years will not result in additional NOLs in the U.S. to be carried forward and used against future net income of the U.S. operations.

***The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.***

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under TCJA we revalued the ending net deferred tax assets at December 31, 2017 and given we are still subject to a valuation allowance did not recognize any tax expense (related to such reduced tax rate) in our consolidated statement of income for the year ended December 31, 2017. See income tax section below for further discussion. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse. This report does not discuss any such tax legislation or the manner in which it might affect holders of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

***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 HIPPA, 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 lumateperone 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 may 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 in our patents.

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 the Transfer of Certain Intellectual Property Rights to our Foreign Subsidiary**

***We may need to utilize all of our available net operating losses, and we may be subject to additional income taxes in connection with our transfer of certain intellectual property rights to our foreign subsidiary.***

In September 2016, we licensed certain intellectual property rights to our wholly-owned Bermuda subsidiary, ITI Limited for $125 million and other consideration. The fair value of the intellectual property rights were determined by an independent third party. The proceeds from this license represented a prior year gain for U.S. tax purposes which was offset partially by prior year losses. However, the Internal Revenue Service, or the IRS, could challenge the valuation of the intellectual property rights and assess a greater valuation, which would require us to utilize a portion, or all, of our available NOLs at such time. If an IRS valuation exceeds our available NOLs, we could incur additional income taxes in the future. Our ability to use our NOLs is generally subject to the limitations of IRS Section 382, as well as expiration of federal and state net operating loss carryforwards.

**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 and bipolar disorder would compete with, among other branded products including, Latuda®, marketed by Sunovion, Rexulti® marketed by Otsuka Pharmaceutical, VRAYLAR®, marketed by Allergan, Saphris® marketed by Allergan and Fanapt®, marketed by Vanda Pharmaceuticals. In addition, our product candidates, if approved, will compete with, among other generic antipsychotic products, aripiprazole, haloperidol, paliperidone, risperidone, quetiapine/XR, 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 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**

***Numerous factors could result in substantial volatility in the trading price of our stock.***

During the year ended December 31, 2017, the price per share of our common stock on the Nasdaq Global Select Market has ranged from a high of $22.67 to a low of $7.85. 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. 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:

- timing and announcement of regulatory developments, submissions and approvals or preliminary, interim or final results of clinical trials;
- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of medical innovations or new products or product candidates 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;
- 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, such as the purported class action lawsuits brought against us and certain of our executive officers in May 2017, consolidated in July 2017 and voluntarily dismissed in November 2017, 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 14, 2016, on which we registered for sale up to $350 million of any combination of our 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 October 2, 2017 and October 5, 2017, we completed our public offering of approximately $172 million of shares of our common stock registered on the universal shelf registration statement and received net proceeds of approximately $162 million, after deducting underwriting discounts and commissions and estimated offering expenses. After the public offering in October 2017, approximately $178 million of securities remain available for issuance under this shelf registration statement. This registration statement will remain in effect for up to three years from the date it was declared effective. In addition, we are a "well known seasoned issuer", which allows us to file an automatically effective shelf registration statement on Form S-3, which would allow us to offer and sell our 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. 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.

***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 maintain effective internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. In addition, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. 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. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we fail to maintain the effectiveness of our internal controls or fail to comply in a timely manner with the requirements of the Sarbanes-Oxley Act, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, this 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 and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. 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.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our independent registered public accounting firm as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

***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 us 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, uses of cash, cash equivalents and investment securities, 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, or submit an application for 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 securities offerings;
- any restrictions on our ability to use our net operating loss carryforwards;
- our exposure to investment risk, interest rate risk and capital market risk; 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 16,753 square feet of useable office and laboratory space. The term of the lease, as amended, expires January 31, 2027. We also lease office space in Towson, Maryland on a yearly basis.

## 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

Our common stock is traded on the NasdaqGlobal Select Market under the symbol "ITCI." The high and low sales prices per share of our common stock as reported by Nasdaq for each quarter during the fiscal years ended December 31, 2017 and 2016 are set forth below:

| Year Ended December 31, 2017 | High | Low |
|---|---|---|
| First Quarter | $17.59 | $10.43 |
| Second Quarter | $17.08 | $ 7.85 |
| Third Quarter | $22.67 | $10.25 |
| Fourth Quarter | $17.19 | $13.93 |

| Year Ended December 31, 2016 | High | Low |
|---|---|---|
| First Quarter | $55.35 | $22.41 |
| Second Quarter | $42.03 | $27.13 |
| Third Quarter | $45.20 | $14.44 |
| Fourth Quarter | $17.00 | $10.80 |

### Stockholders

As of February 28, 2018, we had 54,680,452 outstanding shares of common stock and no outstanding shares of preferred stock. As of February 28, 2018, there were approximately 110 holders of record of our outstanding shares of 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

Not applicable.

**Item 6. SELECTED FINANCIAL DATA**

The following table sets forth consolidated financial data with respect to the Company for each of the five years in the period ended December 31, 2017. The selected financial data for each of the five years in the period ended December 31, 2017 have been derived from our audited consolidated financial statements. The consolidated balance sheets as of December 31, 2017 and 2016 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, 2017, 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.

| | 2017 | 2016 | 2015 | 2014 | 2013 |
|---|---|---|---|---|---|
| **Statements of Operations:** | | | | | |
| Revenues: | | | | | |
| License and collaboration revenue | $ — | $ — | $ 30,659 | $ 547,546 | $ 2,737,002 |
| Grant revenue | 245,837 | 330,702 | 60,705 | 29,755 | — |
| Total Revenues | 245,837 | 330,702 | 91,364 | 577,301 | 2,737,002 |
| Costs and expenses: | | | | | |
| Research and development | 79,419,009 | 93,831,530 | 87,718,074 | 21,226,345 | 23,027,578 |
| General and administrative | 23,666,957 | 24,758,063 | 18,187,286 | 10,337,679 | 5,976,276 |
| Total costs and expenses | 103,085,966 | 118,589,593 | 105,905,360 | 31,564,024 | 29,003,854 |
| Loss from operations | (102,840,129) | (118,258,891) | (105,813,996) | (30,986,723) | (26,266,852) |
| Interest income | (4,005,864) | (2,935,077) | (1,022,455) | (303,936) | (29,617) |
| Interest expense | — | 36,781 | — | 7,073 | 612,963 |
| Income tax (benefit) expense | (1,060,851) | 1,065,673 | 1,600 | 1,600 | 18,000 |
| Net Loss | $ (97,773,414) | $(116,426,268) | $(104,793,141) | $ (30,691,460) | $(26,868,198) |
| Net Loss per common share: | | | | | |
| Basic | $ (2.12) | $ (2.69) | $ (2.91) | $ (1.07) | $ (1.56) |
| Diluted | $ (2.12) | $ (2.69) | $ (2.91) | $ (1.07) | $ (1.56) |
| Weighted average number of common shares: | | | | | |
| Basic | 46,181,926 | 43,240,188 | 36,069,237 | 28,650,067 | 17,260,768 |
| Diluted | 46,181,926 | 43,240,188 | 36,069,237 | 28,650,067 | 17,260,768 |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2017 | 2016 | 2015 | 2014 | 2013 |
| **Balance Sheet data:** | | | | | |
| Cash and cash equivalents | $ 37,790,114 | $ 48,642,225 | $ 47,159,303 | $ 61,325,044 | $ 35,150,924 |
| Total assets | 471,486,699 | 388,903,495 | 484,103,528 | 131,111,769 | 38,449,312 |
| Total liabilities | 17,049,738 | 13,400,956 | 7,860,617 | 10,557,064 | 6,834,037 |
| Accumulated deficit | (407,248,780) | (309,475,366) | (193,049,098) | (88,255,957) | (57,564,497) |
| Total stockholders' equity | 454,436,961 | 375,502,539 | 476,242,911 | 120,554,705 | 31,615,275 |

## 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 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. Lumateperone (also known as ITI-007) is our lead product candidate with mechanisms of action that, we believe, may represent an effective treatment across multiple therapeutic indications. In our preclinical and clinical trials to date, lumateperone 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 and for the treatment of bipolar disorder, including bipolar depression. At dopamine D2 receptors, lumateperone has been demonstrated to have dual properties and to act as both a pre-synaptic partial agonist and a post-synaptic antagonist. Lumateperone has also been demonstrated to have affinity for dopamine D1 receptors and indirectly stimulate phosphorylation of glutamatergic NMDA 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 efficacy for a broad array of symptoms associated with schizophrenia and bipolar disorder with improved psychosocial function. The serotonin reuptake inhibition potentially allows for antidepressant activity in the treatment of schizoaffective disorder, other disorders with co-morbid depression, and/or as a stand-alone treatment for MDD. We believe lumateperone may also be useful for the treatment of other psychiatric and neurodegenerative disorders, particularly behavioral disturbances associated with dementia, autism, and other CNS diseases. Lumateperone is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including AD.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. At the lowest doses, lumateperone 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, AD, 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 lumateperone 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, depressive disorders and other neuropsychiatric diseases. Within the ITI-007 portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. Given the encouraging tolerability data to date with oral lumateperone, we believe that a long-acting injectable option, in particular, may lend itself to being an important formulation choice for patients.

Given the potential utility for lumateperone 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, 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 lumateperone 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. ITI-214 is our lead compound in this program. We believe ITI-214 is the first compound in its class to successfully advance into Phase 1 clinical trials. We intend to pursue the development of our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, including cardiovascular disease.

Our pipeline also includes preclinical programs that are focused on advancing drugs for the treatment of schizophrenia, Parkinson's disease, AD and other neuropsychiatric and neurodegenerative disorders. We are also investigating the development of treatments for disease modification of neurodegenerative disorders and non-CNS diseases.

**Results of Operations**

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

***Revenues***

We have not generated any revenue from product sales to date and we do not expect to generate revenues from product sales until at least 2019, if ever. Our revenues for the years ended December 31, 2017 and 2016 have been from a government grant. 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 certainty to estimate either the costs or the timelines in which those costs will be incurred. The clinical development of lumateperone for the treatment of schizophrenia, for the treatment of bipolar depression and for the treatment of agitation in patients with dementia, including AD, consumes and will continue to consume a large portion of our current, as well as projected, resources. We intend to pursue other disease indications that lumateperone may address, but there are significant 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 our PDE program, including ITI-214 for the treatment of several CNS and non-CNS conditions, including cardiovascular disease. We have initiated our development program for ITI-214 for Parkinson's disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson's disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. we plan to initiate a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure in the first quarter of 2018. Our other projects are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to enter into and complete clinical trials. Expenditures that we incur on these projects will be subject to availability of funding in addition to the funding required for the advancement of lumateperone. Any failure or delay in the advancement of lumateperone could require us to re-allocate resources from our other projects to the advancement of lumateperone, 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 preclinical testing, manufacturing and related testing, clinical trial activities and license milestone payments.

General and administrative expenses are incurred in four major categories:

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

We expect that research and development expenses will increase significantly as we proceed with our Phase 3 clinical trials of lumateperone for the treatment of bipolar disorder and for the treatment of agitation in patients with dementia, including AD, and as we proceed with increased manufacturing of drug product for clinical trials and pre-commercialization testing. We also expect that our general and administrative costs will increase from prior periods primarily due to costs to perform pre-product commercialization activities and the increased costs associated with being a public reporting entity, which could include hiring additional personnel. We granted options to purchase 982,993 shares of our common stock in 2017 and have granted options to purchase an additional 651,569 shares of our common stock in January 2018. We also granted time based restricted stock units, or RSUs, for 154,922 of our common stock in 2017 and time based RSUs for 475,820 shares of our common stock in January 2018. We will recognize expense associated with these RSUs and options over the next three years in both research and development expenses and general and administrative expenses. In the first quarter of 2017, we also granted performance based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of a new drug application with the FDA, (ii) the approval of the NDA by the FDA, or the Milestone RSU grants, and (iii) the achievement of certain comparative shareholder returns against our peers, or the TSR RSU grants. The Milestone RSU grants were valued at the closing price on March 8, 2017. The RSUs related to the NDA submission will be amortized through December 31, 2018 based on the probable vesting date. The amortization of the expenses of the RSUs related to the approval of the NDA will commence if and when the filing has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSU grants were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSU agreements which ends December 31, 2019. The Milestone RSU grants and the TSR RSU grants are target based and the ultimate awards, if attained, could be the target amount or higher or lower than the target amount, depending on the timing or achievement of the goal. We expect this non-cash expense to be substantial 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, net and income tax (benefit) expenses for the years ended December 31, 2017, 2016 and 2015 (in thousands):

| | For the Year Ended December 31, | | |
|---|---|---|---|
| | **2017** | **2016** | **2015** |
| **Revenues** | **$ 246** | $ 330 | $ 91 |
| **Expenses** | | | |
| Research and Development | **79,419** | 93,831 | 87,718 |
| General and Administrative | **23,667** | 24,758 | 18,187 |
| Total costs & expenses | **103,086** | 118,589 | 105,905 |
| Loss from operations | **(102,840)** | (118,259) | (105,814) |
| Interest income, net | **(4,006)** | (2,898) | (1,022) |
| Income tax (benefit) expense | **(1,061)** | 1,065 | 1 |
| **Net Loss** | **$ (97,773)** | $(116,426) | $(104,793) |

***Comparison of Years Ended December 31, 2017 and December 31, 2016***

*Revenues*

Revenues decreased for the year ended December 31, 2017 as compared to the year ended December 31, 2016 by approximately $84 thousand, or 26%, due to a government grant that was completed in the fourth quarter of 2017. We do not expect to have any significant grants in the future.

*Research and Development Expenses*

Research and development expenses decreased for the year ended December 31, 2017 as compared to the year ended December 31, 2016 by approximately $14.4 million, or 15%. This change is due primarily to a decrease of approximately $11.4 million in clinical trials related costs, a decrease of approximately $4.6 million in non-clinical costs, and a decrease of approximately $3.2 million of costs associated with manufacturing. These decreases in 2017 are offset in part by an increase of approximately $2.3 million of labor related costs. For the year ended December 31, 2016, the majority of the $93.8 million in research and development costs was related to the second Phase 3 trial of lumateperone in patients with schizophrenia and to a lesser extent the Phase 3 trials of lumateperone in patients with bipolar depression and the Phase 3 trial of lumateperone for the treatment of agitation in patients with dementia, including AD, other supporting trials for lumateperone and costs for manufacturing lumateperone. For the year ended December 31, 2017, the majority of the $79.4 million in research and development costs was related to clinical trial costs of lumateperone in patients with schizophrenia and to a lesser extent the Phase 3 trials of lumateperone in patients with bipolar depression, the Phase 3 trial of lumateperone for the treatment of agitation in patients with dementia, including AD, and costs for manufacturing lumateperone. Amounts paid to external parties comprised most of our research and development costs. For the year ended December 31, 2017, we incurred approximately $64.3 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $81.1 million for the year ended December 31, 2016. Of these external costs, approximately $60.1 million for the year ended December 31, 2017 and approximately $80.6 million in the year ended December 31, 2016 were for lumateperone related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe benefits, materials, stock-based compensation, supplies and facilities and maintenance costs and were approximately $15.1 million and $12.7 million for the years ended December 31, 2017 and 2016, respectively.

As development of lumateperone progresses, we anticipate costs for the lumateperone program to increase due primarily to ongoing and planned clinical trials in 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. We also expect to incur costs in preparing and filing a New Drug Application (NDA) with the FDA and to incur milestone payments under our licensing agreement with BMS.

As of December 31, 2017, we employed 32 full time personnel in our research and development group as compared to 28 full time personnel in our research and development group at December 31, 2016. We expect to hire additional staff as we increase our development efforts and grow our business in the upcoming years.

We currently have several projects, in addition to lumateperone, that are in the research and development stages, including in the treatment of neurological and neurodegenerative diseases, including Parkinson's and AD, among others and pain, substance use disorders and related psychiatric comorbidities including depression and anxiety. We have used internal resources and incurred expenses not only in relation to the development of lumateperone, but also in connection with these additional projects as well, including our PDE program. 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 modest and are reflected in the amounts discussed in this section "—Research and Development Expenses."

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 this Annual Report on Form 10-K.

*General and Administrative Expenses*

General and administrative expenses decreased for the year ended December 31, 2017 as compared to the year ended December 31, 2016 by approximately $1.1 million, or 4.4%, primarily due to a decrease of approximately $1.5 million of marketing and consulting costs in 2017 compared to 2016, offset by higher capital tax expense in 2017. Salaries, bonuses, share based compensation and related benefit costs for our executive, finance and administrative functions for the years ended December 31, 2017 and 2016 were approximately 62% and 61%, respectively, of our total general and administrative costs. Our other general and administrative expenses include patent costs and other professional fees and, to a lesser extent, general office-related overhead.

We expect general and administrative costs to increase significantly as we hire additional staff and expand our operations, including preparation for potential commercial activities.

*Interest Income*

Interest income has increased to approximately $4.0 million from $2.9 million for the year ended December 31, 2017 as compared to the year ended December 31, 2016. This increase is primarily a result of higher than average cash balances and rising interest rates in 2017 as compared to 2016. The higher balances in 2017 were primarily due to the net offering proceeds of $162.1 million that we received in October 2017 and is offset partially by the $80.5 million of cash and investments utilized in 2017.

*Income Taxes*

In September 2016, the Company licensed certain intellectual property rights to its wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. Although the license of intellectual property rights did not result in any gain or loss in the consolidated statements of operations, the transaction generated taxable net income in the U.S in 2016. We utilized a portion of our available federal and state net operating loss carryforwards to offset the majority of this net income but incurred approximately $1.1 million of alternative minimum tax related to intercompany transactions that were treated as tax expense in our consolidated statement of operations in 2016. In December 2017 the Tax Cuts and Jobs Act law was passed which will allow the Company to receive a refund in future periods for these taxes paid. The Company therefore has recognized a current period benefit of approximately $1.1 million for these taxes.

***Comparison of Years Ended December 31, 2016 and December 31, 2015***

*Revenues*

Revenues increased for the year ended December 31, 2016 as compared to the year ended December 31, 2015 by approximately $239 thousand, or 262%, primarily due to a government grant, offset by limited reimbursable costs of $31 thousand paid to us by Takeda in 2015 under the Takeda License Agreement which terminated on October 31, 2014.

*Research and Development Expenses*

Research and development expenses increased for the year ended December 31, 2016 as compared to the year ended December 31, 2015 by approximately $6.1 million, or 7%. This change is due primarily to an increase of approximately $6.5 million of costs associated with manufacturing and $1.6 million of labor related costs offset in part by $2.8 million less in clinical trials related costs in the year ended December 31, 2016 over the year ended December 31, 2015. For the year ended December 31, 2015, the majority of the $87.7 million of research and development costs was related to the first and second Phase 3 trial of lumateperone in patients with schizophrenia (ITI-007-301 and ITI-007-302). For the year ended December 31, 2016, the majority of the $93.8 million in research and development costs was related to the second Phase 3 trial of lumateperone in patients with schizophrenia and to a lesser extent the Phase 3 trials of lumateperone in patients with bipolar depression and the Phase 3 trial of lumateperone for the treatment of agitation in patients with dementia, including AD, other supporting trials for lumateperone which commenced in the third quarter of 2016 and a significant amount of costs for manufacturing lumateperone. Amounts paid to external parties comprised most of our research and development costs. In the year ended December 31, 2016, we incurred approximately $81.1 million of costs to external parties who manufactured, tested and performed clinical trial related activities as compared to $76.8 million for the year ended December 31, 2015. Of these external costs, approximately $80.6 million in the year ended December 31, 2016 and approximately $76.1 million in the year ended December 31, 2015 were for lumateperone related projects. The remaining external costs for each of these periods were spent on other projects. Internal costs are comprised primarily of labor, fringe benefits, materials, stock-based compensation, supplies and facilities and maintenance costs and were approximately $12.7 million and $10.9 million in the years ended December 31, 2016 and 2015, respectively.

*General and Administrative Expenses*

General and administrative expenses increased for the year ended December 31, 2016 as compared to the year ended December 31, 2015 by approximately $6.6 million, or 36%, primarily due to approximately $4.1 million of higher stock option expense and to a lesser extent to commercial development, rent, accounting, legal, and labor costs. Salaries, bonuses, share based compensation and related benefit costs for our executive, finance and administrative functions for the years ended December 31, 2016 and 2015 were approximately 61% and 59%, respectively, of our total general and administrative costs. Our other general and administrative expenses included patent costs and other professional fees and, to a lesser extent, general office-related overhead.

*Interest Income*

Interest income has increased to approximately $2.9 million from $1.0 million for the year ended December 31, 2016 as compared to the year ended December 31, 2015. This increase is primarily a result of higher than average cash balances and interest rates in 2016 as compared to 2015. The higher balances in 2016 were due to the net offering proceeds of $121.8 million that we received in March 2015 and $327.4 million that we received in September 2015 offset partially by the $91.3 million of cash and investments utilized in 2016.

*Income Tax*

In September 2016, we licensed certain intellectual property rights to our wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. Although the license of intellectual property rights did not result in any gain or loss in the consolidated statements of operations, the transaction generated taxable net income in the U.S. We utilized a portion of our available federal and state net operating loss carryforwards to offset the majority of this net income but incurred $1.1 million of taxes related to intercompany transactions that were treated as tax expense in our consolidated statement of operations.

**Liquidity and Capital Resources**

Through December 31, 2017, we provided funds for our operations by obtaining approximately $879.6 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 terminated Takeda License Agreement. We do not believe that grant revenue will be a significant source of funding in the near future. On March 11, 2015, we completed a 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 $121.8 million. On September 28, 2015, we completed an additional public offering of 7,935,000 shares of our common stock for aggregate gross proceeds of approximately $345.2 million and net proceeds of approximately $327.4 million.

On October 2, 2017, we completed a public offering of 9,677,419 shares of our common stock for aggregate gross proceeds of approximately $150 million and net proceeds of approximately $140.6 million. On October 5, 2017, the underwriters exercised in full their option to purchase an additional 1,451,613 shares. All of the shares in the offering were sold by the Company, with gross proceeds to the Company of approximately $172 million from the offering of an aggregate of 11,129,032 shares and net proceeds of approximately $162 million, after deducting underwriting discounts, commissions and estimated offering expenses.

As of December 31, 2017, we had a total of approximately $464.3 million in cash and cash equivalents and available-for-sale investment securities, and approximately $14.2 million of short-term liabilities consisting entirely of liabilities from operations. We spent approximately $85.2 million in cash for operations and equipment. This total does not include an offset for $4.0 million of interest income received. This use of cash was primarily for conducting clinical trials and non-clinical testing,
including manufacturing related activities and funding recurring operating expenses. We increased working capital by approximately $77.3 million for the year ended December 31, 2017 primarily as a result of the public offering in October of 2017.

For the year 2018, subject to the timing of clinical trials, regulatory activities, manufacturing, precommercial and other development activities, we expect to spend between $180 million and $200 million. We expect these expenditures to be due primarily to the development of lumateperone in patients with schizophrenia, behavioral disturbances in dementia, bipolar disorder and depressive disorders, our ITI-007 long acting injectable development program through pre-clinical and early clinical development, research and preclinical development of our other product candidates, including ITI-214, the continuation of manufacturing activities in connection with the development of lumateperone, recurring expenses and costs to produce, develop and validate materials to be used in clinical and non-clinical studies related to lumateperone, and expenses associated with our other development programs, pre-commercialization activities and general operations. We expect that cash expenditures beyond 2018 will at least remain at the 2018 projected level of spending or increase moderately as we further expand the lumateperone clinical stage programs, the ITI-007 long acting injectable development program through pre-clinical and early clinical development, our ITI 214 clinical stage development programs, research and preclinical development of our other product candidates; the continuation of manufacturing, pre-commercial activities in connection with the development of lumateperone and the early stage pre-commercial launch activities for lumateperone. We believe that our existing cash and cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements through the middle of 2020.

We will require significant additional financing in the future to continue to fund our operations. We believe that we have the funding in place to complete the additional clinical and non-clinical trials, manufacturing and pre-commercialization activities needed for potential regulatory approval and commercialization of lumateperone in patients with schizophrenia. With the remaining proceeds from our public offerings in March and September 2015 and October 2017, we believe that we have the funds to complete our ongoing clinical trials of lumateperone in bipolar disorder as a monotherapy and as an adjunctive therapy with lithium or valproate and our ongoing clinical trial of ITI-007 for the treatment of agitation in patients with dementia, including AD. We also plan to fund additional clinical trials of lumateperone for the treatment of behavioral disturbances in dementia; preclinical and clinical development of ITI-007 long acting injectable development program; additional clinical trials of lumateperone; continued clinical development of our PDE program, including ITI-214; research and preclinical development of our other product candidates; and the continuation of manufacturing activities in connection with the development of lumateperone. We anticipate requiring additional funds to obtain regulatory approval for lumateperone in patients with dementia, including AD, for further development of lumateperone in patients with bipolar disorder, depressive disorders 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. For the year ended December 31, 2017, we used net cash in operating activities and purchases of equipment of approximately $85.2 million. This total does not include an offset for $4.0 million of interest income received. While we have several research and development programs underway, the lumateperone 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 the activities necessary to pursue FDA approval of lumateperone and our other product candidates, we expect the amount of cash to be used to fund operations to increase over the next several years.

With the termination of the Takeda License Agreement in October 2014, we are responsible for the costs of developing ITI-214. On September 15, 2015, Takeda completed the transfer of the IND for ITI-214 to us. We intend to pursue the development of our PDE1 program, including ITI-214 for the treatment of several CNS and non-CNS conditions. We anticipate a moderate increase in our operating expenses related to our PDE development programs. Following the positive safety and tolerability results in our Phase 1 program, we have initiated our development program for ITI-214 for Parkinson’s disease and commenced patient enrollment in the third quarter of 2017 in a Phase 1/2 clinical trial of ITI-214 in patients with Parkinson’s disease to evaluate safety and tolerability in this patient population, as well as motor and non-motor exploratory endpoints. We also plan to initiate a randomized, double-blind, placebo-controlled study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure in the first quarter of 2018. We expect these expenses to increase for 2018 and beyond.

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, 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 September 2, 2016, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 14, 2016, on which we registered for sale up to $350 million of any combination of our 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. After the public offering in October 2017, approximately $178 million of securities remain available for issuance under this shelf registration statement. 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 lumateperone 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 we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

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 lumateperone, 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 mutual funds, U.S. government agency securities, 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. We do not expect interest income to be a significant source of funding over the next several quarters. 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.

In 2014, we entered into a long-term lease, which was amended in December 2015, for 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Due to the amortization of total lease payments, we have recognized $3.0 million of deferred rent through the end of 2017. We occupied these facilities as our headquarters in March 2015, replacing our previous laboratories and offices. The lease, as amended, has a term of 12 years. We expect that our facility related costs will increase moderately from year to year as a result of leasing this facility

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**Contractual Obligations and Commitments**

Total contractual obligations as of December 31, 2017 are summarized in the following table (in thousands):

| | Payments Due By Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 2-3 Years | 4-5 Years | More than 5 Years |
| Operating Lease Obligations | $14,956 | $ 1,457 | $3,046 | $3,232 | $ 7,221 |

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 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 stock-based compensation and clinical trial accruals. 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:

***Research and Development***

Except for payments made in advance of services, we expense our research and development costs as incurred. For payments made in advance, we recognize 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, manufacturing of drug product, outside services, providers, materials and consulting fees.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to us by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing its financial statements, we are required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. Our objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. We account for these expenses according to the progress of the clinical trial as measured by subject progression and the timing of various aspects of the trial. We determine accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, we adjust its clinical expense recognition if actual results differ from its estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. Our clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations, clinical sites and other third-party vendors. Although we do not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2017 and 2016, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

***Stock-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 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. Share-based compensation expense recognized in the statements of operations for the years ended December 31, 2017, 2016 and 2015 is based on share-based awards ultimately expected to vest.

We utilize 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 a combination of the historical volatility of the common stock of comparable publicly traded entities and the limited historical information about 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 limited historical exercise data, the expected life is determined using the "simplified method," which defines expected life as the midpoint between the vesting date and the end of the contractual term.

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

Prior to January 1, 2014, at which time there was no active market for our common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in our business development and performance, the price per share of its convertible preferred stock offerings, and general industry and economic trends. In establishing the estimated fair value of the 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*. For stock options granted on or after January 1, 2014, the exercise price was determined by using the closing market price of our common stock on the date of grant.

An RSU is a stock award that entitles the holder to receive shares of our common stock as the award vests. The fair value of each RSU is based on the fair market value of our common stock on the date of grant. We have granted RSUs that vest in three equal annual installments provided that the employee remains employed with us.

Beginning in the first quarter of 2016, we granted time based RSUs that vest in three equal annual installments. In the first quarter of 2017, we granted additional time-based RSUs as well as performance-based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of an NDA with the FDA, (ii) the approval of the NDA by the FDA (collectively, the "Milestone RSU grants") and (iii) the achievement of certain comparative shareholder returns against the Company's peers (the "TSR RSU grants") . The Milestone RSU grants were valued at the closing price on March 8, 2017. The RSUs that vest upon the NDA submission will be amortized through December 31, 2018 based on the probable vesting date. The amortization of the expenses for RSUs related to the approval of the NDA will commence if and when the NDA filing has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSU grants were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSU agreements which ends December 31, 2019. The Milestone RSU grants and TSR RSU grants are target based and the ultimate awards, if attained, could be the target amount or higher or lower than the target amount, depending on the timing or achievement of the goal.

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 have net operating loss carryforwards as of December 31, 2017, 2016 and 2015, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. In March 2016, the FASB issued ASU 2016-09. ASU 2016-09 simplifies several areas of accounting for stock compensation, including simplification of the accounting for income taxes, classification of excess tax benefits on the Statement of Cash Flows and forfeitures. As of January 1, 2017, the Company adopted ASU 2016-09 for the quarter ended March 31, 2017. Accordingly, the Company recognized previously unrecognized excess tax benefits of $9.7 million recorded as deferred tax assets with a corresponding offsetting full valuation allowance at the beginning of 2017, which yielded no tax impact.

Equity instruments issued to non-employees for services 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 required services 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 FASB issued ASC Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), which has been subsequently updated (as updated, "ASC Topic 606"). The purpose of ASC Topic 606 is to provide enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies using U.S. GAAP and International Financial Reporting Standards. The core principle requires entities to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration to which an entity expects to be entitled in exchange for those goods or services. ASC Topic 606 becomes effective for annual periods beginning after December 15, 2017, at which point we plan to adopt the standard. We currently plan to adopt the standard using the "modified retrospective method." Under that method, we will apply the standard to contracts whose performance has not been completed as of January 1, 2018, and recognize the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings.

We do not expect the adoption of this standard to result in a material impact to its financial statements. Upon adopting FASB ASC Topic 606, we will provide additional disclosures in the notes to the consolidated financial statements related to the relevant aspects of any revenue generating contracts that we have or into which we expect to enter.

In 2018, we are implementing new internal controls as part of its efforts to adopt the new revenue recognition standard. These internal controls include providing training to our finance team and holding regular meetings with our management and the Audit Committee of the Company's Board of Directors to review and approve key decisions. Upon adoption, we expect to implement new internal controls related to its accounting policies and procedures. We will require new internal controls to address risks associated with applying the five-step model. Additionally, we will establish monitoring controls to identify sales arrangements and changes in the Company's business environment that could impact its current accounting assessment. We expect to finalize its impact assessment and redesign impacted processes, policies and controls prior to commercializing our products.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. The standard also clarifies the need to evaluate a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with our other deferred tax assets. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 allows the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and early adoption is permitted. We are currently analyzing the impact of ASU 2016-02 and, at this time, has not yet determined the impact of the new standard, if any, on our consolidated financial statements.

### Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

*Interest Rate Sensitivity.* As of December 31, 2017, we had cash, cash equivalents and marketable securities of $464.3 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, although the recent rise in interest rates has resulted in our unrealized loss on investments as of December 31, 2017 and 2016 totaling approximately $0.8 million and $0.3 million, respectively. Since we plan on holding those investments to maturity, no recognition of impairment is required. 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.


| Index to Financial Statements and Financial Statement Schedules | Number |
|---|---|
| Report of Independent Registered Public Accounting Firm | F-1 |
| Consolidated Balance Sheets as of December 31, 2017 and 2016 | F-2 |
| Consolidated Statements of Operations for the Years Ended December 31, 2017, 2016 and 2015 | F-3 |
| Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2017, 2016 and 2015 | F-4 |
| Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2017, 2016 and 2015 | F-5 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2017, 2016 and 2015 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |


### 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, 2017. 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 (2013).

Based on our assessment, management believes that, as of December 31, 2017, the company's internal control over financial reporting is effective based on those criteria.

Our independent registered public accounting firm has issued an audit report on our assessment of our internal control over financial reporting. This report appears further below in this Item 9A.

**Changes in Internal Controls**

There were no changes in our internal control over financial reporting during the fourth quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Report of Independent Registered Public Accounting Firm**

To the Stockholders and Board of Directors of Intra-Cellular Therapies, Inc.

**Opinion on Internal Control over Financial Reporting**

We have audited Intra-Cellular Therapies, Inc. and subsidiaries' internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Intra-Cellular Therapies, Inc. and subsidiaries' (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively referred to as the "financial statements") of the Company and our report dated March 1, 2018 expressed an unqualified opinion thereon.

**Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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. Also, 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.

/s/ Ernst & Young LLP

Baltimore, MD
March 1, 2018

**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 2018 Annual Meeting of Stockholders.

### Item 11. EXECUTIVE COMPENSATION

The response to this item is incorporated by reference from the discussion responsive thereto under the captions “Executive Officer and Director Compensation,” “Compensation Discussion and Analysis,” “Management and Corporate Governance—Compensation Committee Interlocks and Insider Participation,” “Compensation Committee Report” and “Risks Related to Compensation Practices and Policies” in the Company’s Proxy Statement for the 2018 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 2018 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 2018 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 2018 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 |

| Exhibit Number | | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|---|
| 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 |
| | .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 | | Supply Agreement dated as of January 4, 2017 by and between Siegfried Evionnaz SA and ITI Limited.** | | 10-K (Exhibit 10.3) | 3/1/2017 | 001-36274 |
| 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 | .1 | Employment Agreement effective as of August 3, 2015 by and between Michael I. Halstead and Intra-Cellular Therapies, Inc.* | | 10-Q (Exhibit 10.1) | 11/5/2015 | 001-36274 |
| | .2 | Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Michael I. Halstead and Intra-Cellular Therapies, Inc.* | | 10-Q (Exhibit 10.1) | 11/9/2016 | 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 | 001-36274 |
| 10.6 | .1 | Employment Agreement effective as of November 4, 2015 by and between Robert Davis, Ph.D. and Intra-Cellular Therapies, Inc.* | | 10-K (Exhibit 10.6) | 2/25/2016 | 001-36274 |
| | .2 | Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Robert Davis, Ph.D. and Intra-Cellular Therapies, Inc.* | | 10-Q (Exhibit 10.2) | 11/9/2016 | 001-36274 |

| Exhibit Number | | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|---|
| 10.7 | .1 | Employment Agreement effective as of November 5, 2015 by and between Kimberly Vanover, Ph.D. and Intra-Cellular Therapies, Inc.* | | 10-K (Exhibit 10.7) | 2/25/2016 | 000-54896 |
| | .2 | Amendment No.1 to Employment Agreement dated as of November 9, 2016 by and between Kimberly Vanover, Ph.D. and Intra-Cellular Therapies, Inc.* | | 10-Q (Exhibit 10.3) | 11/9/2016 | 001-36274 |
| 10.8 | | Employment Agreement effective as of November 13, 2017 by and between Andrew Satlin, M.D. and Intra-Cellular Therapies, Inc.* | X | | | |
| 10.9 | | 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 |
| 10.10 | | Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of July 29, 2014 by and between Michael Halstead and Intra-Cellular Therapies, Inc.* | | 10-K (Exhibit 10.11) | 3/12/2015 | 001-36274 |
| 10.11 | | 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 |
| 10.12 | | Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of November 4, 2015 by and between Robert Davis, Ph.D. and Intra-Cellular Therapies, Inc.* | | 10-K (Exhibit 10.11) | 2/25/2016 | 001-36274 |
| 10.13 | | 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 |
| 10.14 | | Employee Proprietary Information, Inventions, Inventions, and Non-Competition Agreement effective as of November 13, 2017 by and between Andrew Satlin, M.D. and Intra-Cellular Therapies, Inc.* | X | | | |

| Exhibit Number | | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|---|
| 10.15 | | 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 |
| 10.16 | | 2003 Equity Incentive Plan, as amended.* | | 8-K (Exhibit 10.14) | 9/5/2013 | 000-54896 |
| 10.17 | | Form of Stock Option Agreement under the 2003 Equity Incentive Plan, as amended.* | | 8-K (Exhibit 10.15) | 9/5/2013 | 000-54896 |
| 10.18 | | Amended and Restated 2013 Equity Incentive Plan.* | | 8-K (Exhibit 10.1) | 6/18/2015 | 001-36274 |
| 10.19 | | Form of Stock Option Agreement under the 2013 Equity Incentive Plan.* | | 10-K (Exhibit 10.19) | 3/25/2014 | 001-36274 |
| 10.20 | | Non-Employee Director Compensation Policy, as amended.* | X | | | |
| 10.21 | | 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 |
| 10.22 | | 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 |
| 10.23 | | 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. | | 10-K (Exhibit 14.1) | 2/25/2016 | 001-36274 |
| 21.1 | | Subsidiaries. | | 10-K (Exhibit 21.1) | 3/1/2017 | 001-36274 |
| 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 | | | |

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| Exhibit Number | Exhibit Description | Filed Herewith | Incorporated by Reference herein from Form or Schedule | Filing Date | SEC File/ Reg. Number |
|---|---|---|---|---|---|
| .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.

**Item 16. Form 10-K Summary**

Not Applicable.

## SIGNATURES

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 1, 2018

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 and on the dates indicated.

| Signatures | Title | Date |
|---|---|---|
| By: /s/ Sharon Mates, Ph.D.<br>Sharon Mates, Ph.D. | Chairman, President and Chief Executive Officer (principal executive officer) | March 1, 2018 |
| By: /s/ Lawrence J. Hineline<br>Lawrence J. Hineline | Vice President of Finance and Chief Financial Officer (principal financial officer and principal accounting officer) | March 1, 2018 |
| By: /s/ Christopher Alafi, Ph.D.<br>Christopher Alafi, Ph.D. | Director | March 1, 2018 |
| By: /s/ Richard Lerner, M.D.<br>Richard Lerner, M.D. | Director | March 1, 2018 |
| By: /s/ Joel S. Marcus<br>Joel S. Marcus | Director | March 1, 2018 |
| By: /s/ Rory B. Riggs<br>Rory B. Riggs | Director | March 1, 2018 |
| By: /s/ Robert L. Van Nostrand<br>Robert L. Van Nostrand | Director | March 1, 2018 |

## Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Intra-Cellular Therapies, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Intra-Cellular Therapies, Inc. and subsidiaries (the Company) as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2017 and 2016, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2018 expressed an unqualified opinion thereon.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.
Baltimore, MD
March 1, 2018

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Balance Sheets

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | **$ 37,790,114** | $ 48,642,225 |
| Investment securities, available-for-sale | **426,540,921** | 335,458,459 |
| Accounts receivable | **—** | 94,339 |
| Prepaid expenses and other current assets | **4,884,293** | 4,005,093 |
| Total current assets | **469,215,328** | 388,200,116 |
| Property and equipment, net | **1,137,171** | 627,614 |
| Long term deferred tax asset, net | **1,058,435** | — |
| Other assets | **75,765** | 75,765 |
| Total assets | **$ 471,486,699** | $ 388,903,495 |
| **Liabilities and stockholders’ equity** | | |
| Current liabilities: | | |
| Accounts payable | **$ 6,173,539** | $ 3,754,647 |
| Accrued and other current liabilities | **6,424,221** | 5,329,293 |
| Accrued employee benefits | **1,611,846** | 1,448,394 |
| Total current liabilities | **14,209,606** | 10,532,334 |
| Long-term deferred rent | **2,840,132** | 2,868,622 |
| Total liabilities | **17,049,738** | 13,400,956 |
| Stockholders’ equity: | | |
| Common stock, $.0001 par value: 100,000,000 shares authorized; 54,597,679 and 43,292,906 shares issued and outstanding at December 31, 2017 and 2016, respectively | **5,460** | 4,329 |
| Additional paid-in capital | **862,479,505** | 685,290,815 |
| Accumulated deficit | **(407,248,780)** | (309,475,366) |
| Accumulated comprehensive loss | **(799,224)** | (317,239) |
| Total stockholders’ equity | **454,436,961** | 375,502,539 |
| Total liabilities and stockholders’ equity | **$ 471,486,699** | $ 388,903,495 |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Operations

| | Years Ended December 31, 2017 | 2016 | 2015 |
|---|---|---|---|
| Revenues: | | | |
| License and collaboration revenue | **$ —** | $ — | $ 30,659 |
| Grant revenue | **245,837** | 330,702 | 60,705 |
| Total revenues | **245,837** | 330,702 | 91,364 |
| Costs and expenses: | | | |
| Research and development | **79,419,009** | 93,831,530 | 87,718,074 |
| General and administrative | **23,666,957** | 24,758,063 | 18,187,286 |
| Total costs and expenses | **103,085,966** | 118,589,593 | 105,905,360 |
| Loss from operations | **(102,840,129)** | (118,258,891) | (105,813,996) |
| Interest income | **(4,005,864)** | (2,935,077) | (1,022,455) |
| Interest expense | **—** | 36,781 | — |
| Loss before (benefit) provision for income taxes | **(98,834,265)** | (115,360,595) | (104,791,541) |
| Income tax (benefit) expense | **(1,060,851)** | 1,065,673 | 1,600 |
| Net loss | **$ (97,773,414)** | $(116,426,268) | $(104,793,141) |
| Net loss per common share: | | | |
| Basic & Diluted | **$ (2.12)** | $ (2.69) | $ (2.91) |
| Weighted average number of common shares: | | | |
| Basic & Diluted | **46,181,926** | 43,240,188 | 36,069,237 |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Loss

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2017** | **2016** | **2015** |
| Net loss | **$ (97,773,414)** | $ (116,426,268) | $ (104,793,141) |
| Other comprehensive loss: | | | |
| Unrealized (loss) gain on investment securities | **(481,985)** | 273,171 | (485,777) |
| Comprehensive loss | **$ (98,255,399)** | $ (116,153,097) | $ (105,278,918) |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

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, 2014 | 29,499,059 | $2,950 | $208,912,345 | $ (88,255,957) | $ (104,633) | $ 120,554,705 |
| Common shares issued March 11, 2015 | 5,411,481 | 541 | 121,803,828 | — | | 121,804,369 |
| Common shares issued September 28, 2015 | 7,935,000 | 793 | 327,435,412 | — | | 327,436,205 |
| Exercise of stock options | 305,005 | 31 | 653,015 | — | | 653,046 |
| Stock issued for services | 5,330 | 1 | 182,598 | | | 182,599 |
| Share-based compensation | — | — | 10,890,905 | — | | 10,890,905 |
| Net loss | — | — | — | (104,793,141) | | (104,793,141) |
| Other comprehensive loss | — | — | — | — | (485,777) | (485,777) |
| Balance at December 31, 2015 | 43,155,875 | $4,316 | $669,878,103 | $(193,049,098) | $ (590,410) | $ 476,242,911 |
| Exercise of stock options | 123,745 | 12 | 477,722 | — | | 477,734 |
| Restricted Stock issued to employee | 1,757 | — | — | | | — |
| Stock issued for services | 11,529 | 1 | 233,771 | | | 233,772 |
| Share-based compensation | — | — | 14,701,219 | — | | 14,701,219 |
| Net loss | — | — | — | (116,426,268) | | (116,426,268) |
| Other comprehensive gain | — | — | — | — | 273,171 | 273,171 |
| Balance at December 31, 2016 | **43,292,906** | **$4,329** | **$685,290,815** | **$(309,475,366)** | **$ (317,239)** | **$ 375,502,539** |
| Common shares issued October 2017 | **11,129,032** | **1,113** | **162,071,143** | | | **162,072,256** |
| Exercise of stock options and issuances of restricted stock | **162,642** | **17** | **285,143** | **—** | | **285,160** |
| Stock issued for services | **13,099** | **1** | **190,884** | | | **190,885** |
| Share-based compensation | **—** | **—** | **14,641,520** | **—** | | **14,641,520** |
| Net loss | **—** | **—** | **—** | **(97,773,414)** | | **(97,773,414)** |
| Other comprehensive loss | **—** | **—** | **—** | **—** | **(481,985)** | **(481,985)** |
| Balance at December 31, 2017 | **54,597,679** | **$5,460** | **$862,479,505** | **$(407,248,780)** | **$ (799,224)** | **$ 454,436,961** |

*See accompanying notes to consolidated financial statements.*

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Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

| | Years Ended December 31, 2017 | 2016 | 2015 |
|---|---|---|---|
| **Operating activities** | | | |
| Net loss | **$ (97,773,414)** | $(116,426,268) | $(104,793,141) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation expense | **213,872** | 196,872 | 139,626 |
| Share-based compensation expense | **14,641,520** | 14,701,219 | 10,890,905 |
| Issuance of stock for services | **190,885** | 233,772 | 182,599 |
| Amortization of premiums on investment activities | **429,839** | 544,354 | 712,675 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | **94,339** | (63,679) | 20,943 |
| Prepaid expenses and other assets | **(879,200)** | 4,016,164 | (6,737,125) |
| Long term deferred tax asset, net | **(1,058,435)** | — | — |
| Accounts payable | **2,418,892** | 2,121,742 | (419,860) |
| Accrued liabilities and employee benefits | **1,211,103** | 2,147,080 | (3,873,692) |
| Deferred rent | **18,787** | 1,271,517 | 1,597,105 |
| Net cash used in operating activities | **(80,491,812)** | (91,257,227) | (102,279,965) |
| **Investing activities** | | | |
| Purchases of investments | **(520,926,824)** | (395,757,168) | (514,308,249) |
| Maturities of investments | **428,932,538** | 488,068,547 | 153,389,448 |
| Purchases of property and equipment | **(723,429)** | (48,964) | (860,595) |
| Net cash (used in) provided by investing activities | **(92,717,715)** | 92,262,415 | (361,779,396) |
| **Financing activities** | | | |
| Proceeds from line of credit | — | 125,000,000 | — |
| Repayment of line of credit | — | (125,000,000) | — |
| Proceeds from stock option exercises | **285,160** | 477,734 | 653,046 |
| Proceeds of public offerings | **162,149,996** | — | 449,996,887 |
| Payment of costs of public offerings | **(77,740)** | — | (756,313) |
| Net cash provided by financing activities | **162,357,416** | 477,734 | 449,893,620 |
| Net (decrease) increase in cash and cash equivalents | **(10,852,111)** | 1,482,922 | (14,165,741) |
| Cash and cash equivalents at beginning of period | **48,642,225** | 47,159,303 | 61,325,044 |
| Cash and cash equivalents at end of period | **$ 37,790,114** | $ 48,642,225 | $ 47,159,303 |
| Cash paid for interest | **$ —** | $ 36,781 | $ — |
| Cash paid for taxes | **$ —** | $ 1,000,000 | $ — |

*See accompanying notes to consolidated financial statements.*

Intra-Cellular Therapies, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

December 31, 2017

**1. Organization**

Intra-Cellular Therapies, Inc. (the “Company”), through its wholly-owned operating subsidiaries, ITI, Inc. (“ITI”) and ITI Limited, 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, lumateperone, is in Phase 3 clinical development as a novel treatment for schizophrenia, bipolar depression and agitation associated with dementia, including Alzheimer’s disease.

The Company was 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 (the “Merger”), Oneida Resources Corp. was a “shell” company registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), with no specific business plan or purpose until it began operating the business of ITI, through the Merger transaction on August 29, 2013. ITI was incorporated in Delaware in May 2001 to focus primarily on the development of novel drugs for the treatment of neuropsychiatric and neurologic diseases and other disorders of the 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.

In September 2016, the Company licensed certain intellectual property rights to its wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. Although the license of intellectual property rights did not result in any gain or loss in the consolidated statements of operations, the $125 million of gain related to the transaction helped generate net taxable income for tax purposes in the U.S. and the Company utilized a portion of its available federal and state net operating loss carryforwards to offset the majority of this gain. Any taxes incurred related to intercompany transactions were treated as tax expense in the Company’s consolidated statement of operations. In addition to the license, the Company also entered into a research and development agreement with ITI Limited pursuant to which the Company will conduct research and development services related to the license agreement and charge ITI Limited for these services.

On October 2, 2017 and October 5, 2017, the Company completed a public offering of common stock in which the Company sold 11,129,032 shares of common stock, which included the exercise of the underwriters’ option to purchase an additional 1,451,613 shares, at an offering price of $15.50 per share for aggregate gross proceeds of approximately $172 million. After deducting underwriting discounts, commissions and offering expenses, the net proceeds to the Company were approximately $162 million.

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 September 2, 2016, 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 14, 2016, on which the Company registered for sale up to $350 million of any combination of its common stock, preferred stock, debt securities, warrants, rights, purchase contracts and/or units from time to time and at prices and on terms that the Company may determine. After the public offering in October 2017, approximately $178 million of securities remain available for issuance under this shelf registration statement. This registration statement will remain in effect for up to three years from the initial effective date.

## 2. Summary of Significant Accounting Policies

### Basis of Presentation

The accompanying consolidated financial statements of Intra-Cellular Therapies, Inc. and its wholly own subsidiaries have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles set forth in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). All intercompany accounts and transactions have been eliminated in consolidation. The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is discovering and developing drugs for the treatment of neurological and psychiatric disorders.

### Use of Estimates

The preparation of financial statements in conformity with GAAP 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 mutual funds, and certificates of deposit with a maturity date of three months or less. The carrying values of cash and cash equivalents approximate the fair market value. 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.

### Investment Securities

Investment 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 consisted of the following (in thousands):

| | December 31, 2017 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized (Losses) | Estimated Fair Value |
| U.S. government agency securities | $126,330 | $ — | $ (348) | $125,982 |
| FDIC certificates of deposit (1) | 8,306 | — | — | 8,306 |
| Certificates of deposit | 103,500 | — | — | 103,500 |
| Commercial paper | 51,414 | — | (61) | 51,353 |
| Corporate bonds/notes | 137,790 | — | (390) | 137,400 |
| | $427,340 | $ — | $ (799) | $426,541 |

| | December 31, 2016 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized (Losses) | Estimated Fair Value |
| U.S. government agency securities | $ 67,199 | $ 1 | $ (74) | $ 67,126 |
| FDIC certificates of deposit (1) | 20,740 | 1 | — | 20,741 |
| Certificates of deposit | 64,500 | — | — | 64,500 |
| Commercial paper | 67,352 | 11 | (52) | 67,311 |
| Corporate bonds/notes | 115,985 | — | (205) | 115,780 |
| | $335,776 | $ 13 | $ (331) | $335,458 |

(1) “FDIC certificates of deposit” consist of deposits that are $250,000 or less.

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, 2017 and 2016, the Company held $93.3 million and $47.9 million, respectively, of available-for-sale investment securities with contractual maturity dates more than one year and less than two years.

The Company monitors its investment portfolio for impairment quarterly or more frequently if circumstances warrant. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, the Company records an impairment charge within earnings attributable to the estimated credit loss. In determining whether a decline in the value of an investment is other-than-temporary, the Company evaluates currently available factors that may include, among others: (1) general market conditions; (2) the duration and extent to which fair value has been less than the carrying value; (3) the investment issuer’s financial condition and business outlook; and (4) the Company’s assessment as to whether it is more likely than not that the Company will be required to sell a security prior to recovery of its amortized cost basis. As of December 31, 2017, the Company had $37.3 million of investments that had been held for greater than one year that have a temporary impairment of approximately $42,000. As of December 31, 2016, the Company had approximately $25.5 million of investments that have been held for greater than one year which had a temporary impairment of approximately $25,000.

The Company attributes the unrealized losses on the available-for-sale securities as of December 31, 2017 and 2016 to the rise in related market interest rates. The Company does not intend to sell these securities, nor is it more likely than not that the Company will be required to sell them prior to the end of their contractual terms. Furthermore, the Company does not believe that these securities expose the Company to undue market risk or counterparty credit risk. As such, the Company does not consider these securities to be other-than-temporarily impaired.

**2. Summary of Significant Accounting Policies (continued)**

**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.

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, 2017 and December 31, 2016. The carrying value of cash held in money market funds of approximately $26.2 million as of December 31, 2017 and $10.7 million as of December 31, 2016 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):

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2017 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Money market funds | $ 26,181 | $ 26,181 | $ — | $ — |
| U.S. government agency securities | 125,982 | — | 125,982 | — |
| FDIC certificates of deposit | 8,306 | — | 8,306 | — |
| Certificates of deposit | 103,500 | — | 103,500 | — |
| Commercial paper | 51,353 | — | 51,353 | — |
| Corporate bonds/notes | 137,400 | — | 137,400 | — |
| | $ 452,722 | $ 26,181 | $ 426,541 | $ — |

**2. Summary of Significant Accounting Policies (continued)**

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2016 | Quoted Prices in Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Money market funds | $ 10,724 | $ 10,724 | $ — | $ — |
| U.S. government agency securities | 67,126 | — | 67,126 | — |
| FDIC certificates of deposit | 20,741 | — | 20,741 | — |
| Certificates of deposit | 64,500 | — | 64,500 | — |
| Commercial paper | 67,311 | — | 67,311 | — |
| Corporate bonds/notes | 115,780 | — | 115,780 | — |
| | $ 346,182 | $ 10,724 | $ 335,458 | $ — |

**Financial Instruments**

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued liabilities, to approximate their fair value because of their relatively short maturities at December 31, 2017 and December 31, 2016. 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, cash and cash equivalents 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.

**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 not probable.

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, 2017 and 2016, 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

**2. Summary of Significant Accounting Policies (continued)**

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.

**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, manufacturing of drug product, outside services, providers, materials and consulting fees.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information provided to the Company by its vendors with respect to their actual costs incurred. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the financial statements as prepaid or accrued research and development expense, as the case may be.

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the progress of the clinical trial as measured by subject progression and the timing of various aspects of the trial. The Company determines accrual estimates through financial models taking into account discussion with applicable personnel and outside service providers as to the progress or state of consummation of trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations, clinical sites and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2017 and 2016, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

**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 their 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

**2. Summary of Significant Accounting Policies (continued)**

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 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.

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. See the tax footnote below for further discussion related to the tax impact to the Company.

**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. Share-based compensation expense recognized in the statements of operations for the years ended December 31, 2017, 2016 and 2015 is based on share-based awards ultimately expected to vest.

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 a combination of the historical volatility of the common stock of comparable publicly traded entities and the limited historical information about 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 limited historical exercise data, the expected life is determined using the "simplified method," which defines expected life 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

**2. Summary of Significant Accounting Policies (continued)**

inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero.

Prior to January 1, 2014, at which time there was no active market for the Company's common stock, the exercise price of the stock options on the date of grant was determined and approved by the board of directors using several factors, including progress and milestones achieved in 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 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 stock options granted on or after January 1, 2014, the exercise price was determined by using the closing market price of the Company's common stock on the date of grant.

A restricted stock unit ("RSU") is a stock award that entitles the holder to receive shares of the Company's common stock as the award vests. The fair value of each RSU is based on the fair market value of the Company's common stock on the date of grant. The Company has granted RSUs that vest in three equal annual installments provided that the employee remains employed with the Company.

Beginning in the first quarter of 2016, the Company granted time based RSUs that vest in three equal annual installments. In the first quarter of 2017, the Company granted additional time-based RSUs as well as performance-based RSUs, which vest based on the achievement of certain milestones that include (i) the submission of a new drug application ("NDA") with the U.S. Food and Drug Administration (the "FDA"), (ii) the approval of the NDA by the FDA (the "Milestone RSU grants") and (iii) the achievement of certain comparative shareholder returns against the Company's peers (the "TSR RSU grants"). The Milestone RSU grants were valued at the closing price on March 8, 2017. The RSUs that vest upon the NDA submission will be amortized through December 31, 2018 based on the probable vesting date. The amortization of the expenses for RSUs related to the approval of the NDA will commence if and when the NDA filing has been approved through the last day of the calendar year in which the milestone is achieved. The TSR RSU grants were valued using the Monte Carlo Simulation method and will be amortized over the life of the RSU agreements which ends December 31, 2019. The Milestone RSU grants and TSR RSU grants are target based and the ultimate awards, if attained, could be the target amount or higher or lower than the target amount, depending on the timing or achievement of the goal. The expense recognition related to these equity grants is based on the Company's best estimate.

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 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, 2017, 2016 and 2015, no excess tax benefits for the tax deductions related to share-based awards were recognized in the statements of operations. In March 2016, the FASB issued ASU No. 2016-09, Compensation—Stock Compensation ("ASU 2016-09"). ASU 2016-09 simplifies several areas of accounting for stock compensation, including simplification of the accounting for income taxes, classification of excess tax benefits on the Statement of Cash Flows and forfeitures. As of January 1, 2017, the Company adopted ASU 2016-09 for the quarter ended March 31, 2017. Accordingly, the Company recognized previously unrecognized excess tax benefits of $9.7 million recorded as deferred tax assets with a corresponding offsetting full valuation allowance at the beginning of 2017, which yielded no tax impact.

Equity instruments issued to non-employees for services 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

**2. Summary of Significant Accounting Policies (continued)**

fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the required services 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 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 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 and RSUs.

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 net loss for the years ended December 31, 2017, 2016 and 2015:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2017 | 2016 | 2015 |
| Common Stock Equivalents | 476,252 | 1,225,614 | 1,322,311 |
| RSUs | 87,988 | 32,781 | — |
| TSR RSUs | 65,852 | — | — |

### Recently Issued Accounting Standards

In May 2014, the FASB issued ASC Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), which has been subsequently updated (as updated, "ASC Topic 606"). The purpose of ASC Topic 606 is to provide enhancements to the quality and consistency of how revenue is reported while also improving comparability in the financial statements of companies using U.S. GAAP and International Financial Reporting Standards. The core principle requires entities to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration to which an entity expects to be entitled in exchange for those goods or services. ASC Topic 606 becomes effective for annual periods beginning after December 15, 2017, at which point the Company plans to adopt the standard. The Company currently plans to adopt the standard using the "modified retrospective method." Under that method, the Company will apply the standard to contracts whose performance has not been completed as of January 1, 2018, and recognize the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings.

The Company does not expect the adoption of this standard to result in a material impact to its financial statements. Upon adopting FASB ASC Topic 606, the Company will provide additional disclosures in the notes to the consolidated financial statements related to the relevant aspects of any revenue generating contracts that the Company has or into which the Company expects to enter.

In 2018, the Company is implementing new internal controls as part of its efforts to adopt the new revenue recognition standard. These internal controls include providing training to the Company's finance team and holding regular meetings with the Company's management and the Audit Committee of the Company's Board of Directors to review and approve key decisions. Upon adoption, the Company expects to implement new internal controls related to its accounting policies and procedures. The Company will require new internal controls to address risks associated with applying the five-step model. Additionally, the Company will establish monitoring controls to identify sales arrangements and changes in the Company's business environment that could impact its current accounting assessment. The Company expects to finalize its impact assessment and redesign impacted processes, policies and controls prior to commercializing its products.

In January 2016, the FASB issued ASU No. 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 eliminates the requirement to disclose the methods and

**2. Summary of Significant Accounting Policies (continued)**

significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. The standard also clarifies the need to evaluate a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the Company's other deferred tax assets. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 allows the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. The classification criteria for distinguishing between finance leases and operating leases are substantially similar to the classification criteria for distinguishing between capital leases and operating leases in the previous leases guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018 and early adoption is permitted. The Company is currently analyzing the impact of ASU 2016-02 and, at this time, has not yet determined the impact of the new standard, if any, on the Company's consolidated financial statements.

**3. Property and Equipment**

Property and equipment consist of the following:

| | December 31, 2017 | December 31, 2016 |
|---|---|---|
| Computer equipment | $ 33,584 | $ 39,095 |
| Furniture and fixtures | 301,509 | 292,423 |
| Scientific equipment | 3,494,866 | 2,844,865 |
| | 3,829,959 | 3,176,383 |
| Less accumulated depreciation | (2,692,788) | (2,548,769) |
| | $ 1,137,171 | $ 627,614 |

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was $213,872, $196,872 and $139,626, respectively.

**4. Share-Based Compensation**

The Company's Amended and Restated 2013 Equity Incentive Plan (the "Plan") provides for the granting of stock-based awards, such as stock options, restricted common stock, RSUs and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. As of December 31, 2017, there were options to purchase 3,755,736 shares of common stock outstanding under the Plan. On June 16, 2015, the stockholders of the Company approved, at the Company's 2015 Annual Meeting of Stockholders, an amendment to the Plan to increase the number of shares of common stock available for issuance under the Plan by 3,100,000 shares, to increase by 100,000 shares the maximum number of shares available for the issuance of options, stock appreciation rights and other similar awards to any one participant in any calendar year for purposes of meeting the requirements for qualified performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended in 2017 (the "Code"), and to eliminate the evergreen provisions of the Plan under which 800,000 shares were automatically added to the plan on each of January 1, 2014 and 2015. Stock options granted under the Plan may be either incentive stock options ("ISOs") as defined by the Code, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally two 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 Plan must be at least equal to the fair market value of the common stock on the date of grant.

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**4. Share-Based Compensation (continued)**

Total stock-based compensation expense related to all of the Company's share-based awards, including stock options and RSUs granted to employees, directors and consultants recognized during the years ended December 31, 2017, 2016 and 2015, was comprised of the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2017** | **2016** | **2015** |
| Research and development | **$ 5,082,823** | $ 4,472,658 | $ 4,768,131 |
| General and administrative | **9,558,697** | 10,228,561 | 6,122,774 |
| Total share-based compensation expense | **$ 14,641,520** | $ 14,701,219 | $ 10,890,905 |

The following table describes the assumptions used for calculating the value of options granted during the years ended December 31, 2017, 2016 and 2015:

| | **2017** | **2016** | **2015** |
|---|---|---|---|
| Dividend yield | **0%** | 0% | 0% |
| Expected volatility | **87.4%-90.4%** | 80.0%-90.0% | 80.0% |
| Weighted-average risk-free interest rate | **2.1%** | 1.7% | 1.8% |
| Expected term (in years) | **6.0** | 5.9 | 5.9 |

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of December 31, 2017, 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, 2016 | 3,101,032 | $ 19.63 | $9,351,908 | 7.18 years |
| Options granted | 982,993 | $ 15.08 | | 9.29 years |
| Options exercised | (135,999) | $ 2.27 | | 2.28 years |
| Options canceled or expired | (192,290) | $ 25.79 | | 7.91 years |
| Outstanding at December 31, 2017 | 3,755,736 | $ 18.75 | $7,450,293 | 7.04 years |
| Vested or expected to vest at December 31, 2017 | 3,755,736 | $ 18.75 | | |
| Exercisable at December 31, 2017 | 2,362,595 | $ 16.86 | $7,212,195 | 6.19 years |

The weighted-average grant date fair value for awards granted during the years ended December 31, 2017, 2016 and 2015 was $15.08, $48.85 and $21.00 per share, respectively. Total intrinsic value of the options exercised during the years ended December 31, 2017, 2016 and 2015 was approximately $1,609,268, $2,984,283 and $10,951,057, respectively. The total fair value of shares vested in the years ended December 31, 2017, 2016 and 2015 was approximately $7,212,195, $9,310,898 and $5,207,073, respectively.

During 2017, 2016 and 2015, the Company granted options to certain scientific advisory board members of the Company to purchase 0, 5,000 and 45,571 shares of common stock, respectively, at an average exercise price per share of $0, $53.63 and $17.57, respectively. The options vest ratably over a period of 1 to 2 years. Stock compensation related to these grants will fluctuate with any changes in the underlying value of the Company's common stock.

As of December 31, 2017 and 2016, there were $2,866,164 and $3,022,843, respectively, of unrecognized compensation costs related to unvested time based RSUs which will be recognized over a weighted-average period 1.5 years. The unrecognized share-based compensation expense related to stock option awards at December 31, 2017 is $12,322,422 and will be recognized over a weighted-average period of 1.8 years.

**4. Share-Based Compensation (continued)**

The fair value of an RSU is based on the closing price of the Company's common stock on the date of grant. Information regarding RSU activity, including with respect to grants to employees as of December 31, 2017, and changes during the year then ended, is summarized as follows:

| | Number of Shares | Weighted-Average Grant Date Fair Value |
|---|---|---|
| Outstanding at December 31, 2016 | 82,321 | $ 53.77 |
| RSU's granted in 2017 | 154,922 | $ 15.73 |
| RSU's vested in 2017 | (28,013) | $ 53.84 |
| RSU's cancelled in 2017 | (18,297) | $ 26.80 |
| Outstanding at December 31, 2017 | 190,933 | $ 25.48 |

The Company recognized non-cash stock-based compensation expense related to RSU's for the years ended December 31, 2017 and 2016 of approximately $2.1 million and $1.5 million, respectively.

Information related to the Company's Milestone RSU grants and the TSR RSU grants during the year ended December 31, 2017 are summarized as follows:

| | Number of Shares | Weighted-Average Grant Date Fair Value Per Share |
|---|---|---|
| Outstanding at December 31, 2016 | — | $ — |
| RSU's granted in 2017 | 379,629 | $ 15.35 |
| RSU's cancelled in 2017 | (32,430) | $ 15.35 |
| Outstanding at December 31, 2017 | 347,199 | $ 15.35 |

The weighted average estimated fair value per share of the TSR RSUs granted in the year ended December 31, 2017 was $17.08, which was derived from a Monte Carlo simulation. Significant assumptions utilized in estimating the value of the awards granted include an expected dividend yield of 0%, a risk free rate of 1.6%, and expected volatility of 95.4%. The TSR RSUs granted in the year ended December 31, 2017 will entitle the grantee to receive a number of shares of the Company's common stock determined over a three-year performance period ending and vesting on December 31, 2019, provided the grantee remains in the service of the Company on the settlement date. The Company expenses the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs will be settled will be a percentage of shares for which the award is targeted and will depend on the Company's total shareholder return (as defined below), expressed as a percentile ranking of the Company's total shareholder return as compared to the Company's peer group (as defined below). The number of shares for which the TSR RSUs will be settled vary depending on the level of achievement of the goal. Total shareholder return is determined by dividing the average share price of the Company's common stock over the 30 calendar days preceding January 1, 2020 by the average share price of the Company's common stock on March 8, 2017, with a deemed reinvestment of any dividends declared during the performance period. The Company's peer group includes the companies which comprise the Nasdaq Biotechnology Index, which was selected by the Compensation Committee of the Company's Board of Directors and includes a range of biotechnology companies operating in several business segments.

As of December 31, 2017 and 2016 there were $4,177,362 and $0 respectively of unrecognized compensation costs related to unvested Milestone RSU grants and TSR RSU grants which will be recognized over a weighted average period of 1.9 years.

**5. Line of Credit**

On September 30, 2016, the Company entered into a secured line of credit with a lender for an amount not to exceed $150.8 million. This line of credit was secured by approximately $150.8 million of collateral held by the lender. The interest on advances under this line of credit was fixed at LIBOR plus 2.991% on the date of advance. The Company borrowed $125.0 million on September 30, 2016 and repaid the entire amount on October 3, 2016. Interest expense under this secured line of credit was $36,781 for the year ended December 31, 2016. On October 6, 2016, the line of credit was terminated by the Company.

**6. Income Taxes**

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act," or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under TCJA the Company revalued its ending net deferred tax assets at December 31, 2017 and given we are still subject to a valuation allowance did not recognize any tax expense (related to such reduced tax rate) in the Company's consolidated statement of income for the year ended December 31, 2017. However, the Company did provisionally recognize a $1.1 million tax benefit due to the release of the valuation allowance on its alternative minimum tax credit deferred tax asset as part of the TCJA. The TCJA repealed the corporate alternative minimum tax (AMT). Companies with AMT credit carryovers can generally use the credits to offset regular tax liability for any taxable year beginning in 2018. In addition, the AMT credit is refundable, subject to certain limitations, in any taxable year beginning after 2017. Lastly, any remaining AMT credit carryforward is fully refundable by 2022.

While the TCJA provide for a territorial tax system, beginning in 2018, it includes two new U.S. tax base erosion provisions, the global intangible low-taxed income ("GILTI") provisions and the base-erosion and anti-abuse tax ("BEAT") provisions.

The GILTI provisions require the Company to include in its U.S. income tax return foreign subsidiary earnings in excess of an allowable return on the foreign subsidiary's tangible assets. The Company may be subject to incremental U.S. tax on GILTI income in the future. The Company has elected to account for any GILTI tax in the period in which it is incurred, and therefore has not provided any deferred tax impacts of GILTI in its consolidated financial statements for the year ended December 31, 2017.

The BEAT provisions eliminates the deduction of certain base-erosion payments made to related foreign corporations, and impose a minimum tax if greater than regular tax. The Company does not expect it will be subject to this tax in 2018, but will continue to monitor. Therefore, the Company has not included any tax impacts of BEAT in its consolidated financial statements for the year ended December 31, 2017.

The SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company has recognized the provisional tax impacts related to the release of the valuation allowance with respect to AMT credits and the revaluation of deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. We continue to evaluate the effects of the TCJA and consider the amounts recorded to be provisional. Additional time is needed to ensure that we have fully analyzed and computed the tax effects of the 2017 Tax Act on our tax accounts. We will complete our accounting during the measurement period provided under SAB 118 as we obtain further clarity on the application of the TCJA to our particular facts and report appropriately in 2018.

**6. Income Taxes (continued)**

Income (loss) before income taxes is as follows:

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| U.S. | **$(20,486,935)** | $ (86,965,860) | $(104,791,541) |
| Non-U.S. | **(78,347,330)** | (28,394,735) | — |
| Total loss before taxes | **(98,834,265)** | (115,360,595) | $(104,791,541) |

Total income tax (benefit) expense for the years ended December 31, 2017, 2016 and 2015 is allocated as follows:

| | 2017 | 2016 | 2015 |
|---|---|---|---|
| Current | $ (2,416) | $ 1,065,673 | $ 1,600 |
| Deferred | 13,713,987 | 19,605,520 | 51,165,859 |
| Valuation allowance | (14,772,422) | (19,605,520) | (51,165,859) |
| (Benefit) provision for income taxes | $ (1,060,851) | $ 1,065,673 | $ 1,600 |

A reconciliation of the difference between the statutory federal income tax rate and the effective income tax rate for the years ended December 31, 2017, 2016 and 2015 is as follows:

| | | December 31, | |
|---|---|---|---|
| | 2017 | 2016 | 2015 |
| Income tax benefit at statutory federal rate | 35.00% | 35.00% | 35.00% |
| Royalty Income | 0.00 | (37.93) | 0.00 |
| Other Permanent differences | (0.43) | (0.78) | (0.56) |
| Foreign rate differential | (27.75) | (8.61) | 0.00 |
| 2017 US Tax Reform impact | (21.89) | (0.03) | 0.00 |
| R&D Credit | (0.05) | 2.11 | 4.19 |
| Change in effective state tax rates | 0.84 | (6.98) | (0.05) |
| State income tax expense | 0.40 | (0.70) | 10.24 |
| Change in valuation allowance | 14.95 | 16.99 | (48.82) |
| Benefit (provision) for income taxes | 1.07% | (0.93)% | (0.00)% |

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, 2017, the Company had $131.1 million of federal net operating loss carryforwards, which expire at various dates through 2035. 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. For the year ended December 31, 2017, the Company performed a Section 382 ownership analysis and determined that an ownership change occurred (within the meaning of Section 382 of the Code) in 2015 but not in subsequent periods. Based on the analysis performed, however, the Company does not believe that the Section 382 annual limitation will impact the Company's ability to utilize the tax attributes that existed as of the date of the ownership change in a material manner. If the Company experiences an ownership change in the future, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

**6. Income Taxes (continued)**

In September 2016, the Company licensed certain intellectual property rights to its wholly-owned subsidiary, ITI Limited, which was formed in the third quarter of 2016. The costs to develop, test, manufacture and perform other activities related to the lumateperone (also known as ITI-007) program will be the responsibility of ITI Limited and will be incurred outside of the United States. Therefore, the majority of expected losses incurred by the Company during the next several years will not result in additional NOLs to be carried forward and used against future net income in the U.S. The following summarizes the significant components of the Company's deferred tax assets and liabilities as of December 31, 2017 and 2016, respectively:

| | December 31, 2017 | 2016 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 40,746,589 | $ 49,627,652 |
| Accrued employee benefits | 378,058 | 535,158 |
| Research and development credit | 9,321,214 | 9,367,227 |
| Stock compensation | 8,711,721 | 9,360,025 |
| Federal AMT credit | 1,058,435 | 1,062,451 |
| Deferred rent | 699,560 | 1,095,220 |
| Unrealized comprehensive loss | 187,714 | — |
| Deferred tax liabilities: | | |
| Depreciation | (31,796) | (44,732) |
| Net deferred tax asset | 61,071,495 | 71,003,001 |
| Valuation allowance | (60,013,060) | (71,003,001) |
| Net deferred tax asset | $ 1,058,435 | $ — |

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 full valuation allowance against its net deferred tax assets, excluding the refundable alternative minimum tax credit in 2017, for financial reporting purposes because it is not more likely than not that these deferred tax assets will be realized.

The total amount of unrecognized tax benefits as of December 31, 2017 and December 31, 2016 were $1.7 million and $1.7 million, respectively. If recognized none of these tax benefits would affect the effective tax rate due to valuation allowances.

The following summarizes the significant components of gross unrecognized tax benefits as of December 31, 2017 and 2016, respectively:

| | December 31, 2017 | 2016 |
|---|---|---|
| Balance at January 1, | **$ 1,738,815** | $ 1,720,912 |
| Current Year Uncertain Tax Positions: | | |
| Gross Increases | — | 17,903 |
| Balance at December 31, | **$ 1,738,815** | $ 1,738,815 |

**7. 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

**7. Collaborations and License Agreements (continued)**

BMS relating to lumateperone 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 lumateperone 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 lumateperone 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.

In September 2016, the Company transferred certain of its rights under the BMS Agreement to its wholly owned subsidiary, ITI Limited. In connection with the transfer, the Company guaranteed ITI Limited's performance of its obligations under the BMS Agreement.

**8. Commitments and Contingencies**

The Company currently has an operating lease agreement with a commitment for $14,956,082 for laboratory and office facilities through 2027.

At December 31, 2017, 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 | |
|---|---|
| 2018 | 1,457,008 |
| 2019 | 1,500,718 |
| 2020 | 1,545,740 |
| 2021 | 1,592,112 |
| 2022 | 1,639,876 |
| Thereafter | 7,220,628 |
| | $ 14,956,082 |

Rent expense for the years ended December 31, 2017, 2016 and 2015 was $1,427,716, $1,419,940 and $1,385,207, respectively.

### 9. 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 made a matching contribution of 100% on the first 6% of contributions made by participants in the year ended December 31, 2017 and a matching contribution of 50% on the first 6% of contributions in prior years. Participant and Company contributions vest immediately. During the years ended December 31, 2017, 2016 and 2015, the Company recorded matching contribution expense of $378,233, $157,244 and $109,963, respectively.

### 10. Related Parties

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 16,753 square feet of useable laboratory and office space**.** The lease has a term of 12 years. The deferred rent balance began to decrease in the first quarter of 2017. A member of the Company's board of directors is the Chairman of the board of directors, Chief Executive Officer and President of the parent company to the landlord under this lease.

### 11. Unaudited Quarterly Financial Information

The tables herein set forth the Company's unaudited condensed consolidated 2017 and 2016 quarterly statements of operations.

*The following table sets for the Company's unaudited condensed consolidated statements of operations for the 2017 quarters ended:*

| 2017 Quarter Ended | December 31, | September 30, | June 30, | March 31, |
|---|---|---|---|---|
| Revenue | $ 5,055 | $ 30,754 | $ 114,741 | $ 95,287 |
| Net loss | (30,208,712) | (22,870,416) | (17,760,704) | (26,933,582) |
| Basic and diluted net loss per share | $ (0.56) | $ (0.53) | $ (0.41) | $ (0.62) |

*The following table sets for the Company's unaudited condensed consolidated statements of operations for the 2016 quarters ended:*

| 2016 Quarter Ended | December 31, | September 30, | June 30, | March 31, |
|---|---|---|---|---|
| Revenue | $ 97,895 | $ 4,362 | $ 228,445 | $ — |
| Net loss | (27,485,039) | (30,265,327) | (30,834,454) | (27,841,449) |
| Basic and diluted net loss per share | $ (0.64) | $ (0.70) | $ (0.71) | $ (0.64) |

**Exhibit 10.8**

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), is effective this 13th day of November, 2017 (the "Effective Date") between Dr. Andrew Satlin ("Executive") and Intra-Cellular Therapies, Inc. (the "Company").

1. Title; Capacity. Subject to terms set forth herein, the Company agrees to employ Executive in the position of Executive Vice President, Chief Medical Officer. Executive shall serve in an executive capacity and shall perform such duties as are assigned to Executive from time to time, consistent with the Bylaws of the Company and as required by the Company's Board of Directors (the "Board"). During the term of his employment with the Company, Executive will devote his best efforts and substantially all of his business time and attention to the business of the Company. Notwithstanding the foregoing, or any other provision of this Agreement, it shall not be a breach or violation of this Agreement for the Executive to (i) serve on civic or charitable boards or committees, (ii) with the express written permission of the Company serve on corporate boards of companies that do not present a conflict of interest or compete directly or indirectly with the Company, (iii) deliver lectures, fulfill speaking engagements or teach at educational institutions, or (iv) manage personal investments, so long as such activities do not significantly interfere with or significantly detract from the performance of the Executive's responsibilities to the Company in accordance with this Agreement. The Board has approved the Executive's participation in the activities listed on ***Schedule A*** to this Agreement.

2. Term. The term of this Agreement shall commence on the Effective Date, and shall continue for three (3) years from that date, unless terminated prior thereto by either the Company or the Executive as provided in Section 4. If either the Company or the Executive does not wish to renew this Agreement when it expires at the end of the initial or any renewal term hereof, as hereinafter provided, or if either the Company or the Executive wishes to renew this Agreement on different terms than those contained herein, it or he shall give written notice in accordance with Section 13 below of such intent to the other party at least sixty (60) days prior to the expiration date. In the absence of such notice, this Agreement shall be renewed on the same terms and conditions contained herein for a term of one year from the date of expiration. The parties expressly agree that designation of a term and renewal provisions in this Agreement does not in any way limit the right of the parties to terminate this Agreement at any time as hereinafter provided. Reference herein to the term of this Agreement shall refer both to the initial term and any successive term as the context requires. Should the Company elect not to renew this Agreement for reasons other than death or Disability (as defined in Section 4.3 below), or Cause (as defined in Section 4.1 below), the Executive shall be eligible for the same severance payments and benefits as Executive would receive under Section 5.2 and on the same conditions as if Executive had been terminated by the Company without Cause, *provided* that Executive executes a Release of claims in favor of the Company as defined in Section 5.2(a). *Provided however*, Executive shall not receive any such severance payments and benefits unless he executes the Release within the consideration period specified therein and until the Release becomes effective and can no longer be revoked by Executive under its terms. Executive's ability to receive such payment and benefits is further conditioned upon his: returning all Company property; complying with his post termination obligations under this Agreement and

the Proprietary Information, Inventions, and Non-Competition Agreement between the Executive and the Company; and complying with the Release including without limitation any non-disparagement and confidentiality provisions contained therein. Executive shall not be eligible for any severance payments and benefits if either the Executive or the Company wishes to renew this Agreement on different terms than those contained herein.

3. Compensation and Benefits.

3.1 Salary. Executive will receive for Executive's services to be rendered under this Agreement an initial annualized base salary at the rate of $500,000 per year, subject to annual review and adjustment by the Company in the discretion of the Board, payable subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

3.2 Incentive Compensation. In addition to Executive's Base Salary, the Executive shall be eligible during the term of this Agreement for such bonus payments and/or equity grants as awarded to the Executive by the Board.

3.3 Policies and Fringe Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. The Executive will be eligible to participate on the same basis as other executive level employees in the Company's benefit plans in effect from time to time during his employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. While this Agreement is in effect, the Company will provide the Executive with life insurance, for which the Executive may designate the beneficiary or beneficiaries in an amount of $150,000, and long-term disability insurance.

3.4 Reimbursement of Certain Expenses. The Company will reimburse Executive for reasonable business expenses in accordance with the Company's expense reimbursement policies.

4. Termination of Employment. Either Executive or the Company may terminate the employment relationship at any time, for any reason, in accordance with this Section 4.

4.1 Termination for Cause. At the election of the Company, the employment relationship may be terminated for Cause upon written notice by the Company to Executive specifying the provision or provisions of this Section 4.1 upon which the decision to terminate is based. For the purposes of this Section 4.1, "Cause" for termination shall be deemed to exist upon the occurrence of any of the following:

(a) a good faith finding by the Company that Executive has engaged in gross negligence or gross misconduct that is materially injurious to the Company;

(b) Executive's conviction of a felony or crime involving fraud or embezzlement of Company property;

(c) Executive's material breach of this Agreement which, if curable, has not been cured by Executive within 60 days after he shall have received written notice from the Company stating with reasonable specificity the nature of such breach;

(d) material breach of fiduciary duty; or

(e) refusal to follow or implement a clear and reasonable directive of the Board as a whole, or an officer of the Company, provided that such directive is ethical and legal and which, if curable, has not been cured by Executive within 60 days after he shall have received written notice from the Company stating with reasonable specificity the nature of such refusal.

4.2 Termination by the Company Without Cause or by the Executive for Good Reason. At the election of the Company it may terminate Executive's employment for reasons other than Cause, death or Disability, at any time upon written notice by the Company to Executive. The Executive may resign from Executive's employment for "Good Reason" within sixty (60) days after the occurrence of one of the events specified below, by giving prior written notice, *provided that* Executive has not consented in writing to one of the specified events or been notified previously of the Company's intention to terminate Executive's employment. As used in this Agreement Good Reason shall mean:

(a) The assignment to Executive of any duties or responsibilities which result in the material diminution of Executive's position;

(b) a 5% or greater reduction by the Company in Executive's annual Base Salary;

(c) a material change in the geographic location at which the Executive is required to perform services; or

(d) material breach by the Company of any material provision of this Agreement; *provided however*, that any actions taken by the Company to accommodate a disability of the Executive or pursuant to the Family and Medical Leave Act shall not be a Good Reason for purposes of this Agreement. Notwithstanding the occurrence of any of the events enumerated in Section 4.2 (a) through (d), such occurrence shall not be deemed to constitute Good Reason if, within 30 days after the giving by Executive of notice of the occurrence or existence of an event or circumstance specified above, such event or circumstance has been fully corrected (provided that such right of correction by the Company shall only apply to the first such notice given by Executive). In the absence of such correction, Executive's resignation shall be effective thirty (30) days following the Executive's notice.

4.3 Death or Disability. The Executive's employment will terminate upon the death or determination of disability of Executive. As used in this Agreement, the determination of "disability" shall occur when the Executive is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 90 consecutive days, or 180 days in the aggregate whether or not consecutive, during any 360-day period, or based on the written certification by a licensed physician of the likely continuation of such condition for such period. A determination of disability shall be made by a physician satisfactory to both Executive and the Company, *provided that* if Executive and the Company do not agree on a physician, Executive and the Company shall each select a physician and these two together shall select a third physician, whose determination as to disability shall be binding on all parties. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

4.4 Termination by Executive without Good Reason. At the election of Executive, he may terminate employment upon not less than 30 days prior written notice by Executive to the Company.

5. Effect of Termination.

5.1 General; Termination for Cause or by the Executive Without Good Reason. In the event that Executive's employment is terminated for any reason, the Company shall pay to Executive the compensation and benefits, including payment for accrued but untaken vacation days, payable to Executive through the last day of Executive's actual employment by the Company. If the termination is by the Company for Cause pursuant to Section 4.1 or at the election of Executive pursuant to Section 4.4, the Company shall have no further obligations under this Agreement.

5.2 Termination by the Company Without Cause or by the Executive for Good Reason.

(a) Employee shall not receive any of the benefits pursuant to this Section 5.2 unless he executes a general release in favor of the Company, in a form acceptable to the Company and substantially similar to the form attached hereto as ***Schedule B (***the "Release") within the consideration period specified therein (the "Release Review Period") and until the Release becomes effective and can no longer be revoked by Employee under its terms. Employee's ability to receive benefits pursuant to this Section 5.2 is further conditioned upon his: returning all Company property; complying with his post termination obligations under this Agreement and the Proprietary Information, Inventions and Non-Competition Agreement; and complying with the Release including without limitation any non-disparagement and confidentiality provisions contained therein.

(b) In the event that Executive's employment is terminated pursuant to Section 4.2 by the Company without Cause or by the Executive for Good Reason, the Company shall pay to Executive as severance twelve months of his annual Base Salary then in effect, together with an additional amount calculated by dividing by 365 the number of days employed in the year of termination and multiplying that number by the amount of the Executive's previous year's bonus (if any), such amount to be paid in one lump sum on the date the Release becomes effective, subject to standard payroll deductions and withholdings, provided, however, that if the Release Review Period begins in one tax year and ends in a later tax year, the payments under this Section 5.2(b) will be made following the date that the Release is effective that occurs in the later tax year . Additionally, if Executive timely elects and remains eligible for continued coverage under COBRA, the Company, as part of this Agreement, will pay that portion of Executive's COBRA premiums it was paying prior to the Separation Date for twelve (12) months.

(c) In the event Executive's employment is terminated pursuant to Section 4.2, and not for Cause, death or Disability, all unvested equity awards shall become fully vested, all unvested stock options shall become fully vested and exercisable and any ISO's issued to Executive will automatically convert to a non-qualified options on the 91st day following termination, provided it has not been exercised, subject to the terms of the applicable stock plan and option agreement.

(d) Termination for Death or Disability. In the event that Executive's employment is terminated by death or because of Disability pursuant to Section 4.3, in addition to the payment of accrued salary and unused vacation provided in Section 5.1, the Company shall pay to Executive's estate or to Executive, as the case may be, compensation which would otherwise be payable to Executive through the end of the month in which such termination occurs, and payment for any accrued but untaken vacation days.

5.3 Code Sections 409A and 280G.

(a) In the event that the payments or benefits set forth in Section 5.2 of this Agreement constitute "non-qualified deferred compensation" subject to Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), then the following conditions apply to such payments or benefits:

(i) Any termination of Executive's employment triggering payment of benefits under Section 5 must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence. To the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments under Section 5 that constitute deferred compensation under Section 409A of the Code shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h). For purposes of clarification, this Section 5.3(a) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs.

(ii) Notwithstanding any other provision with respect to the timing of payments under Section 5.2 if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A of the Code, any payments to which Executive may become entitled under Section 5 which are subject to Section 409A of the Code (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive under the terms of Section 5.

(b) It is intended that each installment of the payments and benefits provided under Section 5 of this Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Code. Neither Company nor Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A of the Code.

(c) Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A of the Code, or the payment of increased taxes, excise taxes or other penalties under Section 409A of the Code. The parties intend this Agreement to be in compliance with Section 409A of the Code. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A of the Code.

(d) If any payment or benefit Executive would receive under Section 5.4 of this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this section, a "Payment") would: (i) constitute a "parachute payment" within the meaning of Section 280G the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount (with cash payments being reduced before equity compensation) as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employments taxes, income taxes, and the Excise Tax, results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax.

5.4 Effect of a Change in Control.

(a) In the event either (i) Executive's employment with the Company is terminated by the Company for reasons other than death or Disability (as defined above) within three months before or 12 months following a Change in Control (as defined below) or (ii) Executive terminates his employment for Good Reason (as defined above) within three months before or 12 months following a Change in Control (as defined below), then provided that Executive executes the Release (as defined in Section 5.2) within the consideration period specified therein and it becomes effective and can no longer be revoked by Executive under its terms, and provided further that Executive returns all Company property' complies with his post termination obligations under this Agreement and the Proprietary Information, Inventions and Non-Competition Agreement, and complies with the Release including without limitation any non-disparagement and confidentiality provisions contained therein, Executive shall be entitled to the payments, equity acceleration and benefits described in this Section 5.4 in lieu of, and not in addition to, the benefits provided for in Section 5.2. The Company shall pay to the Executive, in lieu of the severance described in Section 5.2(a), severance equivalent to 18 months of his annual Base Salary then in effect, together with an additional amount calculated by dividing by 365 the number of days employed in the year of termination and multiplying that number by the amount of the Executive's previous year's bonus (if any), paid in a lump sum on the eighth day following the date the Release becomes effective, subject to standard payroll deductions and withholdings, provided, however, that if the Release Review Period begins in one tax year and ends in a later tax year, the payments under this Section 5.4(a) will be made following the date that the Release is effective that occurs in the later tax year. On the date of termination of Executive's employment, any unvested equity awards granted to the Executive shall immediately vest and, in the case of stock options, become exercisable. Additionally, if Executive timely elects and remains eligible for continued coverage under COBRA, the Company, as part of this Agreement, will pay that portion of Executive's COBRA premiums it was paying prior to the Separation Date for eighteen (18) months.

(b) Definition of Change in Control. For purposes of this Agreement, a "Change in Control" means the occurrence of any of the following events:

(i) a sale, lease or other disposition of all or substantially all of the assets of the Company;

(ii) a consolidation or merger of the Company with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of the Company immediately prior to such consolidation, merger or reorganization, own less than fifty percent (50%) of the outstanding voting power of the surviving entity (and its parent) following the consolidation, merger or reorganization; or

(iii) any transaction (or series of related transactions involving a person or entity, or a group of affiliated persons or entities) in which in excess of fifty percent (50%) of the Company's outstanding voting power is transferred.

Notwithstanding the above, a Change in Control shall not be deemed to occur on account of the sale or acquisition of the Company's capital stock by institutional investors or venture capital firms for the primary purpose of obtaining financing for the Company.

6. No Mitigation. Executive shall have no obligation to mitigate any amount of any payment or benefit contemplated by this agreement.

7. Cooperation. For one month following termination of the Executive's employment for any reason, and, additionally, for the number of months for which the Executive is receiving severance following termination, he will reasonably cooperate with the Company in all matters relating to the winding up of his pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company. The Company will reimburse the Executive for any out-of-pocket expenses associated with such cooperation.

8. Insurance and Indemnification. The Company shall purchase a directors and officers insurance policy for which Executive shall receive usual and customary coverage for all acts undertaken as an officer of the Company. In addition, the Company shall indemnify Executive to the fullest extent permitted by its charter, bylaws and by law for all costs, charges, damages, fees including without limitation, attorneys fees or other expenses that Executive incurs or potentially may incur in connection with Executives' duties herewith and also enter into an indemnification agreement with Executive.

9. Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

10. Complete Agreement. This Agreement constitutes the entire agreement between Executive and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Executive and an authorized officer of the Company. The parties have entered into a separate Proprietary Information, Inventions, and Non-Competition Agreement and have or may enter into separate equity grant agreements. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of the Executive's employment under this Agreement, may be amended or superseded by the parties without regard to this agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement. In the event of a conflict between this Agreement and any other agreement between the Executive and the Company, this Agreement shall control.

11. Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and Executive.

12. Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the laws of the State of New York and any action arising from or relating to this Agreement shall be commenced in the Federal or State courts located in New York County.

13. Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) when sent by electronic mail, telex or confirmed facsimile if sent during normal business hours on the day sent, and, if not, then on the next business day; (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company payroll, or at such other address as the Company or the Employee may designate by ten (10) days advance written notice to the other.

14. Successors and Assigns.

14.1 Assumption by Successors. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise and whether or not after a Change in Control) to all or substantially all of the business or assets of the Company to assume in writing prior to such succession and to agree to perform its obligations under this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. Successions by virtue of the sale of stock shall be governed by operation of law.

14.2 Successor Benefits. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation into which the Company may be merged or which may succeed to its assets or business, *provided, however*, that the obligations of Executive are personal and shall not be assigned by Executive.

15. Miscellaneous.

15.1 No Waiver. No delay or omission by either party in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by either party on any one occasion shall be effective only in that instance and shall not be construed as a bar or waiver of any right on any other occasion.

15.2 Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

15.3 Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

15.4 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

**INTRA-CELLULAR THERAPIES, INC.**

**BY: /S/ LAWRENCE HINELINE**
**LAWRENCE HINELINE**
**CHIEF FINANCIAL OFFICER**

**EXECUTIVE**

**/S/ DR. ANDREW SATLIN**
**DR. ANDREW SATLIN**
**EXECUTIVE VICE PRESIDENT, CHIEF MEDICAL OFFICER**

## SCHEDULE A

## PERMITTED ACTIVITIES

## SCHEDULE B

### RELEASE OF CLAIMS

This Release of Claims ("***Release***") is made as of _______________ by and between _______________ ("***the Executive***") and Intra-Cellular Therapies, Inc. (the "***Company***") (together, the "***Parties***").

1. In consideration for Executive's execution of this Release, the Company will make a severance payment to Executive in the amount set forth in the Employment Agreement between the Executive and the Company. This amount will be paid following the Effective Date (as defined below) in accordance with the Employment Agreement, provided the Company has received the executed Agreement from Executive on or before that date. This payment will be subject to standard payroll deductions and withholdings. If Executive timely elects and remains eligible for continued coverage under COBRA, the Company will pay that portion of Executive's COBRA premiums it was paying prior to the Separation Date for the time period set forth in the Employment Agreement between the Executive and the Company.

2. Executive hereby releases, acquits and forever discharges the Company, its parents and subsidiaries, and their officers, directors, agents, servants, employees, stockholders, successors, assigns and affiliates, of and from any and all claims, liabilities, demands, causes of action, costs, expenses, attorneys fees, damages, indemnities and obligations of every kind and nature, in law, equity, or otherwise, which were known or through reasonable diligence should have been known, arising out of or in any way related to Releases, events, acts or conduct at any time prior to the date Executive executes this Settlement Release, including, but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with Executive's employment with the Company, including but not limited to, claims of intentional and negligent infliction of emotional distress, any and all tort claims for personal injury, claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law or cause of action including, but not limited to, any and all claims and causes of action that the Company, its parents and subsidiaries, and its and their respective officers, directors, agents, servants, employees, attorneys, shareholders, successors, assigns or affiliates:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;
- has discriminated against him on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: Title VII of the Civil Rights Act of 1964, as amended; 42 U.S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Family and Medical Leave Act; the New York State Law Human Rights Law; the New York City Human Rights Law; the Employee Retirement Income Security Act; Section 510; and the National Labor Relations Act;

- has violated any statute, public policy or common law (including but not limited to claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to him or any member of his family and/or promissory estoppel).

Excluded from this Release are any claims which cannot be waived by law. Executive is waiving, however, his right to any monetary recovery should any governmental agency or entity, such as the EEOC or the DOL, pursue any claims on his behalf. Executive acknowledges that he is knowingly and voluntarily waiving and releasing any rights he may have under the ADEA, as amended. Executive also acknowledges that (i) the consideration given to his in exchange for the waiver and release in this Release is in addition to anything of value to which he was already entitled, and (ii) that he has been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which he is eligible, and have not suffered any on-the-job injury for which he has not already filed a claim. Executive further acknowledges that he has been advised by this writing that: (a) his waiver and release do not apply to any rights or claims that may arise after the execution date of this Release; (b) he has been advised hereby that he has the right to consult with an attorney prior to executing this Release; (c) he has twenty-one (21) days to consider this Release (although Executive may choose to voluntarily execute this Release earlier and if he does he will sign the Consideration Period waiver below); (d) he has seven (7) days following his execution of this Release to revoke the Release; and (e) this Release shall not be effective until the date upon which the revocation period has expired unexercised (the “Effective Date”), which shall be the eighth day after Executive executes this Release.

3. On or before the last day of Executive’s employment, Executive agrees to return to the Company all Company documents (and all copies thereof) and other Company property that Executive has had in his possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Executive shall coordinate the return of Company property with Allen Fienberg, Vice President of Business Development or an appropriated officer designated by the Board of Directors.

4. Executive further agrees that both during and after Executive’s employment Executive acknowledges his continuing obligations under his Proprietary Information, Inventions and Non-Competition Agreement not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitation and competitive activities.

5. It is understood that Executive shall hold the provisions of this Release in strictest confidence and shall not publicize or disclose it in any manner whatsoever; *provided, however*, that: (a) Executive may disclose this Release to his immediate family; (b) Executive may disclose this Release in confidence to his attorney, accountant, auditor, tax preparer, and financial advisor; and (c) Executive may disclose this Release insofar as such disclosure may be required by law.

6. Executive agrees not to disparage the Company, and the Company's attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that Executive may respond accurately and fully to any question, inquiry or request for information when required by legal process.

7. This Release does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

8. Executive agrees that upon any breach of this Release Executive will forfeit all amounts paid or owing to Executive under this Release. Executive further acknowledges that it may be impossible to assess the damages caused by violation of the terms of paragraphs 3, 4, 5 and 6 of this Release and further agree that any threatened or actual violation or breach of those paragraphs of this Release will constitute immediate and irreparable injury to the Company. Executive therefore agrees that any such breach of this Release is a material breach of this Release, and, in addition to any and all other damages and remedies available to the Company upon Executive's breach of this Release, the Company shall be entitled to an injunction to prevent Executive from violating or breaching this Release. Executive agrees that if the Company is successful in whole or part in any legal or equitable action against Executive under this Release, Executive agree to pay all of the costs, including reasonable attorney's fees, incurred by the Company in enforcing the terms of this Release.

9. This Release constitutes the complete, final and exclusive embodiment of the entire Release between the Parties with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Release may not be modified or amended except in a writing signed by both Executive and a duly authorized officer of the Company. This Release will bind the heirs, personal representatives, successors and assigns of the Parties, and inure to the benefit of the Parties, their heirs, successors and assigns. If any provision of this Release is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Release and the provision in question will be modified by the court so as to be rendered enforceable. This Release will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New York as applied to contracts made and to be performed entirely within New York.

**IN WITNESS WHEREOF**, the Parties have duly authorized and caused this Agreement to be executed as follows:

| | |
|---|---|
| | **INTRA-CELLULAR THERAPIES, INC.** |
| ______________________________ | **By:** ______________________________ |
| **[NAME]** | **[NAME]** |
| ______________________________ | ______________________________ |
| Date | Date |

**Exhibit 10.14**

**INTRA-CELLULAR THERAPIES, INC.**

**EMPLOYEE PROPRIETARY INFORMATION,
INVENTIONS, AND NON-COMPETITION AGREEMENT**

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

**1. NONDISCLOSURE.**

**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: November 13, 2017.

**I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS. I HAVE COMPLETELY FILLED OUT EXHIBIT A TO THIS AGREEMENT.**

Dated : November 13, 2017

/s/ Andrew Satlin
**(Signature)**

Andrew Satlin
**(Printed Name)**

**ACCEPTED AND AGREED TO:**

**INTRA-CELLULAR THERAPIES, INC.**

By: /s/ Lawrence Hineline

Title: Chief Financial Officer

430 E. 29th St.
(Address)

New York, NY

Dated: November 13, 2017

**Exhibit 10.20**

**INTRA-CELLULAR THERAPIES, INC.**

**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

**(adopted June 30, 2014; amended March 30, 2016 and December 14, 2017)**

The Board of Directors of Intra-Cellular Therapies, Inc. (the "Company") has approved the following Non-Employee Director Compensation Policy (this "Policy"), which establishes compensation to be paid to non-employee directors of the Company, to provide an inducement to obtain and retain the services of qualified persons to serve as members of the Company's Board of Directors.

**Applicable Persons**

This Policy shall apply to each director of the Company who is not an employee of, or compensated consultant to, the Company or any Affiliate (each, an "Outside Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

**Compensation**

**A. EquityGrants**

1. Annual Stock Option Grants

Each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Company's 2013 Equity Incentive Plan or any successor plan (the "Equity Plan"), (i) a non-qualified stock option (the "Annual Option Grant") to purchase 20,000 shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), or (ii) at such Outside Director's written election at least 30 days prior to the date of grant, the number of restricted stock units of the Company (the "Annual Restricted Stock Unit Grant", and together with the Annual Option Grant, the "Annual Equity Grant") having equivalent value (using the applicable Black Scholes valuation methodology) to the Annual Option Grant, each year on the date of the Company's annual meeting of stockholders; provided, however, that if there has been no annual meeting of stockholders held by the first business day of the third fiscal quarter, each Outside Director shall be granted, automatically and without any action on the part of the Board of Directors such Annual Equity Grant on the first business day of the third fiscal quarter of such year.

The foregoing Annual Equity Grants shall commence with the 2018 Annual Meeting of Stockholders.

2. Initial Stock Option Grants for Newly Appointed or Elected Directors

Each new Outside Director shall be granted, automatically and without any action on the part of the Board of Directors, under the Equity Plan, a non-qualified stock option to purchase 20,000 shares of Common Stock on the date that the Outside Director is first appointed or elected to the Board of Directors.

3. Terms of Equity Grants

All Annual Option Grants and initial stock option grants to Outside Directors under this Policy shall vest in one year on the anniversary of the date of grant, subject to the Outside Director's continued service on the Board of Directors, shall have a term of ten years, and shall have an exercise price equal to the fair market value of the Company's Common Stock as determined under the Equity Plan on the date of grant. The stock options shall become fully vested immediately prior to a Change of Control (as defined below).

All Annual Restricted Stock Unit Grants to Outside Directors under this Policy shall vest in one year on the anniversary of the date of grant, subject to the Outside Director's continued service on the Board of Directors. Annual Restricted Stock Unit Grants shall become fully vested immediately prior to a Change of Control (as defined below).

"Change of Control" means the occurrence of any of the following events: (i) any "Person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities (excluding for this purpose any such voting securities held by the Company or its affiliates or by any employee benefit plan of the Company) pursuant to a transaction or a series of related transactions; or (ii)(a) a merger or consolidation of the Company whether or not approved by the Board of Directors, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such corporation) more than 50% of the total voting power represented by the voting securities of the Company or such surviving entity or parent of such corporation, as the case may be, outstanding immediately after such merger or consolidation; or (b) the sale or disposition by the Company of all or substantially all of the Company's assets in a transaction requiring stockholder approval.

**B.** CashFees or Fully-Vested Stock or Fully Vested Stock Options in Lieu of Cash Fees

1. Annual Cash Fees

The following annual cash fees shall be paid to the Outside Directors serving on the Board of Directors and the Audit Committee, Compensation Committee and Nominating and Governance Committee, as applicable.

| Board of Directors or Committee of Board of Directors | Annual Retainer Amount for Chair (or Lead Independent Director, as applicable) | Annual Retainer Amount for Other Members |
|---|---|---|
| Board of Directors | $ 50,000 | $ 40,000 |
| Audit Committee | $ 20,000 | $ 10,000 |
| Compensation Committee | $ 15,000 | $ 8,000 |
| Nominating and Governance Committee | $ 10,000 | $ 5,000 |

2. Payment Terms for All Cash Fees

Cash fees payable to Outside Directors shall be paid quarterly in arrears as of the last business day of each fiscal quarter.

Following an Outside Director's first election or appointment to the Board of Directors, such Outside Director shall receive his or her cash compensation pro-rated during the first fiscal quarter in which he or she was initially appointed or elected for the number of days during which he or she provides service. If an Outside Director dies, resigns or is removed during any quarter, he or she shall be entitled to a cash payment on a pro-rated basis through his or her last day of service that shall be paid on the last business day of the fiscal quarter.

3. Election to Receive Fully-Vested Shares of Common Stock or Fully Vested Stock Options in Lieu of Annual Cash Fees

In lieu of all or a portion of the annual cash fees, an Outside Director may elect by prior written notice to the Company to receive fully-vested shares of Common Stock (a "Stock Award") or fully-vested non-qualified stock options under the Equity Plan on the last business day of each fiscal quarter for the equivalent value of the cash fees due. Such grant shall be made automatically and without any action on the part of the Board of Directors under the Equity Plan. The number of shares with respect to a Stock Award shall be calculated by dividing the cash fees as determined above by the fair market value of the Common Stock as determined under the Equity Plan on the last business day of each fiscal quarter. Should the Outside Director elect to receive stock options, the number of shares underlying a stock option shall be calculated by determining the number of shares that is equivalent to the cash fees due as determined above using the Black Scholes value applicable to the Company's stock option grants calculated on the last business day of each fiscal quarter. Each stock option grant shall have a term of ten years, unless the Director ceases serving as a member of the Board of Directors and shall have an exercise price equal to the fair market value of the Company's Common Stock as determined under the Equity Plan on the date of grant.

**Expenses**

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Outside Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board of Directors and Committees thereof or in connection with other business related to the Board of Directors. Each Outside Director shall abide by the Company's travel and other expense policies applicable to Company personnel.

**Amendments**

The Compensation Committee or the Board of Directors shall review this Policy from time to time to assess whether any amendments in the type and amount of compensation provided herein should be adjusted in order to fulfill the objectives of this Policy.

**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. 333-213495) of Intra-Cellular Therapies, Inc.,

(2) Registration Statement (Form S-8 No. 333-205070) of Intra-Cellular Therapies, Inc. pertaining to the Intra-Cellular Therapies, Inc. Amended and Restated 2013 Equity Incentive Plan,

(3) Registration Statement (Post-Effective Amendment No. 3 to Form S-1 on Form S-3 No. 333-191238) of Intra-Cellular Therapies, Inc., and

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

of our reports dated March 1, 2018, with respect to the consolidated financial statements of Intra-Cellular Therapies, Inc. and the effectiveness of internal control over financial reporting of Intra-Cellular Therapies, Inc. included in this Annual Report (Form 10-K) of Intra-Cellular Therapies, Inc. for the year ended December 31, 2017.

/s/ Ernst & Young LLP
Baltimore, MD
March 1, 2018

**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 1, 2018

/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 1, 2018

/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, 2016 (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 1, 2018 | /s/ Sharon Mates, Ph.D. |
| | Sharon Mates, Ph.D.<br>Chairman, President and Chief Executive Officer<br>(principal executive officer) |
| Dated: March 1, 2018 | /s/ Lawrence J. Hineline |
| | Lawrence J. Hineline<br>Vice President of Finance and Chief Financial Officer<br>(principal financial officer and principal accounting officer) |