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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value Per Share	**ITCI**	**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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	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 $613.7 million.

As of February 28, 2020, the registrant had 66,133,183 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 2020 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, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. In December 2019, we announced that CAPLYTA™ (lumateperone) has been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of schizophrenia in adults (42mg/day). We expect to initiate the commercial launch of CAPLYTA late in the first quarter of 2020. In support of our commercialization efforts, we expect to deploy a national sales force consisting of approximately 240 sales representatives. At the time of launch CAPLYTA will be priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia. As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia.

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

Lumateperone is also in Phase 3 clinical development as a novel treatment for bipolar depression. Our lumateperone bipolar depression Phase 3 clinical program currently consists of three monotherapy studies and one adjunctive study. In the first quarter of 2020 we initiated our third monotherapy Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. We anticipate reporting topline results from Study 403 in the second half of 2021. On July 8, 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the U.S., and our second monotherapy study, Study 404, conducted globally, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 404, lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the Montgomery-Åsberg Depression Rating Scale, or MADRS, total score ($p<0.0001$; effect size = 0.56). Study 401 tested two doses of lumateperone, 42 mg and 28mg along with placebo. In this trial, neither dose of lumateperone met the primary endpoint of statistical separation from placebo as measured by change from baseline on the MADRS total score. There was a high placebo response in this trial. Lumateperone was generally well-tolerated in both bipolar depression studies. The rates of discontinuation due to treatment emergent adverse events for both doses of lumateperone were low. Our global study evaluating adjunctive lumateperone in bipolar depression (Study 402) is ongoing and we anticipate reporting topline results from this study in mid-2020. Subject to the results of Study 402 and our interactions with the FDA regarding our bipolar depression program, in late 2020 we expect to submit a supplemental new drug application, or sNDA, to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression.

Lumateperone for the Treatment of Agitation in Patients with Dementia, Including Alzheimer's Disease

In the second quarter of 2016, we initiated Phase 3 development of lumateperone for the treatment of agitation in patients with dementia, including Alzheimer's disease, or AD. Our ITI-007-201 trial was 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 the fourth quarter of 2018, an independent data

monitoring committee, or DMC, completed a pre-specified interim analysis of the ITI-007-201 trial, and concluded that the trial was not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial. Lumateperone was generally well tolerated in the ITI-007-201 trial and the decision to discontinue the study was not related to safety. We are analyzing the data set from this trial and will determine the next steps in our program following completion of this analysis.

Other Indications for Lumateperone

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. We believe lumateperone may have utility for treating agitation, aggression and sleep disturbances in diseases that include dementia, AD, Huntington's disease and autism spectrum disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range may merit further investigation for the treatment of depressive disorders and other neuropsychiatric diseases.

Within the lumateperone portfolio, we are also developing a long-acting injectable formulation to provide more treatment options to patients suffering from mental illness. We have completed the preclinical development of a long-acting injectable formulation and plan to initiate a Phase 1 clinical trial in 2020. 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.

We may investigate the use of lumateperone, either on our own or with a partner, as a treatment for 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 inhibit the enzyme phosphodiesterase type 1, or PDE1. PDE1 enzymes are highly active in multiple disease states and our PDE1 inhibitors are designed to reestablish normal function in these disease states. Abnormal PDE1 activity is associated with cellular proliferation and activation of inflammatory cells. Our PDE1 inhibitors ameliorate both of these effects in animal models. We intend to pursue the development of our phosphodiesterase, or PDE, program, for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, and other non-CNS disorders. 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. Following the favorable safety and tolerability results in our Phase 1 program, we initiated our development program for ITI-214 for Parkinson's disease and commenced 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. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of ITI-214 has been completed and topline results demonstrated ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. In addition, in the first quarter of 2018, the investigational new drug application, or IND, went into effect for ITI-214 for the treatment of heart failure. Clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled Phase 1/2 study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure, is ongoing and we anticipate reporting topline results from this study in the first half of 2020.

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. Preclinical safety studies with ITI-333 are currently ongoing and we expect to initiate a clinical program in 2020.

We have assembled a management team with significant industry experience to lead the discovery, development and potential commercialization 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.

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 Intra-Cellular Therapies, Inc. 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, develop and commercialize 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 adequately treated by currently marketed drugs or can be effective with fewer side effects.

The key elements of our strategy are to:

- initiate the commercialization of CAPLYTA, which was approved in December 2019 by the FDA for the treatment of schizophrenia in adults, in the United States;
- complete the development of lumateperone for additional neuropsychiatric indications, such as bipolar disorder, behavioral disturbances in dementia, including AD, residual symptoms in schizophrenia and major depressive disorder, or MDD;

- 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;
- 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 late 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.

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.

According to the Schizophrenia and Related Disorders Alliance of America. and the National Institute of Mental Health, about 1% of the population or 2.4 million Americans suffer from schizophrenia in any given year. The U.S. market value of antipsychotic drugs exceeded $10 billion in 2019. 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. Antipsychotic treatments can have significant side effects like extrapyramidal symptoms, weight gain, dyslipidemia and other metabolic abnormalities. 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.

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, 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 6 million adults in the United States in any given year, or about 2.8 percent of the adult U.S. population. Decision Resources Group estimated global sales for therapeutics used to treat bipolar disorder to be approximately $6 billion in 2019.

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

The World Health Organization estimates that approximately 50 million people worldwide have dementia, and this number is expected to increase to 152 million by 2050. The Alzheimer's Association estimates 5.8 million Americans are living with Alzheimer's dementia in 2019. 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. 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.

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.

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. According to Decision Resources Group, global sales of therapeutics such as L-DOPA, and dopamine agonists used to treat the disease were approximately $3 billion in 2019.

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. We believe there is a large unmet medical need for the treatment of non-motor symptoms associated with Parkinson's disease.

Major Depressive Disorder

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. According to Decision Resources Group, global sales of therapeutics to treat the depression is approximately $6.5 billion in 2019. The antidepressant market is primarily composed of selective serotonin reuptake inhibitors such as escitalopram and selective norepinephrine reuptake inhibitors, or SNRIs, such as duloxetine. Antipsychotics such as quetiapine, aripriprazole and Rexulti® 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 with depression do not fully recover on an anti-depressant medication.

Heart Failure

Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. In some types of heart failure, the left ventricle loses its ability to contract normally. The heart is unable to pump with enough force to push enough blood into circulation (heart failure with reduced ejection fraction). Eventually the heart and body cannot compensate, and the person experiences fatigue, breathing problems or other symptoms.

Approximately 6.5 million adults in the United States have heart failure. One in eight deaths in 2017 included heart failure as contributing cause. About half of people who develop heart failure die within 5 years of diagnosis. Heart failure costs the nation an estimated $30.7 billion each year. This total includes the cost of health care services, medications to treat heart failure, and missed days of work. Current treatments prolong life and improve the heart's function, but there is no cure. There is a pressing need for improved treatments to improve and reverse these changes in cardiac function.

Our Product

In December 2019, we announced that CAPLYTA has been approved by the FDA for the treatment of schizophrenia in adults (42mg/day). We expect to initiate the commercial launch of CAPLYTA late in the first

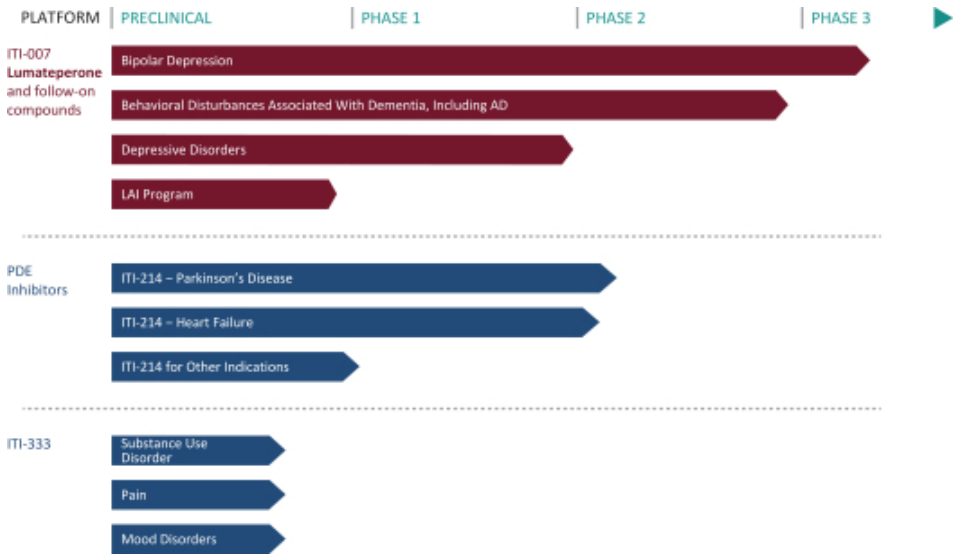
quarter of 2020. In support of our commercialization efforts, we expect to employ a national sales force consisting of approximately 240 sales representatives. At the time of launch CAPLYTA will be priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia.

The efficacy of CAPLYTA 42 mg was demonstrated in two placebo-controlled trials, showing a statistically significant separation from placebo on the primary endpoint, the Positive and Negative Syndrome Scale, or PANSS, total score. The most common adverse reactions (>5% and twice the rate of placebo) for the recommended dose of CAPLYTA vs. placebo were somnolence/sedation (24% vs.10%) and dry mouth (6% vs. 2%). In pooled data from short term studies, mean changes from baseline in weight gain, fasting glucose, triglycerides and total cholesterol were similar between CAPLYTA and placebo. The incidence of extrapyramidal symptoms was 6.7% for CAPLYTA and 6.3% for placebo. The label for CAPLYTA contains a "boxed" warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death and that CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

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 Development Program

The efficacy of lumateperone could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors. In terms of pharmacodynamics, lumateperone has high binding affinity for serotonin 5-HT2A receptors and moderate binding affinity for dopamine D2 receptors, serotonin transporters, dopamine D1 receptors, dopamine D4 receptors and adrenergic alpha 1A and alpha 1B receptors. It has low binding affinity for muscarinic and histaminergic receptors. As a result, we believe lumateperone may represent a potential treatment across multiple

therapeutic indications including the treatment of bipolar disorder, including bipolar depression, 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 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 have the potential treat a wide array of symptoms in patients with bipolar disorder, including improvement of cognition and sleep.

Our lumateperone bipolar depression program currently consists of four Phase 3 multi-center, randomized, double-blind, placebo-controlled clinical trials. In the ITI-007-401 (Study 401) and the ITI-007-404 (Study 404) trials, lumateperone was evaluated as a monotherapy and in the ITI-007-402 trial (Study 402), lumateperone is being evaluated as an adjunctive therapy with lithium or valproate. In the first quarter of 2020, we initiated a Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. We anticipate reporting topline results from Study 403 in the second half of 2021. All four trials evaluate lumateperone in patients with a clinical diagnosis of Bipolar I or Bipolar II disorder and who are experiencing a current major depressive episode. In Study 401 and Study 402, 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 Study 404, patients were randomized to receive 60 mg ITI-007 or placebo in a 1:1 ratio orally once daily for 6 weeks. In Study 403, patients are randomized to receive 60 mg ITI-007 or placebo in a 1:1 ratio orally once daily for 6 weeks. 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.

In July, 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the U.S., and our second monotherapy study, Study 404, conducted globally, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 404, lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the MADRS total score ($p<0.0001$; effect size = 0.56). Study 401 tested two doses of lumateperone, 42 mg and 28mg along with placebo. In this trial, neither dose of lumateperone met the primary endpoint of statistical separation from placebo as measured by change from baseline on the MADRS total score. There was a high placebo response in this trial. Lumateperone was generally well-tolerated in both bipolar depression studies, with a favorable safety profile. The rates of discontinuation due to treatment emergent adverse events for both doses of lumateperone were low. Our global study evaluating adjunctive lumateperone in bipolar depression (Study 402) is ongoing and we anticipate reporting topline results from this study in mid-2020. Subject to the results of Study 402 and our interactions with the FDA regarding our bipolar depression program, in late 2020 we expect to submit a sNDA to the FDA for regulatory approval for the treatment of bipolar depression.

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 results 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 has a positive safety profile and is 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 was 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 were planned to be randomized to receive 9 mg ITI-007 or placebo in a 1:1 ratio orally once daily for four weeks. The primary efficacy measure was 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 were to be 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 was the CGI-S. Other exploratory secondary endpoints included measures of other behavioral disturbances associated with dementia. Safety and tolerability were also to be assessed in the trial. In the fourth quarter of 2018, an independent data monitoring committee, or DMC, completed a pre-specified interim analysis of the ITI-007-201 trial, concluded that the trial is not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial. Lumateperone was generally well tolerated in the ITI-007-201 trial and the decision to discontinue the study was not related to safety. We are analyzing the data set from this trial and will determine the next steps in our program following completion of this analysis.

Lumateperone for the treatment of major depressive disorder 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 represent a potential treatment for mood disorders including MDD, post-traumatic stress

disorder and intermittent explosive disorder. We have commenced our program of lumateperone in MDD. Recent preclinical data support the potential for rapid-acting antidepressant effects with lumateperone. In order to explore the effect of different modes of drug administration and the potential for rapid-onset antidepressant activity, our program includes the assessment of novel formulations of lumateperone. Pharmacokinetic studies evaluating these novel formulations are currently ongoing. We anticipate initiating a Phase 2 clinical trial in MDD in 2020.

ITI-002 (PDE1) Program

We have a second major program called ITI-002 that has yielded a portfolio of compounds that selectively inhibit the enzyme phosphodiesterase type 1, or PDE1. PDE1 enzymes are highly active in multiple disease states and our PDE1 inhibitors are designed to reestablish normal function in these disease states. Abnormal PDE1 activity is associated with cellular proliferation and activation of inflammatory cells. Our PDE1 inhibitors ameliorate both of these effects in animal models. We intend to pursue the development of our phosphodiesterase, or PDE, program, for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, and other non-CNS disorders. ITI-214 is our lead compound in this program.

ITI-214 has been evaluated in 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.

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 favorable 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. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of ITI-214 has been completed and topline results demonstrated ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. In addition, in the first quarter of 2018, the investigational new drug application, or IND, went into effect for ITI-214 for the treatment of heart failure. Clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled Phase 1/2 study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure, is ongoing and we anticipate reporting topline results from this study in the first half of 2020.

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. If successfully translated to humans, this unique pharmacological profile may yield clinical utility for the treatment of substance use disorders and pain. Preclinical safety studies with ITI-333 are currently ongoing and we expect to initiate a clinical program in 2020.

Intellectual Property

Our Patent Portfolio

As of February 1, 2020, 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 program on novel compounds for neuropsychiatric and neurodegenerative diseases includes patents exclusively in-licensed from Bristol-Myers Squibb on families of compounds, including lumateperone. Lumateperone tosylate is now FDA-approved as CAPLYTA™ for the treatment of schizophrenia. We have extensively characterized this compound and related compounds and filed additional patent applications on salt forms, polymorphs, pharmaceutical formulations, new indications, improved methods of manufacture, metabolites, derivatives, and structurally related novel compounds. As of February 1, 2020, our lumateperone program consisted of approximately 30 patent families that we own or control, filed in the United States and other major markets, including 31 issued or allowed U.S. patents, 13 pending U.S. patent applications, 126 issued or allowed foreign patents and 65 pending foreign patent applications. Nine patents are currently Orange Book listed in the United States, which provides the further benefit of five years of new chemical entity data exclusivity with the FDA. Patent protection for lumateperone includes:

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
Base ITI-007 Patent (lumateperone tosylate)	**Granted:** US (RE39,680*; 7,183,282*), JP, EP (AT, BE, CH, DE, ES, FR, GB, IE, IT, LU, MC)	June 15, 2020 (does not include expected 6-month extension in US for pediatric studies)
ITI-007 Product Patent (approved drug product—lumateperone tosylate—in any pharmaceutical form)	**Granted:** US (10,464,938*), Pending in AU, EP (allowed), IN JP, KR, and MX	March 12, 2028 (US: does not include expected 6-month extension in US for pediatric studies)
ITI-007 Crystal Form Patent (approved drug product—lumateperone tosylate—in solid crystalline form)	**Granted:** US (8,648,077*; 9,199,995*; 9,586,960*), 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, HK, JP and MX; Pending in IL, IN	December 1, 2029 (US; does not include expected 6-month extension for pediatric studies; additional patent term extension possible through 2033**); March 12, 2029 (ex-US)

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
ITI-007 Dosage and Method of Treatment Patents (including schizophrenia, bipolar depression, sleep disorder indications)	**Granted:** US (8,598,119*; 9,616,061*), AU, CN, JP, MX Pending: US (continuation), CA, (divisional), EP, IN, KR, MX (divisional)	December 28, 2029 (US; does not include expected 6-month extension for pediatric studies; additional patent term extension possible through 2033**); May 27, 2029 (ex-US)
ITI-007 Residual Symptoms Patent (treatment of negative/residual symptoms of schizophrenia)	**Granted:** US (9,956,227*), AU, JP, RU Pending: US (continuation), AU (divisional), JP (divisional), EP, IN, KR, MX, CA, BR IL, CN	December 3, 2034 (US and ex-US; does not include expected US 6-month extension for pediatric studies;)
Patents for Additional Dosage Forms	Pending: US provisional, US national and/or PCT	2037-2039
Patents for Additional Indications (including post-traumatic stress disorder, impulse control disorder, symptoms associated with dementia, acute depression, and acute anxiety)	Granted or pending in US, EP, JP, and other countries	2033-2034

* Orange-Book listed U.S. patents

** We have filed patent term extension applications on three U.S. patents. The U.S. Patent and Trademark Office, or USPTO, has not completed its review of these applications. In the United States, we are permitted to extend the term of one U.S. patent for lumateperone or the use thereof. Accordingly, on completion of the USPTO's review of our patent term extension applications, we must select one of the three patents to which any patent term extension granted will attach. Patent terms may be subject to change not only due to potential patent term extensions but also to any terminal disclaimer that reduces patent term, as well as other factors. Because the U.S. patent laws and related judicial interpretations change, modifications or new interpretations of the laws may impact our patent terms.

Our program on PDE1 inhibitors for cognition, dopamine-mediated and other disorders, cardiovascular disorders, as well as several others, includes patent protection across 19 families 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 have obtained patent coverage for ITI-214 in the treatment of cardiovascular disorders, including heart failure, that extends to 2034. We are also evaluating potential follow-on compounds for ITI-214 which would have patent protection beyond 2030.

Our ITI-333 program relates to novel compounds for the non-addictive treatment of pain and for the treatment of opiate use disorder. 12 families of patent applications have been filed, including one which has already resulted in a U.S. patent. These patent families will protect the lead compound, as well as many other analogs under development, beyond 2037 (exclusive of any patent term extensions and regulatory exclusivities).

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 schizophrenia. Upon FDA acceptance of an NDA filing for lumateperone, we were obligated to pay BMS a $2.0 million milestone payment. The FDA accepted our NDA filing for lumateperone for the treatment of schizophrenia in the third quarter of 2018 and, as a result, we accrued the $2.0 million milestone, which was paid in the first quarter of 2019. The FDA approved our NDA filing on December 23, 2019 and as a result, we accrued $5.0 million related to that milestone in the fourth quarter of 2019 which was paid in the first quarter of 2020. Remaining potential milestone payments under the agreement with respect to lumateperone total $5.0 million if approvals to market the product are received in certain countries outside the U.S. Under the agreement, we may be obliged to make other milestone payments to BMS, for licensed products other than lumateperone, of up to an aggregate of approximately $14.75 million. We are also obliged to make tiered single digit percentage royalty payments ranging between 5 – 9% 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 CAPLYTA or 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 commercial sales of CAPLYTA and for our preclinical research and clinical trials, including the Phase 3 trials for lumateperone for the treatment of bipolar depression. 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.

Commercial Operations

We expect to initiate the commercial launch of CAPLYTA in the United States late in the first quarter of 2020. In support of our commercialization efforts, we expect to deploy a national sales force consisting of approximately 240 sales representatives. We have substantially completed the hiring of our U.S. sales force. In the future, we may choose to commercialize CAPLYTA or any other products, in markets outside of the United States, if approved for sale in such markets, by establishing one or more strategic alliances.

Customers

We are currently approved to sell CAPLYTA for the treatment of schizophrenia in adults in the U.S. market. At the time of launch, CAPLYTA will be priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia. We plan to distribute CAPLYTA principally through three third party wholesale drug distributors. We do not expect to have a disproportionate concentration with any one of these distributors and we expect our sales volume to be relatively evenly distributed across these distributors.

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 commercializing CAPLYTA and developing and obtaining approval of our product candidates, we would compete with a variety of established drugs in the areas of our targeted CNS therapeutic indications. CAPLYTA for the treatment of schizophrenia and lumateperone for the treatment of bipolar disorder, if approved, 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, CAPLYTA and 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 our approved product is established in the market or before we are able to sell our product candidates, if approved. 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 the 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 the 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 any approved products, 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 any approved product that 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.

Employees

As of February 28, 2020, we employed 330 employees all of whom were full-time. We consider our relations with our employees to be good. To successfully commercialize CAPLYTA and develop our drug candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring a number of additional employees for sales and marketing, research and development, clinical and regulatory affairs, and general and administrative activities over the next few years. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing.

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

In order to execute our business plan and achieve profitability, we need to effectively commercialize CAPLYTA, which received FDA approval in December 2019 for the treatment of schizophrenia in adults.

CAPLYTA is our only drug that has been approved for sale and it has been approved only for the treatment of schizophrenia in adults in the United States. We are focusing a significant portion of our activities and resources on CAPLYTA, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully commercialize CAPLYTA for the treatment of schizophrenia in adults in the United States.

Successful commercialization of CAPLYTA is subject to many risks. We have never, as an organization, launched or commercialized any product, and there is no guarantee that we will be able to successfully commercialize CAPLYTA for its approved indication. There are numerous examples of failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than us. We are in the process of building our commercial organization and hiring our U.S. sales force and will need to refine and further develop our commercial organization in order to successfully commercialize CAPLYTA. We expect that the initial commercial success of CAPLYTA for the treatment of schizophrenia will depend on many factors, including the following:

- the efficacy, cost, approved use, and side-effect profile of CAPLYTA regimens relative to competitive treatment regimens for the treatment of schizophrenia;
- the timing of the initiation of our commercial launch of CAPLYTA;
- the effectiveness of our commercial strategy for the launch and marketing of CAPLYTA, including our pricing strategy and the effectiveness of our efforts to obtain adequate third-party reimbursements;
- maintaining and successfully monitoring commercial manufacturing arrangements for CAPLYTA with third-party manufacturers to ensure they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of CAPLYTA;
- the acceptance of CAPLYTA by patients, the medical community and third-party payors; and
- the effect of recent or potential health care legislation in the United States.

While we believe that CAPLYTA for the treatment of schizophrenia will have a commercially competitive profile, we cannot accurately predict the amount of revenue that will be generated from the sale of CAPLYTA. If we do not effectively commercialize CAPLYTA, we will not be able to execute our business plan and may not be able to achieve profitability. If our revenues, market share and/or other indicators of market acceptance of CAPLYTA do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

If we do not obtain regulatory approval of lumateperone for other indications in the United States, or for any indication in foreign jurisdictions, we will not be able to market lumateperone for other indications or in other jurisdictions, which will limit our commercial revenues.

While CAPLYTA has been approved by the FDA for the treatment of schizophrenia in adults, lumateperone has not been approved by the FDA for any other indications, and it has not been approved in any other jurisdiction for this indication or for any other indication. In order to market lumateperone for other indications or in other jurisdictions, we must obtain regulatory approval for each of those indications and in each of the applicable jurisdictions, and we may never be able to obtain such approval. Approval of CAPLYTA by the FDA for the treatment of schizophrenia does not ensure that foreign jurisdictions will also approve CAPLYTA for that indication, nor does it ensure that lumateperone will be approved by the FDA for any other indication. Lumateperone is in Phase 3 clinical development as a novel treatment for bipolar depression and for the treatment of agitation in patients with dementia, including Alzheimer's disease. There is no guarantee that any ongoing or future studies of lumateperone in other indications will be successful, or that the FDA or any regulatory authority in foreign jurisdictions will approve lumateperone for any of those indications. The research, testing, manufacturing, labeling, approval, sale, import, export, marketing, and distribution of pharmaceutical product candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country. We will be required to comply with different regulations and policies of the jurisdictions where we seek approval for our product candidates, and we have not yet identified all of the requirements that we will need to satisfy to submit lumateperone for approval for other indications or in other jurisdictions. This will require additional time, expertise and expense, including the potential need to conduct additional studies or development work for other jurisdictions beyond the work that we have conducted to support our NDA submission in schizophrenia. In addition, strategic considerations need to be taken into account when determining whether and when to submit lumateperone for approval in other jurisdictions. If we do not receive marketing approval for lumateperone for any other indication or from any regulatory agency outside of the United States, we will never be able to commercialize lumateperone for any other indication in the United States or for any indication in any other jurisdiction. Even if we do receive additional regulatory approvals, we may not be successful in commercializing those opportunities.

If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to lumateperone do not meet our or others' expectations, the market price of our common stock could decline significantly.

If the sales and marketing capabilities we are establishing or our third-party relationships for the commercialization of lumateperone are not effective, lumateperone may not be successfully commercialized.

We have no experience as a company in marketing drugs or with respect to pricing and obtaining adequate third-party reimbursement for drugs. We are in the process of building our commercial organization and capabilities in the United States in order to prepare to market CAPLYTA for the treatment of schizophrenia. We will need to successfully complete the expansion of our capabilities and/or enter into arrangements with third parties to sell and market CAPLYTA for the treatment of schizophrenia and, if approved, our other product candidates. If our sales and marketing capabilities or our third-party relationships for the commercialization of our products are not effective, our business could be materially harmed.

We have never generated revenue from product sales and there is no guarantee that our revenue from the sale of CAPLYTA following our planned commercial launch will be substantial.

Our ability to generate revenue from product sales and achieve profitability depends on our ability to successfully commercialize CAPLYTA for the treatment of schizophrenia in adults in the United States and to complete the development of and obtain regulatory approvals necessary to commercialize lumateperone in other indications 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 lumateperone or our other product candidates. We cannot guarantee that lumateperone will be successfully commercialized or 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 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 lumateperone bipolar depression Phase 3 clinical program currently consists of three monotherapy studies and one adjunctive study. On July 8, 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the U.S., and our second monotherapy study, Study 404, conducted globally, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. 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 was 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 the fourth quarter of 2018, an independent data monitoring committee, or DMC, completed a pre-specified interim analysis of the ITI-007-201 trial, concluded that the trial is not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial. Lumateperone was generally well tolerated in the ITI-007-201 trial and the decision to discontinue the study was not related to safety. We are analyzing the data set from this trial and will determine the next steps in our dementia program following completion of this analysis.

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 favorable safety and tolerability results in our Phase 1 program, we initiated our development program for ITI-214 for Parkinson’s disease. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of ITI-214 has been completed and topline results demonstrated ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. In addition, in the first quarter of 2018, the investigational new drug application, or IND, went into effect for ITI-214 for the treatment of heart failure. Clinical conduct of the first clinical study in this program, 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, is ongoing.

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.

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. We are conducting and plan to conduct further clinical trials in lumateperone in indications beyond

schizophrenia, and there is no guarantee that we will have the same level of success in these trials as we have had in certain of our previous 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 bipolar depression, behavioral disturbances in dementia, 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 3 clinical trials in the patient populations for these other indications, except for our two Phase 3 monotherapy studies in bipolar depression for which we announced topline results in July 2019 and our ITI-007-201 Phase 3 trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation, which we determined to discontinue following the DMC's recommendation that the study should be stopped for futility.

If we do not successfully complete clinical development and obtain approval of lumateperone in indications beyond schizophrenia, we will be unable to market, sell and generate revenue from lumateperone in any of these other indications. Even though we have successfully completed certain clinical trials for CAPLYTA 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 any indication beyond schizophrenia. Of the vast number of drugs in development, only a small percentage result in the submission of an NDA to the FDA, and even less result in the NDA ultimately being approved by the FDA for commercialization.

We 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, 2019, we had an accumulated deficit of approximately $710.1 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 any revenues from the commercialization of our approved product or 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 lumateperone, we must successfully commercialize lumateperone in its approved indication. 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 $224.0 million at December 31, 2019. In January 2020, we completed an underwritten public offering of shares of our common stock resulting in net proceeds to us of approximately $276.9 million, after deducting underwriting discounts and commissions and estimated offering expenses. We believe that our existing cash, cash equivalents and investment securities, including the net proceeds from our January 2020 public offering, together with interest on cash balances, will be sufficient to fund our operating expenses and capital expenditure requirements through the end of 2021, subject to several factors, including the initiation of commercial launch and level of sales of CAPLYTA for the treatment of schizophrenia in adults in the United States, including the timing and related costs, the relative success and costs 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 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 future NDA submission would likely be delayed.

With our cash, cash equivalents and investment securities, including the net proceeds from our public offering in January 2020, we intend to fund the following: commercialization activities in connection with the commercialization of CAPLYTA for the treatment of schizophrenia; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-214 and ITI-333; working capital needs in connection with the commercialization of CAPLYTA; and the remaining proceeds, if any, to fund new and ongoing research and development activities, manufacturing activities in connection with new products, general corporate purposes, including general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. Accordingly, we will continue to require substantial additional capital beyond the net proceeds from our January 2020 offering to continue our clinical development and commercialization activities. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the costs of maintaining and developing our sales and marketing capabilities for lumateperone;
- the amount of product sales from lumateperone;
- the costs of preparing applications for regulatory approvals for lumateperone in additional indications other than in schizophrenia, and potentially in jurisdictions other than the United States, and for other product candidates, as well as the costs required to support review of such applications;
- the costs of manufacturing and distributing lumateperone for commercial use in the United States;
- our ability to obtain regulatory approval for, and subsequently generate product sales from, lumateperone in additional indications other than in schizophrenia or in jurisdictions other than the United States;
- 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 maintaining or securing manufacturing and supply arrangements for clinical or commercial production of lumateperone or our other product candidates;
- 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 approvals for our product candidates;
- the costs involved in expanding the accounting and data management systems to support commercial operations; and

- the costs associated with litigation, including the costs incurred in defending against any product liability claims that may be brought against us related to lumateperone or our other product candidates.

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 products, 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, products 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 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.

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. In the fourth quarter of 2018, a DMC completed a pre-specified interim analysis of our ITI-007-201 Phase 3 trial in patients with a clinical diagnosis of probable AD and clinically significant symptoms of agitation, concluded that the trial is not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial.

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.

Even though the FDA has granted approval of CAPLYTA for the treatment of schizophrenia, the terms of the approval may limit its commercial potential. Additionally, CAPLYTA is still subject to ongoing regulatory requirements.

Even though the FDA has granted approval of CAPLYTA, the scope and terms of the approval may limit our ability to commercialize CAPLYTA and, therefore, our ability to generate substantial sales revenues. The FDA has approved CAPLYTA only for the treatment of schizophrenia in adults. The label for CAPLYTA also contains a "boxed" warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death and that CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.

The manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for CAPLYTA will also continue to be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing processes, good clinical practices, international council for harmonization guidelines and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our nonclinical and clinical development and for any clinical trials that we conduct post-approval.

Discovery of any issues post-approval, including any safety concerns, such as unexpected side effects or drug-drug interaction problems, adverse events of unanticipated severity or frequency, or concerns over misuse or abuse of the product, problems with the facilities where the product is manufactured, packaged or distributed, or failure to comply with regulatory requirements, may result in, among other things, restrictions on CAPLYTA or on us, including:

- withdrawal of approval, addition of warnings or narrowing of the approved indication in the product label;
- requirement of a Risk Evaluation and Mitigation Strategy to mitigate the risk of off-label use in populations where the FDA may believe that the potential risks of use may outweigh its benefits;
- voluntary or mandatory recalls;
- warning letters;
- suspension of any ongoing clinical studies;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or
- seizure or detention, or refusal to permit the import or export of products.

If any of these actions were to occur, we may have to delay or discontinue the commercialization of CAPLYTA, limit our sales and marketing efforts, conduct further post-approval studies, and/or delay, discontinue or change any other ongoing or planned clinical studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Safety issues with our product candidates or approved product, 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 or approved product could adversely affect the development, regulatory approval and commercialization of our product candidates or approved product. 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. As we continue the development and clinical trials of our product candidates and initiate commercialization of our approved product, there can be no assurance that our product candidates or approved product 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. The label for CAPLYTA contains a “boxed” warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death and that CAPLYTA is not approved for the treatment of patients with dementia-related psychosis. If we or others later identify undesirable side effects caused by the mechanisms of action or classes of our products or product candidates or any specific products or 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 trials 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 trials. Preliminary and interim data of a clinical trial are not necessarily predictive of final data. 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 affect our planned clinical path for our product candidates, including increasing costs of and/or causing delays in such development, and 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.

We are subject to ongoing regulatory obligations and restrictions with regard to CAPLYTA and, following regulatory approval of any of our product candidates, we will be subject to ongoing regulatory obligations and restrictions with regard to such product candidates, which may result in significant expense and limit our ability to commercialize lumateperone and our other potential products.

With regard to CAPLYTA and our product 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 product 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 product 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 product 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.

CAPLYTA and our product candidates, if approved, 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.

The degree of market acceptance by physicians, health care professionals and third-party payors of CAPLYTA, and any product candidate for which we obtain regulatory approval, and our profitability and growth will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the scope of the approved indication(s) for the product;
- the inclusion of any warnings or contraindications in the product label;
- 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;
- patient adherence to treatment;
- prevalence and severity of any adverse side effects; and
- availability of alternative treatments.

If any product 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, sales and marketing, 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, sales and marketing, scientific or technical staff may significantly delay or prevent the achievement of drug development, commercialization 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, sales and marketing, and managerial personnel, due to intense competition and our limited resources, would limit or delay our product development and commercialization efforts, which would adversely affect the development of our drug candidates and commercialization of CAPLYTA 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 approved product or product candidates.

Lumateperone and our other 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 our other potential products, which may not be successful.

Lumateperone and our other 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 active pharmaceutical ingredient, or 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. In addition, there is no assurance that our manufacturers will be able to manufacture lumateperone 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 lumateperone or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of lumateperone 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 lumateperone and our other 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 and to produce lumateperone for commercial sales. 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 or 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 for commercial sale or product candidates in our clinical trials would be jeopardized. Any delay or interruption in the supply of commercial quantities of approved product could have a material adverse impact on our revenue from product sales and 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 conducted following our request for regulatory approval for our product candidates 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, if approved, 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 or approved product, 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, ITI-214 and ITI-333), 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 will need to further develop information technology systems and internal sales, marketing, and distribution capabilities for any drug that we may successfully develop, including CAPLYTA for the treatment of schizophrenia. 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 lumateperone or any of our other potential products does 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 lumateperone or other potential 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 lumateperone or other product candidates, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of those products.

In addition, the market for lumateperone or any product candidate 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, even if not approved for the indication for which lumateperone is approved.

Third-party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs.

The current environment is putting pressure on companies to price products below what they may feel is appropriate. Selling lumateperone at less than an optimized price could impact our revenues and overall success as a company. We do not know if the price we have selected, or may select in the future, for lumateperone is or will be the optimized price. 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 such as lumateperone may 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 drug products such as lumateperone 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.

Health care legislation may make it more difficult to receive revenues from CAPLYTA or future 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 lumateperone and our other potential products 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 lumateperone or any of our other 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 CAPLYTA or any other products for which we receive regulatory approval.

We currently have very limited experience as a company in marketing and distributing pharmaceutical products and rely on third-party distributors to distribute CAPLYTA. If we are unable to effectively commercialize CAPLYTA, we may not be able to generate adequate product revenues.

CAPLYTA, which was approved in December 2019 by the FDA for the treatment of schizophrenia in adults in the United States, is our only drug that has been approved for sale by any regulatory body. We expect to initiate the commercial launch of CAPLYTA late in the first quarter of 2020. As such, we currently have never, as an organization, launched or commercialized any pharmaceutical product. In order to successfully market CAPLYTA, we must continue to develop our sales, marketing, managerial, compliance, and related capabilities or make arrangements with third parties to perform these services. If we are unable to maintain and develop adequate sales, marketing, and distribution capabilities, whether independently or with third parties, we may not be able to appropriately commercialize and generate revenue from sales of CAPLYTA and may not become profitable.

We expect to employ our own internal sales force to commercialize CAPLYTA for the treatment of schizophrenia as part of our commercialization strategy in the United States. We will need to complete the hiring of our U.S. sales force and refine and further develop our sales force as we initiate our commercialization of CAPLYTA, and we will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. These efforts will continue to be expensive and time-consuming, and we cannot be certain that we will be able to successfully complete the hiring of our U.S. sales force and refine and further develop our sales force.

Additionally, our strategy in the United States includes distributing CAPLYTA through third-party distributors. While we have entered into, or will attempt to enter into, agreements with these distributors to distribute CAPLYTA in the United States, they may not perform as agreed or they may terminate their agreements with us. Also, we may need to enter into agreements with additional distributors, and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. If we are unable to maintain and, if needed, expand, our network of distributors, we would be exposed to substantial distribution risk.

In the event we are unable to effectively develop and maintain our commercial team, including our U.S. sales force, or maintain and, if needed, expand, our network of distributors, our ability to effectively commercialize CAPLYTA and generate product revenues would be limited.

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

As of December 31, 2019, we had net operating loss carryforwards, or NOLs, of approximately $183.1 million, which are available to reduce any future federal and state taxable income and will begin to expire at various dates through 2037 and $51.9 million do not expire. 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, changes in our ownership (as defined by the foregoing sections of the Code) may limit the amount of NOLs and tax credit carryforwards that could be utilized annually in the future to offset taxable income.

For the years ended December 31, 2019, 2018 and 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 through December 31, 2019, 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. We have not performed a complete section 382 analysis to determine the effect on ownership related to the January 2020 public offering. If we experience an ownership change related to the January 2020 public offering or 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 lumateperone 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 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. In addition, the TCJA repealed the alternative minimum tax, or AMT, and provides for a refund of AMT paid or a reduction of future taxes payable over a prescribed period of years between 2018 and 2021. With the passing of the TCJA, the Company will receive a refund in future periods for AMT paid in prior years. The Company has recognized a benefit of approximately $1.1 million for these taxes on its December 31, 2017 consolidated statement of operations. As of December 31, 2019, the Company had received refunds of approximately $0.5 million and has recorded receivables of approximately $0.6 million for future AMT refunds, consisting of $0.3 million recorded as a deferred tax asset and $0.3 million recorded as a receivable. We continue to examine the impact this tax reform legislation may have on our business and depending on possible foreign operations, among other things, 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 the Health Insurance Portability and Accountability Act, or HIPAA, 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 commercialization of our approved product and the further development of our product candidates could be delayed or otherwise adversely impacted.

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 products and 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 products and 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, ITI-214 and ITI-333 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 products, 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 products, product candidates or technologies, we may still be barred from making, using and selling our products, 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 CNS disorders and the other fields in which we are developing product candidates. 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 products, 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, enforceability, scope and term of our patents. Additionally, any patent term extensions that we seek may not be granted on a timely basis, if at all. 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 products, product candidates, technologies or activities infringe the intellectual property rights of others. If our drug development or commercialization 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, products and product candidates 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. Our approved product and the product candidates that we are developing are protected by intellectual property rights, including patents and patent applications. For our approved product and any of our product candidates that become a marketable product, if any, 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 products or 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, product candidates 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 products, 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.

We may not be able to protect our intellectual property and proprietary rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents relating to our products, product candidates and technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as U.S. laws. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant difficulties in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult, costly or impossible for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us or any of our future licensors. We may not prevail in any lawsuits or other adversarial proceedings that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

was 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 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 Code 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 CAPLYTA and any other 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. For example, the label for CAPLYTA contains a “boxed” warning that elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death and that CAPLYTA is not approved for the treatment of patients with dementia-related psychosis. 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 lumateperone or our other 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, CAPLYTA for the treatment of schizophrenia and, if approved, lumateperone for the treatment of bipolar depression would compete with, among other branded products, 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, lumateperone and our other 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;
- obtaining FDA and other regulatory approvals; and
- commercializing pharmaceutical products.

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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of lumateperone or any other product for which we obtain regulatory approval, or development or commercialization of our product candidates.

We face an inherent risk of product liability as a result of commercial sales of lumateperone in the United States and the clinical testing of our product candidates, and will face an even greater risk following commercial launch of lumateperone in additional jurisdictions, if approved, or if we engage in the clinical testing of new product candidates or commercialize any additional products.

For example, we may be sued if lumateperone or any other product we develop allegedly causes injury or is found to be otherwise unsuitable for administration in humans. Any such product liability claims may include

allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products or product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products or product candidates; and
- a decline in our stock price.

Although we currently have product liability insurance that covers our clinical trials and the commercialization of CAPLYTA for the treatment of schizophrenia, we may need to increase and expand this coverage, including if lumateperone is approved for the treatment of indications beyond schizophrenia or if other 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. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain such increased coverage on acceptable terms or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Our liability could exceed our total assets if we do not prevail in a lawsuit from any injury caused by our drug products. Product liability claims could have a material adverse effect on our business and results of operations.

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, 2019, the price per share of our common stock on the Nasdaq Global Select Market has ranged from a high of $43.56 to a low of $6.75. 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:

- the success of our commercial launch and commercialization of CAPLYTA in the United States for the treatment of schizophrenia;

- 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 products, product candidates and technology and, to a lesser extent, grant funding, although there can be no assurances such financing can be obtained. We filed a universal shelf registration statement on Form S-3 with the SEC, which was declared effective on September 12, 2019, on which we registered for sale up to $350 million of any combination of our common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that we may determine, including up to $75 million of common stock which we may offer and sell, from time to time at our sole discretion, under our at-the-market program sales agreement that we entered into with SVB Leerink LLC in August 2019. In addition, on January 6, 2020, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which we registered for sale an unlimited amount of any combination of our common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. These registration statements will remain in effect for up to three years from the respective dates they became effective. 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. Additional financial controls are being assessed and implemented to address the increased complexity of revenue recognition associated with commercial sales of a pharmaceutical product. There are no assurances that these controls will be adequate or successfully implemented. 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 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 of the commercial launch of CAPLYTA for the treatment of schizophrenia in adults in the United States;
- the initiation, cost, timing, progress and results of our development activities, non-clinical studies and clinical trials;
- the timing of and our ability to obtain and maintain regulatory approval, or submit an application for regulatory approval, of lumateperone and our other 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 lumateperone and other current and future product candidates;
- the election by any collaborator 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 lumateperone or our other product candidates;
- our ability to successfully commercialize lumateperone and our other product candidates;
- the size and growth of the markets for lumateperone and our other 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 32,287 square feet of useable office and laboratory space. The term of the lease, as amended, expires in March 2029. We also lease a small amount of office space in Towson, Maryland.

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 Nasdaq Global Select Market under the symbol "ITCI."

Stockholders

As of February 28, 2020, we had 66,133,183 outstanding shares of common stock and no outstanding shares of preferred stock. As of February 28, 2020, there were approximately 98 holders of record of our outstanding shares of common stock.

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, 2019. The selected financial data for each of the five years in the period ended December 31, 2019 have been derived from our audited consolidated financial statements. The consolidated balance sheets as of December 31, 2019 and 2018 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, 2019, 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.

	2019	2018	2017	2016	2015
Statements of Operations:					
Revenues:					
License and collaboration revenue	$ —	$ —	$ —	$ —	$ 30,659
Grant revenue	60,613	—	245,837	330,702	60,705
Total Revenues	60,613	—	245,837	330,702	91,364
Costs and expenses:					
Research and development	89,124,838	132,166,913	79,419,009	93,831,530	87,718,074
General and administrative	64,947,625	30,099,855	23,666,957	24,758,063	18,187,286
Total costs and expenses	154,072,463	162,266,768	103,085,966	118,589,593	105,905,360
Loss from operations	(154,011,850)	(162,266,768)	(102,840,129)	(118,258,891)	(105,813,996)
Interest income	(6,291,272)	(7,140,957)	(4,005,864)	(2,935,077)	(1,022,455)
Interest expense	—	—	—	36,781	—
Income tax expense (benefit)	1,600	1,600	(1,060,851)	1,065,673	1,600
Net Loss	$ (147,722,178)	$ (155,127,411)	$ (97,773,414)	$ (116,426,268)	$ (104,793,141)
Net Loss per common share	$ (2.68)	$ (2.84)	$ (2.12)	$ (2.69)	$ (2.91)
Weighted average number of common shares:	55,186,206	54,707,865	46,181,926	43,240,188	36,069,237

	December 31,				
	2019	2018	2017	2016	2015
Balance Sheet data:					
Cash and cash equivalents	$ 107,636,849	$ 54,947,502	$ 37,790,114	$ 48,642,225	$ 47,159,303
Investments	116,373,335	292,583,046	426,540,921	335,458,459	428,041,021
Total assets	251,186,476	357,206,498	471,486,699	388,903,495	484,103,528
Total liabilities	56,179,205	39,491,617	17,049,738	13,400,956	7,860,617
Accumulated deficit	(710,098,369)	(562,376,191)	(407,248,780)	(309,475,366)	(193,049,098)
Total stockholders' equity	195,007,271	317,714,881	454,436,961	375,502,539	476,242,911

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, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. In December 2019, we announced that CAPLYTA (lumateperone) has been approved by the FDA for the treatment of schizophrenia in adults (42mg/day). We expect to initiate the commercial launch of CAPLYTA late in the first quarter of 2020. In support of our commercialization efforts, we expect to deploy a national sales force consisting of approximately 240 sales representatives. At the time of launch, CAPLYTA will be priced in line with other currently marketed branded antipsychotics indicated for the treatment of schizophrenia. As used in this report, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia.

Lumateperone is also in Phase 3 clinical development as a novel treatment for bipolar depression. Our lumateperone bipolar depression Phase 3 clinical program currently consists of three monotherapy studies and one adjunctive study. In the first quarter of 2020 we initiated our third monotherapy Phase 3 study, Study 403, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. We anticipate reporting topline results from Study 403 in the second half of 2021. On July 8, 2019, we announced topline results from our first monotherapy study, Study 401, conducted in the U.S., and our second monotherapy study, Study 404, conducted globally, evaluating lumateperone as monotherapy in the treatment of major depressive episodes associated with Bipolar I or Bipolar II disorder. In Study 404, lumateperone 42 mg met the primary endpoint for improvement in depression as measured by change from baseline versus placebo on the MADRS total score ($p<0.0001$; effect size = 0.56). Study 401 tested two doses of lumateperone, 42 mg and 28mg along with placebo. In this trial, neither dose of lumateperone met the primary endpoint of statistical separation from placebo as measured by change from baseline on the MADRS total score. There was a high placebo response in this trial. Lumateperone was generally well-tolerated in both bipolar depression studies, with a favorable safety profile. The rates of discontinuation due to treatment emergent adverse events for both doses of lumateperone were low. Our global study evaluating adjunctive lumateperone in bipolar depression (Study 402) is ongoing and we anticipate reporting topline results from this study in mid-2020. Subject to the results of Study 402 and our interactions with the FDA regarding our bipolar depression program, in late 2020 we expect to submit a supplemental new drug application, or sNDA, to the FDA for potential regulatory approval of lumateperone for the treatment of bipolar depression.

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 was 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 the fourth quarter of 2018, an independent data monitoring committee, or DMC, completed a pre-specified interim analysis of the ITI-007-201 trial, and concluded that the trial was not likely to meet its primary endpoint upon completion and therefore recommended the study should be stopped for futility. As a result, we determined to discontinue the ITI-007-201 trial. Lumateperone was generally well

tolerated in the ITI-007-201 trial and the decision to discontinue the study was not related to safety. We are analyzing the data set from this trial and will determine the next steps in our program following completion of this analysis.

We are also pursuing clinical development of lumateperone for the treatment of additional CNS diseases and disorders. We believe lumateperone may have utility for treating agitation, aggression and sleep disturbances in diseases that include dementia, AD, Huntington's disease and autism spectrum disorders. At a dose of 42 mg, lumateperone has been shown effective in treating the symptoms associated with schizophrenia, and we believe this higher dose range may merit further investigation for the treatment of bipolar disorder, depressive disorders and other neuropsychiatric diseases.

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 option, in particular, may lend itself to being an important formulation choice for patients.

We may investigate the use of lumateperone, either on our own or with a partner, as a treatment for 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 inhibit the enzyme phosphodiesterase type 1, or PDE1. PDE1 enzymes are highly active in multiple disease states and our PDE1 inhibitors are designed to reestablish normal function in these disease states. Abnormal PDE1 activity is associated with cellular proliferation and activation of inflammatory cells. Our PDE1 inhibitors ameliorate both of these effects in animal models. We intend to pursue the development of our phosphodiesterase, or PDE, program, for the treatment of several CNS and non-CNS conditions with a focus on diseases where excessive PDE1 activity has been demonstrated and increased inflammation is an important contributor to disease pathogenesis. Our potential disease targets include heart failure, immune system regulation, neurodegenerative diseases, and other non-CNS disorders. 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. Following the favorable 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. In the fourth quarter of 2018, we announced that the Phase 1/2 clinical trial of ITI-214 has been completed and topline results demonstrated ITI-214 was generally well-tolerated with a favorable safety profile and clinical signs consistent with improvements in motor symptoms and dyskinesias. In addition, in the first quarter of 2018, the investigational new drug application, or IND, went into effect for ITI-214 for the treatment of heart failure. Clinical conduct of the first clinical study in this program, a randomized, double-blind, placebo-controlled Phase 1/2 study of escalating single doses of ITI-214 to evaluate safety and hemodynamic effects in patients with systolic heart failure, is ongoing and we anticipate reporting topline results from this study in the first half of 2020.

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. Preclinical safety studies with ITI-333 are currently ongoing and we expect to initiate a clinical program in 2020.

We have assembled a management team with significant industry experience to lead the discovery, development and potential commercialization 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.

Results of Operations

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

Discussions of year-over-year comparisons between 2018 and 2017 that are not included in this Form 10-K can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Revenues

We expect to initiate the commercial launch of CAPLYTA late in the first quarter of 2020, but have not generated any revenue from product sales to date. We had approximately $61,000 of grant revenues for the year ended December 31, 2019 and no revenue for the year ended December 31, 2018. 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 completely 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 costs associated with the commercialization of CAPLYTA will be substantial and will be incurred prior to our generating sufficient revenue to offset these costs. Costs for the clinical development of lumateperone for the treatment of bipolar depression consumes and, together with our anticipated clinical development programs for depressive disorders and ITI-214, 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 1/2 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. In addition, in the first quarter of 2018, the IND went into effect for ITI-214 for the treatment of heart failure. We have initiated clinical conduct of the first clinical study in this program, 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. Our other projects are still in the preclinical stages, and will require extensive funding not only to complete preclinical testing, but to commence 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 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 costs relating to labor and fringe benefits, materials, supplies, facilities and maintenance; and

- fees paid to external parties who provide us with contract services, such as pre-clinical testing, manufacturing and related testing, clinical trial activities and license milestone payments.

General and administrative expenses are incurred in three major categories:

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

Selling expenses are incurred in three major categories:

- salaries and related benefit costs of a dedicated sales force;
- sales operation costs; and
- marketing and promotion expenses.

We expect that research and development expenses will increase moderately as we proceed with our Phase 3 clinical trials of lumateperone for the treatment of bipolar depression and depressive disorders, other clinical trials, increased manufacturing of drug product for clinical trials and pre-clinical development activities. We also expect that our general and administrative costs will increase from prior periods primarily due to costs associated with building infrastructure to support the anticipated commercial sales of CAPLYTA, which will include hiring additional personnel and the cost of additional facility space. On September 28, 2018, we signed a lease with a related party to acquire 15,534 square feet of additional office space in our current headquarters facility. We granted options to purchase 1,175,187 shares of our common stock in 2018 and have granted options to purchase an additional 1,218,494 shares of our common stock on January 8, 2019. We also granted time based restricted stock units, or RSUs, for 544,542 of our common stock in 2018 and time based RSUs for 886,802 shares of our common stock on January 8, 2019. We will recognize expense associated with these RSUs and options over 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 an NDA with the FDA, (ii) the approval of the NDA by the FDA, or the Milestone RSUs, and (iii) the achievement of certain comparative shareholder returns against our peers, or the TSR RSUs. The Milestone RSUs were valued at the closing price on March 8, 2017. The RSUs related to the NDA submission were amortized through December 31, 2018 based on the probable vesting date. The NDA submission milestone was achieved in the third quarter of 2018. The Milestone RSUs related to the NDA submission vested on December 31, 2018. The NDA approval milestone was achieved in the fourth quarter of 2019. The Milestone RSUs related to the NDA approval vested on December 31, 2019. The TSR RSUs were valued using the Monte Carlo simulation method and were amortized over the life of the RSU's which vested on January 24, 2020. In February 2020, we granted employees options to purchase 663,121 shares of our common stock, time based RSUs for 705,017 shares of our common stock, and performance based stock units for 86,046 shares of our common stock that vest based on the achievement of certain milestones. We expect to continue to grant stock options and other stock-based awards in the future, which with our growing employee base 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, 2019, 2018 and 2017 (in thousands):

	For the Year Ended December 31,		
	2019	2018	2017
Revenues	**$ 61**	$ —	$ 246
Expenses			
Research and Development	**89,125**	132,167	79,419
General and Administrative	**64,948**	30,099	23,667
Total costs & expenses	**154,073**	162,266	103,086
Loss from operations	**(154,012)**	(162,266)	(102,840)
Interest income, net	**(6,292)**	(7,141)	(4,006)
Income tax expense (benefit)	**2**	2	(1,061)
Net Loss	**$ (147,722)**	$(155,127)	$ (97,773)

Comparison of Years Ended December 31, 2019 and December 31, 2018

Revenues

Revenues for the year ended December 31, 2019 were approximately $61 thousand due to grant revenues compared to $0 for the year ended December 31, 2018. We expect to have a moderate amount of grant revenue in the future.

We expect to initiate the commercial launch of CAPLYTA late in the first quarter of 2020 and to begin receiving product revenue thereafter.

Research and Development Expenses

	2019	2018
External Costs	**$ 59,141**	$110,700
Internal Costs	**29,984**	21,467
Total Research and Development Expenses	**$ 89,125**	$132,167

	2019	2018
Lumateperone costs	**$ 37,121**	$ 82,288
Manufacturing costs	**20,684**	22,741
Stock based compensation	**9,411**	7,381
Other projects and overhead	**21,909**	19,757
Total Research and Development Expenses	**$ 89,125**	$132,167

Research and development expenses decreased to $89.1 million for the year ended December 31, 2019 as compared to $132.2 million for the year ended December 31, 2018, representing a decrease of approximately $43.1 million, or 33%. This decrease is due primarily to a decrease of approximately $45.7 million of costs associated with lumateperone clinical costs due primarily to substantial completion in 2019 of two bipolar depression trials and a long term safety trial for lumateperone and a decrease of approximately $2.0 million in manufacturing expense, partially offset by an increase of approximately $2.0 million in stock compensation expense, approximately $0.6 million in costs for lumateperone non-clinical efforts and an increase of approximately $2.1 million of non-lumateperone projects and overhead expenses. For the year ended December 31, 2019, the Company recorded a change in estimate of approximately $5.3 million related to the prior year estimates of accrued expenses for clinical trials that resulted in a reduction of research and development expenses. Expenses for other projects and overhead increased as we expanded our preclinical development of ITI-333 and ITI-214, among others.

As development of lumateperone progresses, we anticipate costs for lumateperone to increase due primarily to ongoing and planned clinical trials relating to our lumateperone programs in the next several years as we conduct Phase 3 and other clinical trials. We are also required to complete non-clinical testing to obtain FDA approval and manufacture material needed for clinical trial use, which includes non-clinical testing of the drug product and the creation of an inventory of drug product in anticipation of possible FDA approval. We received FDA approval on December 20, 2019 for lumateperone as a treatment for schizophrenia. There was no lumateperone inventory purchased, received, or produced from the date of approval through December 31, 2019 and therefore no inventory costs are reflected on our balance sheet through December 31, 2019.

As of December 31, 2019, we employed 56 full time personnel in our research and development group as compared to 49 full time personnel in our research and development group at December 31, 2018. 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 areas of cognitive dysfunction and the treatment of neurodegenerative diseases, including AD, among others. 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 increased for the year ended December 31, 2019 as compared to the year ended December 31, 2018 by approximately $34.8 million, or 115.8%. The increase is primarily the result of an increase in pre-commercialization costs of approximately $21.2 million, labor costs of approximately $7.7 million, stock compensation expense of approximately $1.4 million, rent expense of approximately $1.1 million and professional fees of approximately $0.9 million. Salaries, bonuses and related benefit costs for our executive, finance and administrative functions for the years ended 2019 and 2018 constituted approximately 40% and 56%, respectively, of our total general and administrative costs. The next major categories of expenses were patent costs 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. We also expect selling costs which will be separately presented in future periods to increase significantly from the $21.2 million of pre-commercialization costs incurred in 2019. This will primarily be due to hiring approximately 240 sales representatives and a sales management group, incurring sales operations costs and implementing marketing activities to support the commercialization of CAPLYTA.

Interest Income

Interest income has decreased to approximately $6.3 million from $7.1 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018. This decrease is primarily a result of lower cash balances due to cash used in the operations of the company in 2019 and is partially offset by higher interest rates during 2019.

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 AMT related to intercompany transactions that were treated as tax expense in our consolidated statement of operations in 2016. In December 2017 the TCJA granted a refund of the AMT or a reduction of taxes in future periods. The Company has therefore recognized a benefit of approximately $1.1 million for these taxes in 2017. The Company received approximately $529,000 in 2019 and expects to receive the remainder within the next three years.

Liquidity and Capital Resources

Through December 31, 2019, we provided funds for our operations by obtaining approximately $883.6 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 January 10, 2020, we completed a public offering of 10,000,000 shares of our common stock. All of the shares in the offering were sold by the Company, with gross proceeds to the Company of approximately $295.0 million and net proceeds of approximately $276.9 million, after deducting underwriting discounts, commissions and estimated offering expenses.

As of December 31, 2019, we had a total of approximately $224.0 million in cash and cash equivalents and available-for-sale investment securities, and approximately $36.2 million of short-term liabilities consisting entirely of liabilities related to operations. In the year ended December 31, 2019, we spent approximately $135.0 million for operations and equipment, not including $6.3 million of interest income. We reduced working capital by approximately $125.0 million for the year ended December 31, 2019. This use of cash was primarily for conducting clinical trials and non-clinical testing, including manufacturing related activities, conducting pre-commercialization activities and funding recurring operating expenses.

Based on our current operating plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the filing date of this Annual Report. During that time, we expect that our expenses will increase substantially due primarily to our commercialization activities and related infrastructure expansion in connection with the commercialization of CAPLYTA for the treatment of schizophrenia; the development of lumateperone in our late stage clinical programs; the development of our other product candidates, including ITI-214; the continuation of manufacturing activities in connection with the development of lumateperone; and general operations.

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 commercialize CAPLYTA in patients with schizophrenia. With our existing cash, cash equivalents and available-for-sale investment securities, 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. We also plan to fund additional clinical trials of lumateperone for the treatment of behavioral disturbances in dementia and depressive disorders; preclinical and clinical development of our 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 for further development of 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 a license agreement that has been terminated. These losses have resulted in significant cash used in operations. For the year ended December 31, 2019, we used net cash in operating activities and purchases of equipment of approximately $135.0 million. This total does not include an offset for $6.3 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 beyond schizophrenia and our other product candidates, as well as commercialization efforts, we expect the amount of cash to be used to fund operations to increase over the next several years.

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. In addition, in the first quarter of 2018, the IND went into effect for ITI-214 for the treatment of heart failure. We have initiated clinical conduct of the first clinical study in this program, 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. We expect these expenses to increase for 2020 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 August 30, 2019, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 12, 2019, on which we registered for sale up to $350 million of any combination of our common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that we may determine, which includes up to $75 million of common stock that we may issue and sell from time to time, through SVB Leerink LLC acting as our sales agent, pursuant to the sale agreement that we entered into with SVB Leerink on August 29, 2019 for our "at-the-market" equity program. In addition, on January 6, 2020, we filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which we registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that we may determine, so long as we continue to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. These registration statements will remain in effect for up to three years from the respective dates they became 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 magnitude of sales of CAPLYTA, 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 results in the commercialization of CAPLYTA and 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 with a related party which, as amended, provided for a lease of 16,753 square feet of useable laboratory and office space located at 430 East 29th Street, New York, New York 10016. Concurrent with this lease, we entered into a license agreement to occupy certain vivarium related space in the same facility for the same term, rent and escalation provisions as the lease. This license has the primary characteristics of a lease and is characterized as a lease in accordance with ASU 2016-02 for accounting purposes. In September 2018, we further amended the lease to obtain an additional 15,534 square feet of office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years ending in May 2029. We expect that our facility related costs will increase as a result of leasing this additional space. In February 2019, we entered into a long-term lease for 3,164 square feet of office space in Towson, Maryland beginning March 1, 2019. The lease has a term of 3.2 years ending in April 2022. We anticipate acquiring additional space in 2020 to accommodate our commercial and infrastructure expansion which could result in a moderate increase in facility costs.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations and Commitments

Total contractual obligations as of December 31, 2019 are summarized in the following table (in thousands):

	Payments Due By Period				
	Total	2020	2021-2022	2023-2025	After 2025
Operating Lease Obligations	$35,155	$3,346	$ 6,940	$ 11,029	$ 13,840

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 $10 million, including the $5.0 million paid in January 2020; to make other future milestone payments to BMS for each licensed product of up to an aggregate of approximately $14.75 million; to make tiered single digit percentage royalty payments on sales of licensed products; and to pay BMS a percentage of non-royalty payments made in consideration of any sublicense.

Critical Accounting Policies and Estimates

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

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

Research and Development, Including Clinical Trial Expenses

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 our financial statements, we are required to estimate expenses resulting from the 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 our 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 various clinical information provided by vendors and 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 our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date based on the facts and circumstances known to us 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 our estimates to be materially different from amounts actually incurred, our 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 us reporting amounts that are too high or too low for any particular period. For the year ended December 31, 2019, we recorded a change in estimate of approximately $5.3 million related to the prior year estimates of accrued expenses for clinical trials that resulted in a reduction of research and development expenses. For the year ended December 31, 2018, there were no material adjustments to our prior period estimates of accrued expenses for clinical trials.

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 became effective for annual periods beginning after December 15, 2017.

We adopted this standard on January 1, 2018 using the “modified retrospective method” which did not result in an impact to our financial statements as we have not had product sales to date. Upon commercializing a product or executing any revenue generating contracts, 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 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 the Company's other deferred tax assets. ASU 2016-01 is effective for annual reporting periods beginning after December 15, 2017. The Company adopted ASU 2016-01 as of January 1, 2018 but the adoption did not have any 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 requires 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 lease guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company adopted the standard on January 1, 2019 using the simplified transition method, allowing the Company to not restate comparative periods and apply ASU No. 2016-02, Leases (Topic 842) on a prospective basis, resulting in a balance sheet presentation that is not comparable to the prior period in the first year of adoption. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed the Company to carry forward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off the balance sheet. The Company recognizes those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

The adoption of the standard resulted in recognition of additional right of use assets and lease liabilities of approximately $20.2 million and $23.4 million, respectively, as of January 1, 2019. The difference between these amounts represents the net deferred rent as of January 1, 2019 with no impact on the accumulated deficit. The adoption of the new lease standard was a non-cash transaction. The Company concluded the new standard did not have a material impact on its liquidity and income tax position.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments" ("ASU 2016-13"). This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018 and interim periods therein. The Company elected not to early adopt the standard, and therefore, adopted the standard on January 1, 2020. The Company is considering the implications of adopting the new standard, including the applicable financial statement disclosures required by the new guidance. The Company is assessing any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance. Upon adoption of the new standard on January 1, 2020, the Company will begin recognizing an allowance using a forward-looking approach to estimating the expected credit loss related to its financial assets. The Company does not anticipate that the adoption of the new standard will have a significant impact on its operating results, financial position or cash flows.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220)—Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, to address a specific consequence of the TCJA by allowing a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA's reduction of the U.S. federal corporate income tax rate. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, with early adoption permitted, and is to be applied either in the period of adoption or

retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the TCJA is recognized. The Company does not have any stranded tax effects to which this ASU would apply. Therefore, there is no impact to the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). The standard allows for the entity to only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. After adoption, the nonemployee share-based payment awards would be treated similar to employee share-based payment awards going forward. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. We adopted ASU 2018-07 on January 1, 2019. As our nonemployee share-based awards are not significant, we concluded that the adoption did not have a material impact on the consolidated accumulated deficit.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)(ASU 2019-12) final guidance that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation that is applicable to the Company, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences among other changes. For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued. An entity that elects to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, an entity that elects early adoption must adopt all the amendments in the same period. The Company elected to early adopt the ASU 2019-12 as of December 31, 2019. Management concluded that the adoption of the new standard did not have a material impact to income taxes for the year ended December 31, 2019.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity. As of December 31, 2019, we had cash, cash equivalents and marketable securities of approximately $224.0 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 decline in interest rates has resulted in our unrealized gain on investments, net, as of December 31, 2019 of approximately $128,000 and an unrealized loss on investments, net, in 2018 totaling approximately $668,000. 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. Although we expect to begin receiving product revenues following our commercial launch of CAPLYTA, we continue to depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INTRA-CELLULAR THERAPIES, INC.

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

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K, have concluded that, based on such evaluation, our disclosure controls and procedures were effective at the reasonable assurance level 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, 2019. 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, 2019, 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, 2019 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 the 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, 2019, 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, 2019, 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 of the Company as of December 31, 2019 and 2018, 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, 2019, and the related notes and our report dated March 2, 2020 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 2, 2020

Item 9B. OTHER INFORMATION

On February 26, 2020, the Company's board of directors approved a new Code of Business Conduct and Ethics (the "Code"). The revisions to the Code include, among other things, the expansion of sections of the Code relating to compliance with laws and regulations. In addition, non-substantive changes were made to the Code to enhance readability. The adoption of the Code did not relate to or result in any waiver, explicit or implicit, of any provision of the previous Code.

The foregoing description of the Code is qualified in its entirety by the full text of the Code, which is available on the Company's investor relations website at www.intracellulartherapies.com.

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,” “Delinquent Section 16(a) Reports,” and “Code of Conduct and Ethics” in the Company’s Proxy Statement for the 2020 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 2020 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,” “Equity Compensation Plan Information” and “Approval of Amendment to the Intra-Cellular Therapies, Inc. 2018 Equity Incentive Plan” in the Company’s Proxy Statement for the 2020 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 2020 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 “Ratification of Selection of Independent Registered Public Accounting Firm” in the Company’s Proxy Statement for the 2020 Annual Meeting of Stockholders.

PART IV

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

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

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

Item 15(a)(3) Exhibits

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

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
2.1	Agreement and Plan of Merger, dated as of August 23, 2013, by and among the Registrant, ITI, Inc. and Intra-Cellular Therapies, Inc.		8-K (Exhibit 2.1)	8/29/2013	000-54896
2.2	Agreement and Plan of Merger, dated as of August 29, 2013, by and between the Registrant and Intra-Cellular Therapies, Inc., relating to the name change of the Registrant.		8-K (Exhibit 2.2)	9/5/2013	000-54896
3.1	Restated Certificate of Incorporation of the Registrant, filed with the Secretary of State of the State of Delaware on November 7, 2013.		S-1/A (Exhibit 3.1)	11/26/13	333-191238
3.2	Certificate of Merger relating to the Merger of ITI, Inc. with and into Intra-Cellular Therapies, Inc., filed with the Secretary of State of the State of Delaware on August 29, 2013.		8-K (Exhibit 3.3)	9/5/2013	000-54896
3.3	Certificate of Ownership and Merger relating to the Merger of Intra-Cellular Therapies, Inc. with and into the Registrant, filed with the Secretary of State of the State of Delaware on August 29, 2013, relating to the name change of the Registrant.		8-K (Exhibit 3.4)	9/5/2013	000-54896
3.4	Restated Bylaws of the Registrant.		8-K (Exhibit 3.5)	9/5/2013	000-54896
4.1	Form of common stock certificate.		8-K (Exhibit 4.1)	9/5/2013	000-54896
4.2	Description of securities.	X			

Exhibit Number		Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
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		Sales Agreement, dated as of August 29, 2019, by and between SVB Leerink LLC and Intra-Cellular Therapies, Inc.		Form S-3 (Exhibit 1.2)	8/30/2019	333-233537
10.4		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
10.5	.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
10.6		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
10.7	.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
10.8	.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
10.9		Employment Agreement effective as of November 13, 2017 by and between Andrew Satlin, M.D. and Intra-Cellular Therapies, Inc.*		10-K (Exhibit 10.8)	3/1/2018	001-36274
10.10		Employment Agreement effective as of October 15, 2018 by and between Mark Neumann and Intra-Cellular Therapies, Inc.		10-K (Exhibit 10.9)	2/27/2019	001-36274
10.11		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
10.12		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
10.13		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
10.14		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
10.15		Employee Proprietary Information, Inventions, and Non-Competition Agreement effective as of March 5, 2007 by and between Kimberly E. Vanover, Ph.D. and Intra-Cellular Therapies, Inc.*		8-K (Exhibit 10.12)	9/5/2013	000-54896

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.16	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.*		10-K (Exhibit 10.14)	3/1/2018	001-36274
10.17	Employee Proprietary Information, Inventions, Inventions, and Non-Competition Agreement effective as of December 10, 2018 by and between Mark Neumann and Intra-Cellular Therapies, Inc.		10-K (Exhibit 10.16)	2/27/2019	001-36274
10.18	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
10.19	2003 Equity Incentive Plan, as amended.*		8-K (Exhibit 10.14)	9/5/2013	000-54896
10.20	Form of Stock Option Agreement under the 2003 Equity Incentive Plan, as amended.*		8-K (Exhibit 10.15)	9/5/2013	000-54896
10.21	Amended and Restated 2013 Equity Incentive Plan.*		8-K (Exhibit 10.1)	6/18/2015	001-36274
10.22	Form of Stock Option Agreement under the 2013 Equity Incentive Plan.*		10-K (Exhibit 10.19)	3/25/2014	001-36274
10.23	Intra-Cellular Therapies, Inc. 2018 Equity Incentive Plan.*		8-K (Exhibit 10.1)	6/21/2018	001-36274
10.24	Form of Stock Option Agreement under the 2018 Equity Incentive Plan.*		8-K (Exhibit 10.2)	6/21/2018	001-36274
10.25	Form of Director Stock Option Agreement under the 2018 Equity Incentive Plan.*		8-K (Exhibit 10.3)	6/21/2018	001-36274
10.26	Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.*		8-K (Exhibit 10.4)	6/21/2018	001-36274
10.27	Form of Director Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan.*		8-K (Exhibit 10.5)	6/21/2018	001-36274
10.28	Non-Employee Director Compensation Policy, as amended.*	X			

Exhibit Number		Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.29		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
10.30		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
10.31		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
10.32		Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan*	X			
10.33		Form of Restricted Stock Unit Agreement under the 2019 Inducement Award Plan*	X			
10.34		Form of Stock Option Agreement under the 2019 Inducement Award Plan*	X			
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	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X			
	.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
	.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
	.DEF	Inline XBRL Taxonomy Extension Definition.	X			
	.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			

Exhibit Number	Exhibit Description	Filed Herewith	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.	X			
104	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101).	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 2, 2020

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. Sharon Mates, Ph.D.	Chairman, President and Chief Executive Officer (principal executive officer)	March 2, 2020
By: /s/ Lawrence J. Hineline Lawrence J. Hineline	Senior Vice President of Finance and Chief Financial Officer (principal financial officer and principal accounting officer)	March 2, 2020
By: /s/ Christopher Alafi, Ph.D. Christopher Alafi, Ph.D.	Director	March 2, 2020
By: /s/ Richard Lerner, M.D. Richard Lerner, M.D.	Director	March 2, 2020
By: /s/ Joel S. Marcus Joel S. Marcus	Director	March 2, 2020
By: /s/ Rory B. Riggs Rory B. Riggs	Director	March 2, 2020
By: /s/ Robert L. Van Nostrand Robert L. Van Nostrand	Director	March 2, 2020

Report of Independent Registered Public Accounting Firm

To the Stockholders and the 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, 2019 and 2018, 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, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 2, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Clinical trial expenses

Description of the Matter	As described in Note 2 to the consolidated financial statements, at each consolidated balance sheet date 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 Company recorded accrued expenses for the clinical trial accruals, which are included in accrued and other current liabilities on the December 31, 2019 consolidated balance sheet and also recorded prepaid clinical trial expenses, which are included in prepaid expenses and other current assets on the December 31, 2019 consolidated balance sheet. The amounts recorded for clinical trial accruals and for prepaid clinical trial expenses, within the aforementioned balance sheet captions represent the Company's estimate of the unpaid and prepaid clinical trial expenses based on the progress of the research and development services for clinical trials compared to the amounts paid for clinical trials through December 31, 2019. Auditing the Company's clinical trial accruals and prepaid clinical trial expenses involved a high degree of subjectivity due to the significant estimation required in determining the progress to completion of specific tasks conducted under its clinical trials and the costs of those tasks that will be invoiced by the vendors, clinical research organizations and consultants and under clinical site agreements subsequent to the date that the consolidated financial statements are issued.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's estimation of the clinical trial expenses, including the process of estimating the expenses incurred to date based on the status of the clinical trials. For example, we tested controls over management's review of the clinical trial expense calculation, the significant assumptions about the status of research and development services incurred, and the completeness and accuracy of the data used to calculate the estimates. To test the clinical trial accruals and prepaid clinical trial expenses, we performed procedures that included, among others, reading each agreement and change order with the vendors, clinical research organizations and consultants, and under clinical site agreements, and evaluating the significant assumptions described above and the methods used in developing the clinical trial estimates and calculating the amounts that were unpaid and prepaid at the balance sheet date. We made direct inquiries of financial and clinical personnel on the status of the clinical trials, progress to completion of clinical trials, method of allocating contractual charges to specific tasks performed during the clinical trials, and the status of change orders. We compared the current estimate of expenses incurred to estimates previously made my management. We also assessed the historical accuracy of management's estimates and examined payments made to service providers after the consolidated balance sheet date.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.
Baltimore, Maryland
March 2, 2020

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Balance Sheets

	December 31, 2019	2018
Assets		
Current assets:		
Cash and cash equivalents	**$ 107,636,849**	$ 54,947,502
Investment securities, available-for-sale	**116,373,335**	292,583,046
Prepaid expenses and other current assets	**6,313,785**	7,908,133
Total current assets	**230,323,969**	355,438,681
Property and equipment, net	**2,259,740**	1,159,766
Right of use assets, net	**18,252,074**	—
Deferred tax asset, net	**264,609**	529,218
Other assets	**86,084**	78,833
Total assets	**$ 251,186,476**	$ 357,206,498
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	**$ 7,425,024**	$ 13,961,060
Accrued and other current liabilities	**16,138,909**	20,044,866
Lease liabilities, short-term	**3,187,435**	—
Accrued employee benefits	**9,472,651**	2,293,259
Total current liabilities	**36,224,019**	36,299,185
Deferred rent	**—**	3,192,432
Lease liabilities	**19,955,186**	—
Total liabilities	**56,179,205**	39,491,617
Stockholders' equity:		
Common stock, $0.0001 par value: 100,000,000 shares authorized; 55,507,497 and 54,895,295 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	**5,551**	5,490
Additional paid-in capital	**904,971,772**	880,753,339
Accumulated deficit	**(710,098,369)**	(562,376,191)
Accumulated comprehensive gain/(loss)	**128,317**	(667,757)
Total stockholders' equity	**195,007,271**	317,714,881
Total liabilities and stockholders' equity	**$ 251,186,476**	$ 357,206,498

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Operations

	Years Ended December 31,		
	2019	**2018**	**2017**
Grant revenue	**$ 60,613**	$ —	$ 245,837
Costs and expenses:			
Research and development	**89,124,838**	132,166,913	79,419,009
General and administrative	**64,947,625**	30,099,855	23,666,957
Total costs and expenses	**154,072,463**	162,266,768	103,085,966
Loss from operations	**(154,011,850)**	(162,266,768)	(102,840,129)
Interest income	**(6,291,272)**	(7,140,957)	(4,005,864)
Loss before provision (benefit) for income taxes	**(147,720,578)**	(155,125,811)	(98,834,265)
Income tax expense (benefit)	**1,600**	1,600	(1,060,851)
Net loss	**$ (147,722,178)**	$ (155,127,411)	$ (97,773,414)
Net loss per common share:			
Basic & Diluted	**(2.68)**	$ (2.84)	$ (2.12)
Weighted average number of common shares:			
Basic & Diluted	**55,186,206**	54,707,865	46,181,926

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Loss

	Years Ended December 31,		
	2019	**2018**	**2017**
Net loss	**$ (147,722,178)**	$ (155,127,411)	$ (97,773,414)
Other comprehensive income (loss):			
Unrealized gain (loss) on investment securities	**796,074**	131,467	(481,985)
Comprehensive loss	**$ (146,926,104)**	$ (154,995,944)	$ (98,255,399)

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 Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
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 vesting 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
Exercise of stock options and vesting of restricted stock	284,326	29	674,177	—	—	674,206
Stock issued for services	11,468	1	192,529	—	—	192,530
Share-based compensation	—	—	17,396,146	—	—	17,396,146
Stock warrant	1,822	—	10,982	—	—	10,982
Net loss	—	—	—	(155,127,411)	—	(155,127,411)
Other comprehensive income	—	—	—	—	131,467	131,467
Balance at December 31, 2018	**54,895,295**	**$5,490**	**$880,753,339**	**$(562,376,191)**	**$ (667,757)**	**$ 317,714,881**
Exercise of stock options and vesting of restricted stock	**596,558**	**59**	**3,235,542**	**—**	**—**	**3,235,601**
Stock issued for services	**15,644**	**2**	**194,203**	**—**	**—**	**194,205**
Share-based compensation	**—**	**—**	**20,788,688**	**—**	**—**	**20,788,688**
Net loss	**—**	**—**	**—**	**(147,722,178)**	**—**	**(147,722,178)**
Other comprehensive income	**—**	**—**	**—**	**—**	**796,074**	**796,074**
Balance at December 31, 2019	**55,507,497**	**$5,551**	**$904,971,772**	**$(710,098,369)**	**$ 128,317**	**$ 195,007,271**

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

	Years Ended December 31,		
	2019	2018	2017
Operating activities			
Net loss	**$ (147,722,178)**	$ (155,127,411)	$ (97,773,414)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	**477,121**	368,673	213,872
Share-based compensation	**20,788,688**	17,396,146	14,641,520
Stock issued for services	**194,205**	192,530	190,885
Amortization of premiums and discounts on investment activities	**(1,131,597)**	(943,239)	429,839
Changes in operating assets and liabilities:			
Accounts receivable	**—**	—	94,339
Prepaid expenses and other assets	**1,465,384**	(3,026,908)	(879,200)
Long term deferred tax asset, net	**264,609**	529,217	(1,058,435)
Accounts payable	**(6,536,036)**	7,787,521	2,418,892
Accrued liabilities and employee benefits	**3,327,095**	14,386,774	1,211,103
Lease liabilities, net	**889,468**	—	—
Deferred rent	**—**	267,584	18,787
Net cash used in operating activities	**(127,983,241)**	(118,169,113)	(80,491,812)
Investing activities			
Purchases of investments	**(80,720,301)**	(271,156,707)	(520,926,824)
Maturities of investments	**258,857,683**	406,189,288	428,932,538
Purchases of property and equipment	**(700,395)**	(391,268)	(723,429)
Net cash provided by (used in) investing activities	**177,436,987**	134,641,313	(92,717,715)
Financing activities			
Exercise of stock options	**3,235,601**	674,206	285,160
Proceeds of public offerings, net	**—**	—	162,072,256
Proceeds from stock warrant	**—**	10,982	—
Net cash provided by financing activities	**3,235,601**	685,188	162,357,416
Net increase (decrease) in cash and cash equivalents	**52,689,347**	17,157,388	(10,852,111)
Cash and cash equivalents at beginning of period	**54,947,502**	37,790,114	48,642,225
Cash and cash equivalents at end of period	**$ 107,636,849**	$ 54,947,502	$ 37,790,114
Cash paid for taxes	**$ 1,600**	$ 1,600	$ 1,600

See accompanying notes to consolidated financial statements.

Intra-Cellular Therapies, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

December 31, 2019

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, clinical development and commercialization of innovative, small molecule drugs that address underserved medical needs primarily in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system ("CNS"). In December 2019, the Company announced that CAPLYTA (lumateperone) has been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia in adults (42mg/day). As used in these Notes to Consolidated Financial Statements, "CAPLYTA" refers to lumateperone approved by the FDA for the treatment of schizophrenia in adults, and "lumateperone" refers to, where applicable, CAPLYTA as well as lumateperone for the treatment of indications beyond schizophrenia. Lumateperone is in Phase 3 clinical development as a novel treatment for 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.

On January 10, 2020, the Company completed a public offering of common stock in which the Company sold 10,000,000 shares of common stock at an offering price of $29.50 per share for aggregate gross proceeds of $295 million. After deducting underwriting discounts, commissions and estimated offering expenses, the net proceeds to the Company were approximately $276.9 million. 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 commercial activities and 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. The Company currently projects that its cash, cash equivalents and investments will be sufficient to fund operating expenses and capital expenditures for at least one year from the date that these financial statements are filed with the Securities and Exchange Commission (the "SEC"). Possible sources of funds include public or private sales of the Company's equity securities, sales of debt securities, the incurrence of debt from commercial lenders, strategic collaborations, licensing a portion or all of the Company's product candidates and technology and, to a lesser extent, grant funding. On August 30, 2019, the Company filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on September 12, 2019, on which the Company registered for sale up to $350 million of any combination of its common stock, preferred stock, debt securities, warrants, rights and/or units from time to time and at prices and on terms that the Company may determine, which includes up to $75 million of common stock that the Company may issue and sell from time to time, through SVB Leerink LLC acting as its sales agent, pursuant to the sale agreement that the

1. Organization (continued)

Company entered into with SVB Leerink on August 29, 2019 for the Company's "at-the-market" equity program. In addition, on January 6, 2020, the Company filed an automatic shelf registration statement on Form S-3 with the SEC, which became effective upon filing, on which the Company registered for sale an unlimited amount of any combination of its common stock, preferred stock, debt securities, warrants, rights, and/or units from time to time and at prices and on terms that the Company may determine, so long as the Company continues to satisfy the requirements of a "well-known seasoned issuer" under SEC rules. These registration statements will remain in effect for up to three years from the respective dates they became effective.

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 GAAP 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. On December 31, 2019, the Company accrued approximately $5.8 million of expense for 2019 employee bonuses that were paid in the first quarter of 2020. In previous years, employee bonuses were paid in the year they were earned.

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

2. Summary of Significant Accounting Policies (continued)

period, and a new cost basis for the security is established. Dividend and interest income are recognized as interest income on the consolidated statements of operations when earned. The cost of securities sold is calculated using the specific identification method.

Investment securities consisted of the following (in thousands):

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$ 35,462	$ 35	$ (3)	$ 35,494
Certificates of Deposit	3,000	—	—	3,000
Commercial Paper	39,013	10	(5)	39,018
Corporate Notes/Bonds	38,770	91	—	38,861
	$116,245	$ 136	$ (8)	$116,373

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized (Losses)	Estimated Fair Value
U.S. Government Agency Securities	$124,691	$ 24	$ (289)	$124,426
FDIC Certificates of Deposit (1)	245	—	—	245
Certificates of Deposit	1,000	—	—	1,000
Commercial Paper	41,317	—	(45)	41,272
Corporate Notes/Bonds	125,998	7	(365)	125,640
	$293,251	$ 31	$ (699)	$292,583

(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, 2019 and 2018, the Company held $3.0 million and $64.6 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, 2019, the aggregate related fair value of investments with unrealized losses was $29.6 million and the aggregate amount of unrealized losses was approximately $8 thousand. Of the $29.6 million, $17.1 million have been held in a continuous unrealized loss position for less than 12 months and $12.5 million have been held in a continuous loss position for 12 months or longer. The total continuous unrealized loss for investments held for 12 months or longer is approximately $3 thousand as of December 31, 2019. As of December 31, 2018, the aggregate related fair value of investments with unrealized losses was $272.5 million and the aggregate amount of unrealized losses was $0.7 million. Of the $272.5 million, $180.4 million have been held in a continuous unrealized loss position for less than 12 months and $92.1 million

2. Summary of Significant Accounting Policies (continued)

have been held in a continuous loss position for 12 months or longer. The total continuous unrealized loss for investments held for 12 months or longer is approximately $345 thousand as of December 31, 2018.

The Company attributes the unrealized gains on the available-for-sale securities as of December 31, 2019 and the unrealized losses on the available for sales securities as of December 31, 2018 to the decline in related market interest rates in 2019. 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.

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, 2019 and December 31, 2018. The carrying value of cash held in money market funds of approximately $49.9 million as of December 31, 2019 and $39.6 million as of December 31, 2018 is included in cash and cash equivalents and approximates market value based on quoted market price or Level 1 inputs. The carrying value of cash held in certificates of deposit of approximately $47.6 million and $7.5 million as of December 31, 2019 and 2018, respectively, is included in cash and cash equivalents and approximates market value based on quoted market price or Level 2 inputs. The carrying value of cash held in commercial paper of approximately $3.0 million as of December 31, 2019 is included in cash and cash equivalents and approximates market value based on quoted market price or Level 2 inputs.

2. Summary of Significant Accounting Policies (continued)

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

	December 31, 2019	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 49,882	$ 49,882	$ —	$ —
U.S. government agency securities	35,494	—	35,494	—
Certificates of deposit	50,622	—	50,622	—
Commercial paper	42,015	—	42,015	—
Corporate bonds/notes	38,861	—	38,861	—
	$ 216,874	$ 49,882	$ 166,992	$ —

	December 31, 2018	Fair Value Measurements at Reporting Date Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	$ 39,591	$ 39,591	$ —	$ —
U.S. government agency securities	124,426	—	124,426	—
FDIC certificates of deposit	245	—	245	—
Certificates of deposit	8,500	—	8,500	—
Commercial paper	41,272	—	41,272	—
Corporate bonds/notes	125,640	—	125,640	—
	$ 339,674	$ 39,591	$ 300,083	$ —

Financial Instruments

The Company considers the recorded costs of its financial assets and liabilities, which consist of cash equivalents, prepaid expenses, right of use asset, net, other assets, accounts payable, accrued liabilities, accrued employee benefits, and, lease liabilities, to approximate their fair value because of their relatively short maturities at December 31, 2019 and December 31, 2018. Management believes that the risks associated with the Company's 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.

2. Summary of Significant Accounting Policies (continued)

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, 2019 and 2018, as the Company has a history of collecting on all its accounts including government agencies and collaborations funding its research and there were no balances in accounts receivable as of these dates.

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

Research and Development, Including Clinical Trial Expenses

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, among other factors 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 various clinical information provided by vendors and discussion with applicable personnel and external service providers as to the progress or state of consummation of trials, or the services completed. During the course of a

2. Summary of Significant Accounting Policies (continued)

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 year ended December 31, 2019, the Company recorded a change in estimate of approximately $5.3 million related to the prior year estimates of accrued expenses for clinical trials that resulted in a reduction of research and development expenses. For the year ended December 31, 2018, there were no material adjustments to the Company's prior year 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 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.

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, 2019, 2018 and 2017 accounts for forfeitures as they occur.

2. Summary of Significant Accounting Policies (continued)

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 inception and does not plan to pay cash dividends in the foreseeable future. Therefore, the Company has assumed an expected dividend rate of zero. For stock options granted, 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, 2017, 2018 and 2019, the Company granted time-based RSUs that vest in three equal annual installments. In the first quarter of 2017, the Company granted performance-based RSUs, which vested based on the achievement of certain milestones that include (i) the submission of a NDA with the FDA, (ii) the approval of the NDA by the FDA (collectively, the "Milestone RSUs") and (iii) the achievement of certain comparative shareholder returns against the Company's peers (the "TSR RSUs"). The Milestone RSUs were valued at the closing price on March 8, 2017. The Milestone RSUs related to the NDA submission has been fully amortized through December 31, 2018. The NDA submission milestone was achieved in the third quarter of 2018, so the Milestone RSUs related to the NDA submission vested on December 31, 2018. The Milestone RSU's related to the NDA approval was achieved in the fourth quarter of 2019, so the RSU's vested on December 31, 2019. The amortization of the expenses for Milestone RSUs related to the approval of the NDA was fully amortized on December 31, 2019. The TSR RSUs were valued using the Monte Carlo Simulation method and were amortized over the life of the RSUs based on the agreements which vested on January 24, 2020. The expense recognition related to these equity grants was 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.

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.

2. Summary of Significant Accounting Policies (continued)

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.

In June 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan pursuant to which 4,750,000 additional shares of common stock were reserved for future equity grants.

In December 2019, the Company adopted the Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan (the "2019 Inducement Plan") without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. Pursuant to the 2019 Inducement Plan, the Company may grant stock options, restricted stock units, stock awards and other stock-based awards for up to a total of 1,000,000 shares of common stock to new employees of the Company. No shares were granted under the 2019 Inducement Plan as of December 31, 2019.

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 could be anti-dilutive as applied to the net loss for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
Common Stock Equivalents	6,039,945	4,748,391	3,755,739
RSUs	1,268,679	647,411	190,933
TSR RSUs	67,080	206,484	347,199

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 became effective for annual periods beginning after December 15, 2017.

The Company adopted this standard on January 1, 2018 using the "modified retrospective method" which did not result in an impact to its financial statements as the Company has not had product sales to date. Upon commercializing a product or executing any revenue generating contracts, 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 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

2. Summary of Significant Accounting Policies (continued)

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 on January 1, 2018 did not 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 requires 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 lease guidance. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. The Company adopted the standard on January 1, 2019 using the simplified transition method, allowing the Company to not restate comparative periods and apply ASC No. 2016-02, Leases (Topic 842) on a prospective basis, resulting in a balance sheet presentation that is not comparable to the prior period in the first year of adoption. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed the Company to carry forward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off the balance sheet. The Company recognizes those lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

The adoption of the standard resulted in recognition of additional right of use assets and lease liabilities of approximately $20.2 million and $23.4 million, respectively, as of January 1, 2019. The difference between these amounts represents the net deferred rent as of January 1, 2019 with no impact on the accumulated deficit. The adoption of the new lease standard was a non-cash transaction. The Company concluded the new standard did not have a material impact on its liquidity and income tax position.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." (ASU 2016-13) This guidance applies to all entities and impacts how entities account for credit losses for most financial assets and other instruments. For available-for-sale debt securities, entities will be required to recognize an allowance for credit losses rather than a reduction to the carrying value of the asset. For trade receivables, loans and held-to-maturity debt securities, entities will be required to estimate lifetime expected credit losses. This guidance is effective for fiscal years beginning after December 15, 2019 and interim periods therein. Early adoption is permitted for annual periods beginning after December 15, 2018 and interim periods therein. The Company is considering the implications of adopting the new standard, including the applicable financial statement disclosures required by the new guidance. The Company is assessing any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance. Upon adoption of the new standard on January 1, 2020, the Company will begin recognizing an allowance using a forward-looking approach to estimating the expected credit loss related to financial assets. The Company does not anticipate that the adoption of the new standard will have a significant impact on operating results, financial position or cash flows.

In February 2018, the FASB issued ASU No. 2018-02, Income Statement-Reporting Comprehensive Income (Topic 220)—Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income, to address a specific consequence of the TCJA by allowing a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the TCJA's reduction of the U.S. federal corporate income tax rate. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, with early adoption permitted, and is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the TCJA is recognized. The Company does not have any stranded tax effects to which this ASU would apply. Therefore, there is no impact to the Company's consolidated financial statements.

2. Summary of Significant Accounting Policies (continued)

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). The standard allows for the entity to only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. After adoption, the nonemployee share-based payment awards would be treated similar to employee share-based payment awards going forward. The ASU is effective for all entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted ASU 2018-07 on January 1, 2019. As the Company's nonemployee share-based awards are not significant, the Company concluded the adoption did not have a material impact on the consolidated accumulated deficit.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)(ASU 2019-12) final guidance that simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation that is applicable to the Company, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences among other changes. For public business entities, the amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted, including adoption in any interim period for public business entities for periods for which financial statements have not yet been issued. An entity that elects to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, an entity that elects early adoption must adopt all the amendments in the same period. The Company elected to early adopt the ASU 2019-12 as of December 31, 2019. Management concluded that the adoption of the new standard did not have a material impact to income taxes for December 31, 2019.

3. Property and Equipment

Property and equipment consist of the following:

	December 31,	
	2019	2018
Computer equipment	$ 243,532	$ 44,427
Furniture and fixtures	423,097	341,582
Scientific equipment	3,861,227	3,658,209
Leasehold improvements	1,240,315	149,470
	5,768,171	4,193,688
Less accumulated depreciation	(3,508,431)	(3,033,922)
	$ 2,259,740	$ 1,159,766

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was $477,121, $368,673 and $213,872, respectively.

4. Right Of Use Assets and Lease Liabilities

In 2014, the Company entered into a long-term lease with a related party which, as amended, provided for a lease of useable laboratory and office space located in New York, New York. A member of the Company's board of directors is the Executive Chairman of the parent company to the landlord under this lease. Concurrent with this lease, the Company entered into a license agreement to occupy certain vivarium related space in the same facility for the same term and rent escalation provisions as the lease. This license has the primary characteristics of a lease and is characterized as a lease in accordance with ASU 2016-02 for accounting purposes. In September 2018, the Company further amended the lease to obtain an additional office space beginning October 1, 2018 and to extend the term of the lease for previously acquired space. The lease, as amended, has a term of 14.3 years

4. Right Of Use Assets and Lease Liabilities (continued)

ending in May 2029. In February 2019, the Company entered into a long-term lease for office space in Towson, Maryland beginning March 1, 2019. The lease has a term of 3.2 years ending in April 2022 and includes limited rent abatement and escalation provisions. The Company has no other significant leases. In addition, no identified leases require allocations between lease and non-lease components.

In adopting ASU 2016-02 as of January 1, 2019, the Company elected the package of practical expedients, which permit the Company not to reassess under the new standard the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet. The Company also elected the lessee component election, allowing the Company to account for the lease and non-lease components as a single lease component. In determining whether a contract contains a lease, asset and service agreements are assessed at onset and upon modification for criteria of specifically identified assets, control and economic benefit. The Company recognized those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. The Company uses the rate implicit in the contract whenever possible when determining the applicable discount rate. As the majority of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. On the lease commencement dates, the Company estimated the lease liabilities and the right of use assets at present value using its applicable incremental borrowing rates of its two long term leases of 7.2% for the Company's Maryland lease of 3.2 years and 9.1% for the Company's New York leases of 14.3 years. On January 1, 2019, upon adoption of ASU 2016-02, the Company recorded right of use assets of approximately $20.2 million, lease liabilities of $23.4 million and eliminated deferred rent of $3.2 million. At the execution of the Maryland lease in 2019, the Company recorded a right of use asset and a lease liability of $0.2 million which represented a non-cash transaction.

Right of use assets and lease liabilities for operating leases were approximately $18.3 million and $23.1 million as of December 31, 2019, respectively. The operating cash outflows related to operating lease obligations for the year ended December 31, 2019 were $2,521,576.

Maturity analysis under the lease agreements are as follows:

Year ending December 31, 2020	3,346,375
Year ending December 31, 2021	3,448,323
Year ending December 31, 2022	3,491,166
Year ending December 31, 2023	3,566,466
Year ending December 31, 2024	3,675,196
Thereafter	17,627,040
Total	35,154,566
Less: Present value discount	(12,011,945)
Total Lease liability	$ 23,142,621
Less: current portion	(3,187,435)
Long-term lease liabilities	$ 19,955,186

Lease expense for the year ended December 31, 2019, 2018 and 2017 was approximately $3.3 million $1.8 million and $1.4 million, respectively.

5. Share-Based Compensation

On June 18, 2018, the Company's stockholders approved the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan provides for the granting of stock-based awards, such as stock options, restricted common stock, RSUs

5. Share-Based Compensation (continued)

and stock appreciation rights to employees, directors and consultants as determined by the Board of Directors. The 2018 Plan replaced the Company's Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan"). The Company will grant no further stock options or other awards under the 2013 Plan. Any options or other awards outstanding under the 2013 Plan remain outstanding in accordance with their terms and the terms of the 2013 Plan. As of December 31, 2019, the total number of shares reserved under all equity plans is 11,287,390 and the Company had 2,208,317 shares available for future issuance under the 2018 Plan. Stock options granted under the 2018 Plan may be either incentive stock options ("ISOs") as defined by the Internal Revenue Code of 1986, or non-qualified stock options. The Board of Directors determines who will receive options, the vesting periods (which are generally one to three years) and the exercise prices of such options. Options have a maximum term of 10 years. The exercise price of ISOs granted under the 2018 Plan must be at least equal to the fair market value of the common stock on the date of grant.

In December 2019, the Company adopted the 2019 Inducement Plan for the grant of equity awards of up to 1,000,000 shares of common stock primarily to attract new employees to the Company's commercial organization. No awards were granted as of December 31, 2019.

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, 2019, 2018 and 2017, was comprised of the following:

	Years Ended December 31,		
	2019	**2018**	**2017**
Research and development	**$ 9,411,056**	$ 7,380,814	$ 5,082,823
General and administrative	**11,377,632**	10,015,332	9,558,697
Total share-based compensation expense	**$ 20,788,688**	$ 17,396,146	$ 14,641,520

The following table describes the assumptions used for calculating the value of options granted during the years ended December 31, 2019, 2018 and 2017:

	2019	**2018**	**2017**
Dividend yield	**0%**	0%	0%
Expected volatility	**85.7-96.5%**	85.2%-85.8%	87.4%-90.4%
Weighted-average risk-free interest rate	**2.32%**	2.48%	2.1%
Expected term (in years)	**6.0**	6.0	6.0

Information regarding the stock options activity, including with respect to grants to employees, directors and consultants as of December 31, 2019, and changes during the period then ended, are summarized as follows:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Contractual Life**
Outstanding at December 31, 2018	4,748,391	$ 18.26	7.0 years
Options granted	1,833,102	$ 12.98	9.2 years
Options exercised	(264,663)	$ 12.22	4.1 years
Options canceled or expired	(276,885)	$ 20.82	6.8 years
Outstanding at December 31, 2019	6,039,945	$ 16.81	7.0 years
Vested or expected to vest at December 31, 2019	6,039,945	$ 16.81	
Exercisable at December 31, 2019	3,313,108	$ 19.38	5.6 years

5. Share-Based Compensation (continued)

The weighted-average grant date fair value for awards granted during the years ended December 31, 2019, 2018 and 2017 was $9.17, $15.22 and $15.08 per share, respectively. The total intrinsic value of the options exercised during the years ended December 31, 2019, 2018 and 2017 was $3,127,412, $1,683,679 and $1,609,268, respectively. The total intrinsic value of the options outstanding as of December 31, 2019 was $113,241,283. The total intrinsic value of the options exercisable as of December 31, 2019 was $57,173,972. The total fair value of shares vested during the years ended December 31, 2019, 2018 and 2017 was $11,983,108, $11,348,595 and $7,212,195, respectively.

During 2018, the Company granted options to certain scientific advisory board members of the Company to purchase 12,000 shares of common stock, at an average exercise price per share of $15.47. The options vest ratably over a period of 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, 2019, there was $10,522,078 of unrecognized compensation costs related to unvested time based RSUs which will be recognized over a weighted-average period of 1.8 years. The unrecognized share-based compensation expense related to stock option awards at December 31, 2019 was $17,892,399, and will be recognized over a weighted-average period of 1.9 years.

The total intrinsic value of the time based RSUs vested during the years ended December 31, 2019, 2018 and 2017 was $3,109,328, $1,165,323 and $471,779, respectively. The total intrinsic value of the time based RSU's outstanding as of December 31, 2019 was $43,528,382. The total fair value of time based RSUs vested during the years ended December 31, 2019, 2018 and 2017 was $4,623,030, $2,109,705 and $1,508,083, respectively. The fair value of time based RSUs is based on the closing price of the Company's common stock on the date of grant. Information regarding time based RSU activity, including with respect to grants to employees as of December 31, 2019, and changes during the year then ended, is summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2018	647,411	$ 18.16	**1.8 years**
Time based RSUs granted in 2019	950,449	$ 12.79	**2.0 years**
Time based RSUs vested in 2019	(267,143)	$ 21.64	**0.7 years**
Time based RSUs cancelled in 2019	(62,038)	$ 14.14	**1.4 years**
Outstanding at December 31, 2019	1,268,679	$ 13.60	**1.7 years**

The Company recognized non-cash stock-based compensation expense related to Milestone RSU's for the years ended December 31, 2019, 2018 and 2017 of approximately $0.9 million, $0.5 million and $0.4 million, respectively. The total fair value of shares vested with respect to Milestone RSUs during the years ended December 31, 2019, 2018 and 2017 was $921,972, $1,062,212 and $0, respectively.

5. Share-Based Compensation (continued)

Information related to the Company's Milestone RSUs and the TSR RSUs during the year ended December 31, 2019 are summarized as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Weighted-Average Contractual Life
Outstanding at December 31, 2018	278,592	$ 15.35	1.8 years
Milestone RSUs and TSR RSUs vested in 2019	(65,111)	$ 14.16	0.2 years
Milestone RSUs and TSR RSUs cancelled in 2019	(146,401)	$ 15.64	0.2 years
Outstanding at December 31, 2019	67,080	$ 17.08	0.2 years

The weighted average estimated fair value per share of the TSR RSUs granted in 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 2017 entitled the grantee to receive a number of shares of the Company's common stock determined over a three-year performance period ending on December 31, 2019, provided the grantee remained in the service of the Company on the settlement date. The Company expensed the cost of these awards ratably over the requisite service period. The number of shares for which the TSR RSUs were settled as a percentage of shares for which the award was targeted depended 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 Nasdaq. The number of shares for which the TSR RSUs were settled depended on the level of achievement of the goal. Total shareholder return was determined by dividing the average share value of the Company's common stock over the 30 trading days preceding January 1, 2020 by the average share value of the Company's common stock over the 30 trading days beginning on January 1, 2017, with a deemed reinvestment of any dividends declared during the performance period. The TSR RSUs valuation was complete and 67,080 shares subject to the TSR RSU's were issued in the first quarter of 2020. The total intrinsic value of the TSR RSUs outstanding as of December 31, 2019 was $2,301,515.

As of December 31, 2019, there were no unrecognized compensation costs related to unvested Milestone RSU grants and TSR RSU grants.

6. Income Taxes

On December 22, 2017, President Trump signed into law the "Tax Cuts and Jobs Act" ("TCJA") that significantly reforms the Internal Revenue Code of 1986, as amended (the "Code"). 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. In addition, the TCJA repealed the alternative minimum tax ("AMT") and provides for a refund of AMT paid or a reduction of future taxes payable over a prescribed period of years between 2018 and 2021. With the passing of the TCJA, the Company recorded a receivable for prior period AMT, and therefore, the Company recognized an income tax benefit of approximately $1.1 million related to this prior period AMT in December 2017.

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. As of the year ended December 31,

6. Income Taxes (continued)

2019, the Company's foreign operations do not generate income and the Company is not currently subject to the GILTI provisions. The Company has not made an accounting policy election for GILTI and will analyze and formulate its GILTI accounting policy in the period which the Company becomes subject to the GILTI provisions.

The BEAT provisions eliminate the deduction of certain base-erosion payments made to related foreign corporations, and impose a minimum tax if greater than regular tax. The Company has not made any qualifying payments and the BEAT tax is not applicable in 2019. Therefore, the Company has not included any tax impacts of BEAT in its consolidated financial statements for the year ended December 31, 2019.

During December 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. The Company completed its evaluation of the effects of the TCJA during the fourth quarter of 2018 and the provisional amounts the Company accounted for in its December 31, 2017 provision were finalized in 2018 with no adjustments.

Income (loss) before income taxes is as follows:

	2019	2018	2017
U.S.	**(56,121,258)**	$ (30,299,751)	$ (20,486,935)
Non-U.S.	**(91,599,320)**	(124,826,060)	(78,347,330)
Total loss before taxes	**(147,720,578)**	$ (155,125,811)	$ (98,834,265)

Total income tax (benefit) expense for the years ended December 31, 2019, 2018 and 2017 is allocated as follows:

	2019	2018	2017
Current	**$ 1,600**	$ 1,600	$ (2,416)
Deferred	**(8,484,822)**	(5,054,468)	13,713,987
Valuation allowance	**8,484,822**	5,054,468	(14,772,422)
Provision (benefit) for income taxes	**$ 1,600**	$ 1,600	$ (1,060,851)

A reconciliation of the difference between the statutory federal income tax rate and the effective income tax rate for the years ended December 31, 2019, 2018 and 2017 is as follows:

	December 31,		
	2019	2018	2017
Income tax benefit at statutory federal rate	**21.00%**	21.00%	35.00%
Other Permanent differences	**(0.67)**	(0.58)	(0.43)
Foreign rate differential	**(13.02)**	(16.90)	(27.75)
2017 US Tax Reform impact	**0.00**	0.00	(21.89)
R&D Credit	**0.00**	0.00	(0.05)
Change in effective state tax rates	**(0.16)**	(0.38)	0.84
State income tax expense	**(1.40)**	0.12	0.40
Change in valuation allowance	**(5.75)**	(3.26)	14.95
Benefit for income taxes	**0.0%**	0.00%	1.07%

6. Income Taxes (continued)

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, 2019, the Company had $183.1 million of federal net operating loss carryforwards, of which $131.2 million expire at various dates through 2037 and $51.9 million do not expire. 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 years ended December 31, 2019, 2018, 2017, 2016 and 2015, 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 through December 31, 2019, 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. The Company has not performed a complete Section 382 analysis to determine the effect on ownership related to the January 2020 public offering. If the Company experiences an ownership change from the January 2020 public offering or in the future, the tax benefits related to the NOLs and tax credit carryforwards may be further limited or lost.

The following summarizes the significant components of the Company's deferred tax assets and liabilities as of December 31, 2019 and 2018, respectively:

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 49,668,232	$ 43,872,566
Accrued employee benefits	589,667	441,780
Research and development credit	9,321,214	9,321,214
Stock compensation	12,965,250	10,530,859
Federal AMT credit	264,609	529,218
Deferred rent	—	712,314
Capital lease	4,973,618	—
Unrealized comprehensive loss	—	146,531
Depreciation	—	1,082
Deferred tax liabilities:		
Right of use asset—capital lease	(3,922,583)	—
Unrealized gains on investment	(27,577)	—
Depreciation	(230,760)	—
Net deferred tax asset before valuation allowance	73,601,670	65,555,564
Valuation allowance	(73,337,061)	(65,026,346)
Net deferred tax asset	$ 264,609	$ 529,218

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 in 2019 and 2018, excluding the AMT paid in prior years that is refundable or available as a reduction to future taxes payable, for financial reporting purposes because it is not more likely than not that these deferred tax assets will be realized. In 2018, the Company reclassified $529,218 Federal AMT to Other Current Assets. In 2019, the Company collected the $529,218 AMT credit reclassified to Other Current Assets in the prior year and reclassified $264,609 of AMT credit to Other Current Assets.

6. Income Taxes (continued)

The total amount of unrecognized tax benefits was $1.7 million as of December 31, 2019 and December 31, 2018. 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, 2019 and 2018, respectively:

	December 31, 2019	December 31, 2018
Balance at January 1,	**$ 1,738,815**	$ 1,738,815
Current Year Uncertain Tax Positions:		
Gross Change	**—**	—
Balance at December 31,	**$ 1,738,815**	$ 1,738,815

7. Collaborations and License Agreements

The Bristol-Myers Squibb License Agreement

In 2005, the Company entered into a worldwide, exclusive License Agreement with Bristol-Myers Squibb Company ("BMS"), pursuant to which the Company holds a license to certain patents and know-how of BMS relating to lumateperone and other specified compounds. The agreement was amended in November 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 agreement 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. Upon FDA acceptance of an NDA filing for lumateperone, the Company was obligated to pay BMS a $2.0 million milestone payment. The Company achieved the acceptance in the third quarter of 2018 and has therefore accrued the $2.0 million which was paid in January 2019. The FDA approved the NDA filing on December 23, 2019 and as a result the Company accrued an additional milestone liability of $5.0 million in the fourth quarter 2019 which was paid in January 2020. Possible milestone payments remaining total $5.0 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 ranging between 5 – 9% 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

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company does not believe it is currently subject to any material matters where there is at least a reasonable possibility that a material loss may be incurred.

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, 2019, 2018 and 2017. Participant and Company contributions vest immediately. During the years ended December 31, 2019, 2018 and 2017, the Company recorded matching contribution expense of $658,179, $429,318 and $378,233, respectively.

10. Related Parties

In the first quarter of 2015, the Company moved its headquarters to New York, New York. The Company has entered into a long-term lease with a related party for laboratory and office space**.** On September 28, 2018, the Company signed a lease with the same related party to acquire additional office space in the Company's current headquarters facility and to extend the term of the lease for previously acquired space. The amendment includes provisions for yearly rent escalation, a limited rent abatement for the additional space, and an amount provided for leasehold improvements. The lease, as amended, has a term of 14.3 years ending in May 2029. 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 2019 and 2018 quarterly statements of operations.

The following table sets forth the Company's unaudited condensed consolidated statements of operations for the 2019 quarters ended:

2019 Quarter Ended	December 31,	September 30,	June 30,	March 31,
Net loss	(40,582,851)	(34,862,399)	(37,441,164)	(34,835,764)
Basic and diluted net loss per share	$ (0.74)	$ (0.63)	$ (0.68)	$ (0.63)

The following table sets forth the Company's unaudited condensed consolidated statements of operations for the 2018 quarters ended:

2018 Quarter Ended	December 31,	September 30,	June 30,	March 31,
Net loss	(40,748,036)	(41,522,914)	(37,376,383)	(35,480,078)
Basic and diluted net loss per share	$ (0.75)	$ (0.76)	$ (0.68)	$ (0.65)

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

Intra-Cellular Therapies, Inc. (the "Company" or "we") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.0001 per share.

DESCRIPTION OF COMMON STOCK

We are authorized to issue 100,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of preferred stock, par value $0.0001 per share.

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to our restated certificate of incorporation and our restated bylaws, both of which are incorporated by reference as exhibits to the Company's Annual Report on Form 10-K of which this Exhibit is a part. The summary below is also qualified by provisions of applicable law.

General

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. Our outstanding shares of common stock are validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Transfer Agent and Registrar

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

Stock Exchange Listing

Our common stock is listed for quotation on The Nasdaq Global Select Market under the symbol "ITCI."

CERTAIN PROVISIONS OF DELAWARE LAW AND OF THE COMPANY'S CERTIFICATE OF INCORPORATION AND BYLAWS

Anti-Takeover Provisions

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.

Delaware Statutory Business Combinations Provision

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

Classified Board of Directors; Removal of Directors for Cause

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

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors

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

Special Meetings of Stockholders

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

No Stockholder Action by Written Consent

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

Super Majority Stockholder Vote Required for Certain Actions

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

INTRA-CELLULAR THERAPIES, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(adopted June 30, 2014; amended March 30, 2016, December 14, 2017, June 18, 2018 and February 26, 2020)

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. Equity Grants

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. Cash Fees 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	$ 65,000	$ 45,000
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.

INTRA-CELLULAR THERAPIES, INC.

2019 INDUCEMENT AWARD PLAN

ADOPTED BY THE COMPENSATION COMMITTEE: DECEMBER 16, 2019
EFFECTIVE DATE: DECEMBER 16, 2019

1. GENERAL.

(a) Eligible Award Recipients. Awards may only be granted to Employees who satisfy the standards for inducement grants under Rule 5635(c)(4) of the Nasdaq Listing Rules. A person who previously served as an Employee or Director will not be eligible to receive Awards, other than following a bona fide period of non-employment.

(b) Available Awards. The Plan provides for the grant of the following types of Awards: (i) Nonstatutory Stock Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, and (v) Other Stock Awards.

(c) Purpose. The Plan, through the granting of Stock Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide an inducement material for such persons to enter into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c). However, notwithstanding the foregoing or anything in the Plan to the contrary, the grant of Awards will be approved by the Company's independent compensation committee or a majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Listing Rules.

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express terms of the Plan:

(i) To determine (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the terms of each Award, which need not be identical, including when the Participant will be permitted to exercise or otherwise receive Common Stock under the Award; (E) the number of shares of Common Stock subject to an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it determines necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Stock Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which a Stock Award may be exercised or vest, or at which shares of Common Stock may be issued.

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Award without the Participant's written consent except as provided in Section 2(b)(viii).

(vi) To amend the Plan in any respect the Board determines necessary or advisable, including, without limitation, by adopting amendments relating to nonqualified deferred compensation under Section 409A of the Code, and/or to make the Plan or Awards granted under the Plan exempt from or compliant with the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan. Except as provided in Section 9(a) relating to Capitalization Adjustments, the Board may not without stockholder approval reduce the exercise price of an Option or Stock Appreciation Right or cancel any outstanding Option or Stock Appreciation Right in exchange for a replacement option or stock appreciation right having a lower exercise or strike price, or any other Stock Award or for cash. In addition, the Board shall not take any other action that is considered a direct or indirect "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Common Stock is listed, including any action that is treated as a repricing under generally accepted accounting principles. Except as provided in the Plan (including Section 2(b)(viii)) or an Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, without limitation, amendments to the Plan intended to satisfy the requirements of Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, without limitation, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any applicable law or listing requirements and any specified limits in the Plan that are not subject to Board discretion; *provided, however*, that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the affected Participant's consent, and (B) the Participant consents in writing. Notwithstanding the

foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights; and (2) subject to the limitations of applicable law or listing requirements, if any, the Board may amend the terms of any one or more Stock Awards without the affected Participant's consent: (A) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (B) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise the powers and to perform the acts the Board determines necessary or expedient to promote the best interests of the Company and that are not in conflict with the terms of the Plan or Awards.

(x) To adopt any procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees who are foreign nationals or employed outside the United States; *provided*, *however*, that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction.

(c) Delegation to a Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable. Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the terms of the Plan, that the Board or the Committee adopts from time to time. The Committee may, at any time, abolish the subcommittee and revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Rule 16b-3 Compliance. The Committee may consist solely of two or more Non-Employee Directors in accordance with Rule 16b-3.

(d) Effect of the Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) Dividends and Dividend Equivalents. Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to an Award, as determined by the Board and contained in the applicable Award Agreement; *provided*, *however*, that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Award Agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be

subject to all of the terms and conditions applicable to such shares under the terms of such Award Agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Award Agreement.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve. Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards will not exceed 1,000,000 shares (the "***Share Reserve***").

(b) Reversion of Shares to the Share Reserve.

(i) Shares Available for Subsequent Issuance. The following shares of Common Stock will become available again for issuance under the Plan: (A) any shares subject to a Stock Award that are not issued because such Stock Award or any portion thereof expires or otherwise terminates without all of the shares covered by such Stock Award having been issued; (B) any shares subject to a Stock Award that are not issued because such Stock Award or any portion thereof is settled in cash; and (C) any shares issued pursuant to a Stock Award that are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares.

(ii) Shares Not Available for Subsequent Issuance. Any shares reacquired or withheld (or not issued) by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will not again become available for issuance under the Plan. Upon exercise of SARs, the gross number of shares exercised shall be deducted from the total number of shares remaining available for issuance under the Plan. Any shares repurchased by the Company on the open market with the proceeds of the exercise or purchase price of a Stock Award will not again become available for issuance under the Plan.

(c) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Awards. Awards may only be granted to persons who are Employees described in Section 1(a), where the Award is an inducement material to the individual's entering into employment with the Company or an Affiliate within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. For clarity, Awards may not be granted to (1) Consultants or Directors, for service in such capacities, or (2) any individual who was previously an Employee or Director, other than following a bona fide period of non-employment. Notwithstanding the foregoing, Awards may not be granted to Employees who are providing Continuous Service only to any "parent" of the Company, as this term is defined in Rule 405 of

the Securities Act, unless (i) the stock underlying such Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Awards are granted in connection with a corporate transaction such as a spin off transaction), or (ii) the Company, in consultation with its legal counsel, has determined that such Awards are otherwise exempt from or alternatively comply with the distribution requirements of Section 409A of the Code.

(b) Approval Requirements. All Awards must be granted either by a majority of the Company's independent directors or by the Company's compensation committee comprised of independent directors within the meaning of Rule 5605(a)(2) of the Nasdaq Listing Rules.

5. OPTIONS AND STOCK APPRECIATION RIGHTS.

The Board will determine the form and the terms and conditions of each Option or SAR. All Options will be Nonstatutory Stock Options. The terms of separate Options or SARs need not be identical; *provided*, *however*, that each Stock Award Agreement will conform to (through incorporation of provisions of the Plan by reference in the applicable Stock Award Agreement or otherwise) the substance of each of the following terms:

(a) Term. No Option or SAR will be exercisable after the expiration of ten years from the date of its grant or a shorter period specified in the Stock Award Agreement.

(b) Exercise Price. The exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to such Award if the Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right in connection with a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Exercise Price for Options. The exercise price of Common Stock acquired upon the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the following methods of payment. The Board will have the authority to grant Options that permit any one or more of the following methods of payment (or to restrict the ability to use any particular method or methods) and to grant Options that require the Company's consent to use a particular method of payment. The permitted methods of payment are:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock, results in the Company's receipt of cash or check or the receipt of irrevocable instructions to pay the aggregate purchase price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided*, *however*, that the Company will accept cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by a reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable after a "net exercise" to the extent that (A) shares issuable upon the exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of the exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that the Board determines acceptable and specifies in the applicable Stock Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the terms of the Stock Appreciation Right Agreement evidencing the SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under the SAR, and with respect to which the Participant is exercising the SAR on the applicable exercise date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, or in any other form of consideration, as the Board determines and describes in the applicable Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose limitations on the transferability of Options and SARs as the Board determines. In the absence of a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (and pursuant to Sections 5(e)(ii) and 5(e)(iii)), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit a transfer of the Option or SAR in a manner that is permissible under applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or its designated broker), designate a third party who, on the Participant's death, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from the exercise. In the absence of a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from the exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that a designation would be inconsistent with applicable law.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Board will determine whether the Option or SAR is subject to other terms and conditions on the time or times when the Award may or may not be exercised, which may be based on the satisfaction of performance goals or other criteria. The vesting terms of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any term in an Option or SAR specifying the minimum number of shares of Common Stock as to which the Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date three months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement, which period will not be less than 30 days if necessary to comply with applicable law unless the Participant's termination is for Cause); and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the designated time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company or an Affiliate, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (which need not be consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received upon exercise of an Option or

SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of months (which need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Stock Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise the Option or SAR as of the date of termination of Continuous Service), but only within the period of time ending on the earlier of (i) the date 12 months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the Stock Award Agreement, which period will not be less than six months if necessary to comply with applicable law), and (ii) the expiration of the term of the Option or SAR as set forth in the Stock Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period, if any, specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service (for a reason other than death), then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise the Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance, or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (A) the date 18 months following the date of the Participant's death (or such longer or shorter period specified in the Award Agreement, which period will not be less than six months if necessary to comply with applicable laws), and (B) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) Termination for Cause. Except as otherwise provided in the applicable Award Agreement or other agreement or other individual written agreement between the Participant and the Company or any Affiliate, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon the Participant's notification of a termination of Continuous Service for Cause and the Participant will be prohibited from exercising the Option or SAR from and after the time of the Participant's notification of a termination of Continuous Service for Cause.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six months following the date of grant (although the Award may vest prior to that date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if a non-exempt Employee dies or suffers a Disability; (ii) upon a Corporate Transaction in which the Option or SAR is not assumed, continued, or substituted; or (iii) upon the Participant's retirement (as that term may be defined in the applicable Award Agreement in another agreement between the Participant and the Company or an Affiliate, or, if no definition exists, in accordance with the Company's then-current employment policies and guidelines), the vested portion of any Option and SAR held by the Employee may be exercised earlier than six months following the date of grant. This Section 5(l) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under an Option or SAR will be exempt from the employee's regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act, to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, this Section 5(l) will apply to all Stock Awards and is incorporated by reference into the applicable Stock Award Agreements.

6. STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) Restricted Stock Awards. The Board will determine the form and terms and conditions of each Restricted Stock Agreement. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (i) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (ii) evidenced by a certificate, which certificate will be held in the form and manner the Board determines. The terms and conditions of Restricted Stock Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Agreements need not be identical. Each Restricted Stock Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following terms:

(i) Consideration. A Restricted Stock Award may be granted in consideration for (A) cash, check, bank draft or money order payable to the Company; or (B) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock granted under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive, through a forfeiture condition or a repurchase right, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Shares of Common Stock granted to a Participant under a Restricted Stock Award Agreement will be transferable by the Participant only upon the terms and conditions as the Board will determine, in its sole discretion, and described in the Restricted Stock Award Agreement, so long as the shares of Common Stock granted under the Restricted Stock Award Agreement remain subject to the terms of the Restricted Stock Award Agreement.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, the Common Stock may be granted either alone or in addition to other Stock Awards granted under Section 5 and this Section 6. Subject to the terms of the Plan (including, but not limited to, Section 2(e)), the Board will have sole and complete authority to determine the persons to whom and the time or times at which Other Stock Awards will be granted, the number of shares of Common Stock to be granted pursuant to Other Stock Awards, and all other terms and conditions of Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan the authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided*, *however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any regulatory commission or agency the authority that counsel for the Company determines necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of Stock Awards unless and until such authority is obtained. A Participant will not be eligible to receive a grant of an Award or be issued shares of Common Stock pursuant to the Award if the grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise the Participant as to the time or manner of exercising any Stock Award. Further, the Company will have no duty or obligation to warn or otherwise advise the Participant of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to any Participant.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Stock Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (*e.g.*, Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (*e.g.*, exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) the Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to the Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. If a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (i) make a corresponding reduction in the number of shares subject to any portion of the Award that is scheduled to vest or become payable after the date of the Participant's change in time commitment, and (ii) in lieu of or in combination with a reduction, extend the vesting or payment schedule applicable to the Award. In the event of any reduction or modification of the vesting or payment schedule, the Participant will have no right with respect to any portion of the Award that is reduced or modified.

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring the Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to the requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, counsel for the Company determines that the requirement need not be met in the particular circumstances under then applicable securities laws. The Company may, upon advice of Company counsel, place legends on stock certificates issued under the Plan as Company counsel determines necessary or appropriate to comply with applicable securities laws, including, without limitations, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. The Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means (in addition to the Company's right to withhold from any compensation the Company paid to the Participant) or by a combination of the following means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; *provided*, *however*, that the Company may not withhold shares of Common Stock with a value exceeding the maximum amount of tax required to be withheld by law (or such other amount as may be necessary to avoid classification of the Award as a liability for financial accounting purposes); (iii) withholding payment from any amounts otherwise payable to the Participant; or (iv) by any other method as may be described in the Award Agreement.

(h) Electronic Delivery. Any reference in the Plan to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium that the Company controls and to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock upon the exercise, vesting or settlement of all or a portion of an Award may be deferred and may establish programs and procedures for Participants to make deferral elections. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments (including lump sum payments) following the Participant's termination of Continuous Service, and implement any other terms and conditions consistent with the terms of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section

409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(k) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the classes and maximum number of securities subject to the Plan under Section 3(a), (ii) the classes and number of securities and price per share of Common Stock subject to outstanding Stock Awards and (iii) performance conditions applicable to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of the dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the Participant is providing Continuous Service; *provided*, *however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transaction. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award, in any other written agreement between the Company or any Affiliate and the Participant, or in any director compensation policy of the Company, or unless otherwise expressly provided by the Board at the time of grant of a Stock Award.

(i) Stock Awards May Be Assumed. In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all outstanding Stock Awards or may substitute similar stock awards for any or all outstanding Stock Awards (including, but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to any outstanding Stock Awards may be assigned by the Company to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company). For clarity, in the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may choose to assume or continue only a portion of an outstanding Stock Award, to substitute a similar stock award for only a portion of an outstanding Stock Award, or to assume or continue, or substitute similar stock awards for, the outstanding Stock Awards held by some, but not all, Participants. The terms of any such assumption, continuation or substitution will be set by the Board.

(ii) Stock Awards Held by Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) does not assume or continue outstanding Stock Awards, or substitute similar stock awards for outstanding Stock Awards, then with respect to any such Stock Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the "***Current Participants***"), the vesting (and exercisability, if applicable) of such Stock Awards will be accelerated in full to a date prior to the effective time of the Corporate Transaction (contingent upon the closing or completion of the Corporate Transaction) as the Board will determine (or, if the Board does not determine such a date, to the date that is five days prior to the effective time of the Corporate Transaction), and such Stock Awards will terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction in accordance with the exercise procedures determined by the Board, and any reacquisition or repurchase rights held by the Company with respect to such Stock Awards will lapse (contingent upon the closing or completion of the Corporate Transaction).

(iii) Stock Awards Held by Participants other than Current Participants. In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) does not assume or continue outstanding Stock Awards, or substitute similar stock awards for outstanding Stock Awards, then with respect to any such Stock Awards that have not been assumed, continued or substituted and that are held by Participants other than Current Participants, such Stock Awards will terminate if not exercised (if applicable) prior to the effective time of the Corporate Transaction in accordance with the exercise procedures determined by the Board; *provided*, *however*, that any reacquisition or repurchase rights held by the Company with respect to such Stock Awards will not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

(iv) Payment for Stock Awards in Lieu of Exercise. Notwithstanding the foregoing, in the event any outstanding Stock Award held by a Participant will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the Participant may not exercise such Stock Award but instead will receive a payment, in such form as may be determined by the Board, equal in value to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of such Stock Award immediately prior to the effective time of the Corporate Transaction (including, at the discretion of the Board, any unvested portion of such Stock Award), over (B) any exercise price payable by the Participant in connection with such exercise. For clarity, such payment may be zero if the value of such property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Common Stock in connection with the Corporate Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

10. TERMINATION OR SUSPENSION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated. Termination of the Plan shall not affect any Stock Awards theretofore granted.

11. EFFECTIVE DATE OF PLAN.

The Plan will become effective on the Effective Date.

12. CHOICE OF LAW.

The law of the State of Delaware will govern all questions concerning the construction, validity and interpretation of the Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company, as these terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Award***" means a Stock Award.

(c) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) "***Board***" means the Board of Directors of the Company.

(e) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "***Cause***" will have the meaning ascribed to the term in any written agreement between the Participant and the Company or an Affiliate defining the term and, in the absence of such an agreement, the term means, with respect to a Participant, the occurrence of any of the following events: (i) the Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Board or Committee, as applicable, in its sole and exclusive judgment and discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(h) "***Committee***" means a committee of two or more Directors to whom the Board has delegated authority in accordance with Section 2(c).

(i) "***Common Stock***" means the common stock of the Company.

(j) "***Company***" means Intra-Cellular Therapies, Inc., a Delaware corporation.

(k) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for those services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for those services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a "Consultant" for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company's securities to such person. Consultants are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(l) "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the Entity for which the Participant renders service, provided that there is no interruption or termination of the Participant's service with the Company or an Affiliate, will not terminate a Participant's Continuous Service; *provided*, *however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board in its sole discretion, the Participant's Continuous Service will be considered to have terminated on the date the Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave; or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(m) "***Corporate Transaction***" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(n) "***Director***" means a member of the Board. Directors are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(o) "***Disability***" means, with respect to a Participant, the inability of the Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of any medical evidence the Board determines warranted under the circumstances.

(p) "***Effective Date***" means December 16, 2019 which is the date this Plan was originally approved by the Compensation Committee of the Board.

(q) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(r) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(s) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(t) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Section 409A of the Code.

(u) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(v) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 of the Plan that does not qualify as an "incentive stock option" within the meaning of Section 422 of the Code.

(w) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(x) "***Option***" means a Nonstatutory Stock Option to purchase shares of Common Stock granted under the Plan.

(y) "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option. Each Option Agreement will be subject to the terms and conditions of the Plan.

(z) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, any other person who holds an outstanding Option.

(aa) "***Other Stock Award***" means an award based in whole or in part by reference to the Common Stock that is granted pursuant to the terms and conditions of Section 6(c).

(bb) "***Other Stock Award Agreement***" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(cc) "***Participant***" means a person to whom an Award is granted under the Plan or, if applicable, any other person who holds an outstanding Award.

(dd) "***Plan***" means this Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan.

(ee) "***Restricted Stock Award***" means an award of shares of Common Stock that is granted pursuant to the terms and conditions of Section 6(a).

(ff) "***Restricted Stock Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(gg) "***Restricted Stock Unit Award***" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(hh) "***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(ii) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(jj) "***Securities Act***" means the Securities Act of 1933, as amended.

(kk) "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(ll) "***Stock Appreciation Right Agreement***" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(mm) "***Stock Award***" means any right to receive Common Stock granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, or any Other Stock Award.

(nn) "***Stock Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(oo) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, owned by the Company; and (ii) any partnership, limited liability company or other Entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

Exhibit 10.33

Restricted Stock Unit No._____

INTRA-CELLULAR THERAPIES, INC.

Restricted Stock Unit Award Grant Notice
Restricted Stock Unit Award Grant under the Company's
2019 Inducement Award Plan

1. Name and Address of Participant: _____

2. Date of Grant of Restricted Stock Unit Award: _____

3. Maximum Number of Shares underlying Restricted Stock Unit Award: _____

4. Vesting Commencement Date: _____

5. Vesting Schedule: Subject to Section 2 of the Restricted Stock Unit Award Agreement, the Restricted Stock Unit Award will vest as follows: [_____].

The Participant acknowledges receipt of this Restricted Stock Unit Award Grant Notice and agrees to the terms of the Restricted Stock Unit Award Agreement attached hereto and incorporated by reference herein, the Company's 2019 Inducement Award Plan and the terms of this Restricted Stock Unit Award as set forth above.

INTRA-CELLULAR THERAPIES, INC.

By: _____
Name: _____
Title: _____

_____
Participant

ATTACHMENTS: Restricted Stock Unit Award Agreement and 2019 Inducement Award Plan

INTRA-CELLULAR THERAPIES, INC.
2019 INDUCEMENT AWARD PLAN

RESTRICTED STOCK UNIT AWARD AGREEMENT

This Restricted Stock Unit Award Agreement (this "Agreement") is made as of the date of grant set forth in the Restricted Stock Unit Award Grant Notice between INTRA-CELLULAR THERAPIES, INC. (the "Company"), a Delaware corporation, and the individual whose name appears on the Restricted Stock Unit Award Grant Notice (the "Participant").

WHEREAS, the Company has adopted the Intra-Cellular Therapies, Inc. 2019 Inducement Award Plan (the "Plan") to promote the interests of the Company by providing an incentive for Employees of the Company and its Affiliates;

WHEREAS, pursuant to the provisions of the Plan, the Company desires to grant to the Participant restricted stock units ("RSUs") related to the Company's Common Stock, in accordance with the provisions of the Plan, all on the terms and conditions hereinafter set forth; and

WHEREAS, the Company and the Participant understand and agree that any terms used and not defined herein have the meanings ascribed to such terms in the Plan.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Grant of Award. The Company hereby grants to the Participant an award for the number of RSUs set forth in the Restricted Stock Unit Award Grant Notice (the "Award"). Each RSU represents a contingent entitlement of the Participant to receive one share of Common Stock, on the terms and conditions and subject to all the limitations set forth herein and in the Plan, which is incorporated herein by reference. The Participant acknowledges receipt of a copy of the Plan.

2. Vesting of Award.

(a) Subject to the terms and conditions set forth in this Agreement and the Plan, the Award granted hereby shall vest as set forth in the Restricted Stock Unit Award Grant Notice, provided that vesting shall cease upon the termination of the Participant's Continuous Service.

(b) Except as otherwise set forth in this Agreement, if the Participant ceases to be in Continuous Service for any reason prior to a vesting date set forth in the Restricted Stock Unit Award Grant Notice, then as of the date on which the Participant's Continuous Service terminates, all unvested RSUs shall immediately be forfeited to the Company and this Agreement shall terminate and be of no further force or effect. Notwithstanding the foregoing, if (a) the Participant is an Employee at the level of Vice President or above at the time of a termination of the Participant's Continuous Service and, at any time within ninety (90) days prior to or twelve (12) months following the effective date of a Change in Control (or such other period as is, or may be, set forth in an employment, severance or other similar written agreement between the Participant and the Company or any of its Affiliates), or (b) the Participant is an Employee below the level of Vice President or a Consultant at the time of a termination of the

Participant's Continuous Service and, at any time within twelve (12) months following the effective date of a Change in Control, the Participant's Continuous Service terminates by reason of (i) a resignation for Good Reason or (ii) an involuntary termination of the Participant's Continuous Service without Cause (each, a "***Qualifying Termination***"), then any RSUs underlying this Award that have not become vested and that are outstanding at the time of the Qualifying Termination (whether pursuant to this Agreement or other action of the Board or the Committee) shall become fully vested as of (x) the effective date of the Change in Control if the Participant's Qualifying Termination occurs prior to the effective date of the Change in Control and (y) the date of such Qualifying Termination if the Participant's Qualifying Termination occurs on or after the effective date of the Change in Control. In order to give effect to the intent of such accelerated vesting, if the Participant's Qualifying Termination occurs prior to the effective date of a Change in Control, then notwithstanding anything to the contrary in this Agreement or the Plan, in no event will any portion of this Award or Agreement be forfeited or terminate any earlier than the effective date of the Change in Control.

The following terms shall have the following meanings for purposes of this Section 2:

"Change in 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 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, 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.

"Good Reason" means the occurrence of (a) any event constituting "Good Reason" (or an analogous term) as set forth in any employment, consulting, severance or other similar written agreement between the Participant and the Company or any of its Affiliates and (b) any of the following events without the consent of the Participant: (i) if the Participant is an Employee at the level of Vice President or above, a material reduction or change in job duties, responsibilities or authority inconsistent with the Participant's position with the Company and the Participant's prior duties, responsibilities or authority immediately prior to the Change in Control; (ii) for any Employee or Consultant, a relocation of the Participant's primary workplace by more than 25 miles; or (iii) for any Employee or Consultant, a material reduction of the Participant's base compensation; *provided*, *however*, that any event described in clause (b) above shall constitute Good Reason only if (x) the Participant provides the Company with written notice specifying the event alleged to constitute Good Reason within 60 days following the first occurrence of such event, (y) the Company fails to cure such event within

30 days after the Company's receipt from the Participant of such written notice, and (z) the Participant's termination of Continuous Service occurs within 30 days following the Company's failure to cure such event (and in no event later than 120 days following the first occurrence of such event).

3. Issuance of Shares.

(a) The issuance of any shares of Common Stock in respect of this Award is (i) subject to satisfaction of the tax withholding obligations set forth in Section 9 and (ii) intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. The form of such issuance (*e.g.*, a stock certificate or electronic entry evidencing such shares) will be determined by the Company.

(b) In the event one or more RSUs subject to this Award vests, the Company will issue to the Participant, on the applicable vesting date, one share of Common Stock for each RSU that vests on such date (and for purposes of this Agreement, such issuance date is referred to as the "***Original Issuance Date***"); *provided, however*, that if the Original Issuance Date falls on a date that is not a business day, such shares will instead be issued to the Participant on the next following business day.

(c) Notwithstanding the foregoing, if:

(i) this Award is otherwise subject to withholding taxes (as described in Section 9) on the Original Issuance Date,

(ii) the Original Issuance Date does not occur (x) during an "open window period" applicable to the Participant, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (y) on a date when the Participant is otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, and

(iii) the Company elects, prior to the Original Issuance Date, (x) not to satisfy such withholding taxes by withholding shares of Common Stock from the shares of Common Stock otherwise due, on the Original Issuance Date, to the Participant under this Award, (y) not to permit the Participant to enter into a "same day sale" commitment with a broker-dealer pursuant to Section 9 (including, but not limited to, under a previously established 10b5-1 trading plan entered into in compliance with the Company's policies), and (z) not to permit the Participant to pay such withholding taxes in cash,

then the shares that would otherwise be issued to the Participant on the Original Issuance Date will not be issued to the Participant on the Original Issuance Date and will instead be issued to the Participant on the first business day when the Participant is not prohibited from selling shares of Common Stock on an established stock exchange or stock market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of the Participant's taxable year in which the Original Issuance Date occurs), or, if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the year following the year in which the shares of Common Stock in respect of this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

4. Prohibitions on Transfer and Sale. This Award (including any additional RSUs received by the Participant as a result of stock dividends, stock splits or any other similar transaction affecting the Company's securities without receipt of consideration) shall not be transferable by the Participant otherwise than (i) by will or by the laws of descent and distribution, or (ii) pursuant to a qualified domestic relations order as defined by the Internal Revenue Code or Title I of the Employee Retirement Income Security Act or the rules thereunder. Except as provided in the previous sentence, the shares of Common Stock to be issued pursuant to this Agreement shall be issued, during the Participant's lifetime, only to the Participant (or, in the event of legal incapacity or incompetence, to the Participant's guardian or representative). This Award shall not be assigned, pledged or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment or similar process. Any attempted transfer, assignment, pledge, hypothecation or other disposition of this Award or of any rights granted hereunder contrary to the provisions of this Section 4, or the levy of any attachment or similar process upon this Award shall be null and void.

5. Adjustments. The Plan contains provisions covering the treatment of RSUs and shares of Common Stock in a number of contingencies such as Capitalization Adjustments and Corporate Transactions. Provisions in the Plan for adjustment with respect to this Award and the related provisions with respect to successors to the business of the Company are hereby made applicable hereunder and are incorporated herein by reference.

6. Securities Law Compliance. The Participant specifically acknowledges and agrees that any sales of shares of Common Stock shall be made in accordance with the requirements of the Securities Act. The Company currently has an effective registration statement on file with the Securities and Exchange Commission with respect to the Common Stock to be granted hereunder. The Company intends to maintain this registration statement but has no obligation to do so. If the registration statement ceases to be effective for any reason, Participant will not be able to transfer or sell any of the shares of Common Stock issued to the Participant pursuant to this Agreement unless exemptions from registration or filings under applicable securities laws are available. Furthermore, despite registration, applicable securities laws may restrict the ability of the Participant to sell his or her Common Stock, including due to the Participant's affiliation with the Company. The Company shall not be obligated to either issue the Common Stock or permit the resale of any shares of Common Stock if such issuance or resale would violate any applicable securities law, rule or regulation.

7. Rights as a Stockholder. The Participant shall have no right as a stockholder, including voting and dividend rights, with respect to the RSUs subject to this Agreement.

8. Incorporation of the Plan. The Participant specifically understands and agrees that the RSUs and the shares of Common Stock to be issued under the Plan will be issued to the Participant pursuant to the Plan, a copy of which Plan the Participant acknowledges he or she has read and understands and by which Plan he or she agrees to be bound. The provisions of the Plan are incorporated herein by reference. In addition, this RSU (and any compensation paid or shares issued pursuant to this Agreement) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or for a "constructive termination" (or similar term) under any agreement with the Company.

9. Tax Liability of the Participant and Payment of Taxes. The Participant acknowledges and agrees that any income or other taxes due from the Participant with respect to this Award or the shares of Common Stock to be issued pursuant to this Agreement or otherwise sold shall be the Participant's responsibility. Without limiting the foregoing, the Participant

agrees that if under applicable law the Participant will owe taxes at each vesting or settlement date on the portion of the Award then vested or settled, as applicable, the Company shall be entitled to immediate payment from the Participant of the amount of any tax or other amounts required to be withheld by the Company by applicable law or regulation. Any taxes or other amounts due shall be paid as follows:

(a) subject to approval by the Board or Committee, as applicable, through reducing the number of shares of Common Stock entitled to be issued to the Participant on the applicable settlement date in an amount not in excess of the maximum amount of tax required to be withheld by law (or such other amount as may be necessary to avoid classification of this Award as a liability for financial accounting purposes). Fractional shares will not be retained to satisfy any portion of the Company's withholding obligation. Accordingly, the Participant agrees that in the event that the amount of withholding required would result in a fraction of a share being owed, that amount will be satisfied by withholding the fractional amount from the Participant's paycheck;

(b) at the option of the Company, by requiring the Participant to deposit with the Company an amount of cash equal to the amount determined by the Company to be required to be withheld with respect to the statutory minimum amount of the Participant's total tax and other withholding obligations due and payable by the Company or otherwise withholding from the Participant's paycheck an amount equal to such amounts due and payable by the Company; or

(c) if the Company believes that the sale of shares can be made in compliance with applicable securities laws, authorizing, at a time when the Participant is not in possession of material nonpublic information, the sale by the Participant on the applicable vesting date of such number of shares of Common Stock as necessary to sell to satisfy the Company's withholding obligation, after deduction of the broker's commission, and the broker shall be required to remit to the Company the cash necessary in order for the Company to satisfy its withholding obligation. To the extent the proceeds of such sale exceed the Company's withholding obligation, the Company agrees to pay such excess cash to the Participant as soon as practicable. In addition, if such sale is not sufficient to pay the Company's withholding obligation, the Participant agrees to pay to the Company as soon as practicable, including through additional payroll withholding, the amount of any withholding obligation that is not satisfied by the sale of shares of Common Stock. The Participant agrees to hold the Company and the broker harmless from all costs, damages or expenses relating to any such sale. The Participant acknowledges that the broker is under no obligation to arrange for such sale at any particular price. In connection with such sale of shares of Common Stock, the Participant shall execute any such documents requested by the broker in order to effectuate the sale of shares of Common Stock and payment of the withholding obligation to the Company. The Participant acknowledges that this paragraph is intended to comply with Section 10b5-1(c)(1)(i)(B) under the Exchange Act.

The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

10. Participant Acknowledgements and Authorizations.

The Participant acknowledges the following:

(a) The Company is not by the Plan or this Award obligated to continue the Participant as an employee, director or consultant of the Company or an Affiliate.

(b) The Plan is discretionary in nature and may be suspended or terminated by the Company at any time.

(c) The grant of this Award is considered a one-time benefit and does not create a contractual or other right to receive any other award under the Plan, benefits in lieu of awards or any other benefits in the future.

(d) The Plan is a voluntary program of the Company and future awards, if any, will be at the sole discretion of the Company, including, but not limited to, the timing of any grant, the amount of any award, vesting provisions and the purchase price, if any.

(e) The value of this Award is an extraordinary item of compensation outside of the scope of the Participant's employment or consulting contract, if any. As such the Award is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits or similar payments. The future value of the shares of Common Stock is unknown and cannot be predicted with certainty.

(f) The Participant (i) authorizes the Company and each Affiliate and any agent of the Company or any Affiliate administering the Plan or providing Plan recordkeeping services, to disclose to the Company or any of its Affiliates such information and data as the Company or any such Affiliate shall request in order to facilitate the grant of the Award and the administration of the Plan; and (ii) authorizes the Company and each Affiliate to store and transmit such information in electronic form for the purposes set forth in this Agreement.

11. Notices. Any notices required or permitted by the terms of this Agreement or the Plan shall be given by recognized courier service, facsimile, registered or certified mail, return receipt requested, addressed as follows:

If to the Company:

430 East 29th Street
New York, New York 10016
Attn: General Counsel

If to the Participant at the address set forth on the Restricted Stock Unit Award Grant Notice or to such other address or addresses of which notice in the same manner has previously been given.

Any such notice shall be deemed to have been given on the earliest of receipt, one business day following delivery by the sender to a recognized courier service, or three business days following mailing by registered or certified mail.

12. Assignment and Successors.

(a) This Agreement is personal to the Participant and without the prior written consent of the Company shall not be assignable by the Participant otherwise than by will or the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable by the Participant's legal representatives.

(b) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and assigns.

13. Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the conflict of law principles thereof. For the purpose of litigating any dispute that arises under this Agreement, whether at law or in equity, the parties hereby consent to exclusive jurisdiction in the state of New York and agree that such litigation shall be conducted in the state courts of the state of New York or the federal courts of the United States for the District of Manhattan.

14. Severability. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction, then such provision or provisions shall be modified to the extent necessary to make such provision valid and enforceable, and to the extent that this is impossible, then such provision shall be deemed to be excised from this Agreement, and the validity, legality and enforceability of the rest of this Agreement shall not be affected thereby.

15. Entire Agreement. This Agreement, together with the Plan, constitutes the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior oral or written agreements and understandings relating to the subject matter hereof. No statement, representation, warranty, covenant or agreement not expressly set forth in this Agreement shall affect or be used to interpret, change or restrict the express terms and provisions of this Agreement; provided, however, in any event, this Agreement shall be subject to and governed by the Plan.

16. Modifications and Amendments; Waivers and Consents. The terms and provisions of this Agreement may be modified or amended as provided in the Plan. Except as provided in the Plan, the terms and provisions of this Agreement may be waived, or consent for the departure therefrom granted, only by written document executed by the party entitled to the benefits of such terms or provisions. No such waiver or consent shall be deemed to be or shall constitute a waiver or consent with respect to any other terms or provisions of this Agreement, whether or not similar. Each such waiver or consent shall be effective only in the specific instance and for the purpose for which it was given, and shall not constitute a continuing waiver or consent.

17. Section 409A. The Award of RSUs evidenced by this Agreement is intended to be exempt from the nonqualified deferred compensation rules of Section 409A of the Code as a “short term deferral” (as that term is used in the final regulations and other guidance issued under Section 409A of the Code, including Treasury Regulation Section 1.409A-1(b)(4)(i)), and shall be construed accordingly. However, if (i) this Award fails to satisfy the requirements of the short-term deferral rule and is otherwise not exempt from, and therefore deemed to be deferred compensation subject to, Section 409A of the Code, (ii) the Participant is deemed by the Company at the time of the Participant’s “separation from service” (as such term is defined in Treasury Regulations Section 1.409A-1(h) without regard to any alternative definition thereunder) to be a “specified employee” for purposes of Section 409A(a)(2)(B)(i) of the Code, and (iii) any of the payments set forth herein are issuable upon such separation from service, then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to the Participant prior to the earliest of (a) the date that is six (6) months and one (1) day after the date of such separation from service, (b) the date of the Participant’s death, or (c) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 17 will be paid in a lump sum to the Participant, and any remaining payments due will be paid as otherwise provided herein. Each installment of RSUs that vests under this Award is a “separate payment” for purposes of Treasury Regulations Section 1.409A-2(b)(2).

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Exhibit 10.34

INTRA-CELLULAR THERAPIES, INC.
2019 INDUCEMENT AWARD PLAN

OPTION GRANT NOTICE

Intra-Cellular Therapies, Inc. (the "***Company***"), pursuant to its 2019 Inducement Award Plan (the "***Plan***"), hereby grants to Optionholder an option to purchase the number of shares of Common Stock set forth below (the "***Option***"). The Option is subject to all of the terms and conditions set forth in this Option Grant Notice ("***Notice***"), in the Option Agreement and the Plan, both of which are attached to this Notice and incorporated into this Notice in their entirety. Capitalized terms not explicitly defined in this Notice but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this Notice and the Plan, the terms of the Plan will control.

Optionholder:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

Type of Grant: Nonstatutory Stock Option

Vesting Schedule: Subject to Section 1 of the Option Agreement, the Option will vest as follows: [_____].

Additional Terms/Acknowledgements: Optionholder acknowledges receipt of, and understands and agrees to, this Notice, the Option Agreement, the Plan and the stock plan prospectus for the Plan. Optionholder acknowledges and agrees that this Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding the Option and supersede all prior oral and written agreements, promises and representations on that subject.

INTRA-CELLULAR THERAPIES, INC.:

By: _____
Signature
Title: _____
Date: _____

OPTIONHOLDER:

_____
Signature
Date: _____

ATTACHMENTS: Option Agreement and 2019 Inducement Award Plan

INTRA-CELLULAR THERAPIES, INC.
2019 INDUCEMENT AWARD PLAN

OPTION AGREEMENT
(NONSTATUTORY STOCK OPTION)

Pursuant to your Option Grant Notice (the "***Grant Notice***") and this Option Agreement, Intra-Cellular Therapies, Inc. (the "***Company***") has granted you an option under its 2019 Inducement Award Plan (the "***Plan***") to purchase the number of shares of Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service and the number of shares of Common Stock which are unvested as of such date shall be forfeited. Notwithstanding the foregoing, if (a) you are an Employee at the level of Vice President or above at the time of a termination of your Continuous Service and, at any time within ninety (90) days prior to or twelve (12) months following the effective date of a Change in Control (or such other period as is, or may be, set forth in an employment, severance or other similar written agreement between you and the Company or any of its Affiliates), or (b) you are an Employee below the level of Vice President or a Consultant at the time of a termination of your Continuous Service and, at any time within twelve (12) months following the effective date of a Change in Control, your Continuous Service terminates by reason of (i) a resignation for Good Reason or (ii) an involuntary termination of your Continuous Service without Cause (each, a "***Qualifying Termination***"), then any shares underlying this Option that have not become vested and that are outstanding at the time of the Qualifying Termination (whether pursuant to this Option Agreement or other action of the Board or the Committee) shall become fully vested and exercisable as of (x) the effective date of the Change in Control if your Qualifying Termination occurs prior to the effective date of the Change in Control and (y) the date of such Qualifying Termination if your Qualifying Termination occurs on or after the effective date of the Change in Control. In order to give effect to the intent of such accelerated vesting, if your Qualifying Termination occurs prior to the effective date of a Change in Control, then notwithstanding anything to the contrary in this Option Agreement or the Plan, in no event will any portion of your option or this Option Agreement be forfeited or terminate any earlier than the effective date of the Change in Control.

The following terms shall have the following meanings for purposes of this Section 1:

"Change in 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 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, 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.

"Good Reason" means the occurrence of (a) any event constituting "Good Reason" (or an analogous term) as set forth in any employment, consulting, severance or other similar written agreement between you and the Company or any of its Affiliates and (b) any of the following events without your consent: (i) if you are an Employee at the level of Vice President or above, a material reduction or change in job duties, responsibilities or authority inconsistent with your position with the Company and your prior duties, responsibilities or authority immediately prior to the Change in Control; (ii) for any Employee or Consultant, a relocation of your primary workplace by more than 25 miles; or (iii) for any Employee or Consultant, a material reduction of your base compensation; *provided*, *however*, that any event described in clause (b) above shall constitute Good Reason only if (x) you provide the Company with written notice specifying the event alleged to constitute Good Reason within 60 days following the first occurrence of such event, (y) the Company fails to cure such event within 30 days after the Company's receipt from you of such written notice, and (z) your termination of Continuous Service occurs within 30 days following the Company's failure to cure such event (and in no event later than 120 days following the first occurrence of such event).

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments as provided in the Plan.

3. METHOD OF PAYMENT. You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price as follows:

(a) In cash or by check, bank draft or money order payable to the Company.

(b) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash or check by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise," "same day sale," or "sell to cover."

(c) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by such delivery in cash or other permitted form of payment. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of the shares of Common Stock in a form the Company approves. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(d) Subject to the consent of the Board or Committee, as applicable, prior to exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock otherwise issuable to you upon exercise of your option by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment.

4. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

5. SECURITIES LAW COMPLIANCE. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that the exercise would not be in material compliance with applicable laws and regulations.

6. TERM. The term of your option expires upon the earliest of the following:

(a) immediately upon notification to you of a termination of your Continuous Service for Cause;

(b) three months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death, except as otherwise provided in Sections 6(d) and 6(e) below; *provided*, *however*, that if during any part of such three month period your option is not exercisable solely because doing so would violate the registration requirements under the Securities Act, your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three months (which need not be consecutive) after the termination of your Continuous Service; provided further, if during any part of such three month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three months (which need not be consecutive) after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy;

(c) twelve months after the termination of your Continuous Service due to your Disability, except as otherwise provided in Sections 6(d) and 6(e) below;

(d) eighteen months after your death if you die either (i) during your Continuous Service, (ii) within three months after the termination of your Continuous Service for any reason other than Cause or your Disability, or (iii) within twelve months after the termination of your Continuous Service due to your Disability, in each case except as otherwise provided in Section 6(e) below;

(e) if your Qualifying Termination occurs prior to the effective date of a Change in Control, the later of the following ("the ***Qualifying Termination Period***"): (i) the period determined under Section 6(b), 6(c) or 6(d) above, as applicable, or (ii) one month after the effective date of the Change in Control; *provided*, *however*, that if the Qualifying Termination Period is the one-month period after the effective date of the Change in Control and you die during such Qualifying Termination Period, such Qualifying Termination Period will be extended until eighteen months after your death; or

(f) the Expiration Date indicated in your Grant Notice.

7. EXERCISE. You may exercise the vested portion of your option during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or making the required electronic election with the Company's designated broker, and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with any additional documents as the Company may then require.

8. TRANSFERABILITY OF OPTION. Except as otherwise provided in this Section 8, your option is not transferable except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

(b) Beneficiary Designation. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, after your death, will be entitled to exercise the option and receive the Common Stock or other consideration resulting from the exercise. In the absence of such a designation, in the event of your death, your executor or administrator of your estate will be entitled to exercise the option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

9. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the service of the Company or an Affiliate, or of the Company or an Affiliate to continue your service. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as an Employee, Director or Consultant for the Company or an Affiliate.

10. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for

(including by means of a “same day sale” pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) Upon your request and subject to approval by the Board or Committee, as applicable, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the maximum amount of tax required to be withheld by law (or such other amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure will be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

11. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

12. NOTICES. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five days after deposit in the U.S. mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

13. GOVERNING PLAN DOCUMENT. Your option is subject to all the terms of the Plan, which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for “good reason” or for a “constructive termination” (or similar term) under any agreement with the Company.

14. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of your option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

15. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to your option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in your option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

16. SEVERABILITY. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

17. MISCELLANEOUS.

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by you of the Option Grant Notice to which it is attached.

ATTACHMENT

INTRA-CELLULAR THERAPIES, INC.
2019 INDUCEMENT AWARD PLAN

[ATTACH A COPY OF THE PLAN WHEN DISTRIBUTING TO OPTIONHOLDERS]

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. 333-235817) of Intra-Cellular Therapies, Inc.,

(2) Registration Statement (Form S-3 No. 333-233537) of Intra-Cellular Therapies, Inc.,

(3) Registration Statement (Form S-8 No. 333-225799) pertaining to the Intra-Cellular Therapies, Inc. 2018 Equity Incentive Plan of Intra-Cellular Therapies, Inc.,

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

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

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

of our reports dated March 2, 2020, 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, 2019.

/s/ Ernst & Young LLP
Baltimore, Maryland
March 2, 2020

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 2, 2020

/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 2, 2020

/s/ Lawrence J. Hineline
Lawrence J. Hineline
Senior 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, 2019 (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 2, 2020

/s/ Sharon Mates, Ph.D.

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

Dated: March 2, 2020

/s/ Lawrence J. Hineline

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